

**Bundle of documents for Oral hearings
commencing from 19 August 2024 in
relation to the Queen Elizabeth University
Hospital and the Royal Hospital for
Children, Glasgow**

**Bundle 20 – Documents referred to in the
Expert Reports by Andrew Poplett and
Allan Bennett**

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The Following document is a Request for Information (RFI) response received by the Scottish Hospital Inquiry from NHS GGC

Request for Information - Section 21 Notice - No 18 (Ventilation Systems)

1. **Physical changes to the ventilation system operation:** From handover on 26 January 2015 to date, please provide: -
 - a) **A list of all physical changes made by the Board to the operation of ventilation system which were made as a result of concerns about its safety or as a result of a hypothesis/risk but not a known safety concern. For the avoidance of doubt, this request includes permanent and interim steps taken to rectify, remediate, or upgrade the ventilation system.**
 - b) **A succinct explanation of the reason why each of the steps identified was taken.**
 - c) **A description of any steps that the Board took to install HEPA filtration. The Inquiry would like to understand the position at handover and the current position in the Hospital. For the avoidance of doubt, this request includes permanent and interim steps taken to rectify, remediate or upgrade the HEPA filtration. This should include any steps that were taken to use mobile HEPA filtration units.**
-

Wards 4C, 5C, 5D, 7B, 7C and 7D

This response seeks to address the information requested about physical changes to the ventilation system operation for 4C, 5C, 5D, 7B, 7C and 7D ward areas. This response should be read in conjunction with RFI S21 No 10 submitted on 9th December 2022.

In this response we have include the description of works undertaken on the ventilation systems to adjust pressure cascades and direction of air flows which are standard mechanisms for balancing and adjustment but not strictly physical changes to the ventilation system.

In November 2018, the Lead Infection Control Doctor (LICD) and a colleague undertook a limited survey on 4 rooms in each of wards 4C, 5C and 5D. The purpose was to confirm positive protection of patients in ward 4C from room to corridor and negative protection of others from the patient room to the corridors in wards 5C and 5D.

Following this review the LICD indicated they had specific concern around wards 5C and 5D that housed patients with infectious diseases. The concern was around the potential risk of infection being spread by this patient group to staff and members of the public in the ward area if the rooms were not negatively pressured. Estates were asked to undertake a complete survey of all patient rooms in 5C, 5D and 4C and also to include Wards 7A and 7D. Estates undertook initial surveys to record the room pressure differentials from patient room to corridor and reported the findings to the LICD. Estates then engaged an external ventilation company to make adjustments to the fan speeds and damper positions. On completion of this work, reports were issued to Estates and then forwarded to the LICD.

A summary of what was instructed for each of the wards, how each ward is served from the plantrooms and the outcome of the adjustments as recorded in the reports is noted below.

Ward 4C houses renal and renal oncology patients. The area is served by 3 Air Handling Units (AHUs) located in plantroom 124 on level 12 identified as 124 AHU 04, 124 AHU 05 and 124 AHU 06 and there have been no physical changes to the 3 ventilation units serving Ward 4C since handover on 26 January 2015. Due to the patient group housed in 4C, there was a need for the rooms to be positive to the corridor, that is, air flow from room to the corridor, with a target pressure differential of 1Pa or more. The report issued on 3rd December 2018 for Ward 4C provided pressure cascade readings which indicated that by increasing extraction fan speed in units 04 and 05 and adjustment of dampers within the ductwork this had been achieved.

In March 2019, the F7 secondary filters within the AHUs serving levels 4 to 7 in plantroom 124 were replaced with a higher grade F9 filter to improve the source air quality delivered to these spaces.

There is no HEPA filtration within the plant room AHUs or within the ductwork serving Ward 4C. The ward has 18 rooms allocated for renal patients and 10 rooms for renal oncology patients. January 2019, the ventilation system to the 10 oncology rooms was supplemented by floor standing HEPA filter air scrubbers. These scrubbers filter and recirculate air within the space improving the air quality within the patient bedroom. In January 2019 the Ceiling Ventilation Grilles were removed and replaced with a standard ceiling tile to reduce the risk of particulate moving from the corridor ceiling void into the corridor transfer area and rooms.

In the period between October and December 2020, a programme of works was undertaken to fit HEPA filtered air scrubbers within the ceiling voids of the en-suites in all 28 patient rooms of the ward. These units are not integrated within the existing ductwork system. These units recirculate air within the en-suite space through HEPA filtration improving the air quality within the space. **Ward 5C** is served by 3 Air Handling Units (AHUs) located in plantroom 124 on level 12 identified as 124 AHU 04, 124 AHU 05 and 124 AHU 06 and there have been no physical changes to the 3 ventilation units serving Ward 5C since handover on 26 January 2015.

The desired outcome of adjustments was for patient rooms to be negative pressure to the corridor, that is, air flow from corridor to room, with a target pressure differential of 1Pa or more. The report issued on 3rd December 2018 for Ward 5C provides pressure cascade readings which indicated this had been achieved.

In March 2019, the F7 secondary filters within the AHUs serving levels 4 to 7 in plantroom 124 were replaced with a higher grade F9 filter to improve the source air quality delivered to these spaces.

There has been no HEPA filtration, portable or fixed, added to any areas within the rooms or en-suites within Ward 5C. There is no HEPA filtration within the plant room AHUs or within the ductwork serving Ward 5C.

Ward 5D is served by 3 Air Handling Units (AHUs) located in plantroom 123 on level 12 identified as 123 AHU 04, 123 AHU 05 and 123 AHU 06 and there have been no physical changes to the 3 ventilation units serving Ward 5D since handover on 26 January 2015.

The desired outcome of adjustments was for patient rooms to be negative pressure to the corridor, that is, air flow from corridor to room, with a target pressure differential of 1Pa or more. The report issued on 23rd December 2018 for Ward 5D provides pressure cascade readings which indicated this had been achieved.

There has been no HEPA filtration, portable or fixed, added to any areas within the rooms or en-suites within Ward 5D. There is no HEPA filtration within the plant room AHUs or within the ductwork serving Ward 5D.

Wards 7B, 7C and 7D

Ward 7B is served by 3 AHUs in plantroom 121, located on level 12. There are 3 AHUs serving ward 7B which are identified as 121 AHU 04, 121 AHU 05 and 121 AHU 06. There have been no physical changes to the ventilation system serving ward 7B since handover on 26 January 2015. There have been no alterations to the fan speeds. There has been no HEPA filtration, portable or fixed, added to any areas within the rooms or en-suites within Ward 7B. There is no HEPA filtration within the plant room AHUs or within the ductwork serving Ward 7B.

Ward 7C is served by 3 Air Handling Units (AHUs) located in plantroom 124 on level 12 identified as 124 AHU 04, 124 AHU 05 and 124 AHU 06 and there have been no physical changes to the 3 ventilation units serving Ward 7C since handover on 26 January 2015. There have been alterations to the fan speeds serving Ward 7C. These alterations were a consequence of the required pressure changes on Wards 4C and 5C as 7C is served by the same group of AHU's. On completion of the works to these wards the air flows to Ward 7C were rebalanced to their original state.

There has been no HEPA filtration, portable or fixed, added to any areas within the rooms or en-suites within Ward 7C. There is no HEPA filtration within the plant room AHUs or within the ductwork serving Ward 7C.

In March 2019, the F7 secondary filters within the AHUs serving levels 4 to 7 in plantroom 124 were replaced with a higher grade F9 filter to improve the source air quality delivered to these spaces.

Ward 7D is served by 3 Air Handling Units (AHUs) located in plantroom 123 on level 12 identified as 123 AHU 04, 123 AHU 05 and 123 AHU 06 and there has been no physical changes to the 3 ventilation units serving Ward 7D since handover on 26 January 2015.

The desired outcome of adjustments was for patient rooms to be negative pressure to the corridor, that is, air flow from corridor to room, with a target pressure differential of 1Pa or more. The report issued on 23rd December 2018 for Ward 7D provides pressure cascade readings which indicated this had been achieved.

There has been no HEPA filtration, portable or fixed, added to any areas within the rooms or en-suites within Ward 7D. There is no HEPA filtration within the plant room AHUs or within the ductwork serving Ward 7D.

Original Specification

The original clinical output specification from 2009 for the Haemato-oncology area at the New SGUH clearly specified that this patient group is vulnerable to infection and therefore require the provision of a protected environment. The ventilation section of this document details the following requirements in relation to this:

Please note that the haemato-oncology ward has a very specific function. There should be no opening windows. The space should be sealed and ventilated. Positive pressure to the rest of the department and all highly filtered air >90%, probably best HEPA with adequate number of positive pressure sealed HEPA filtered side rooms for neutropaenic patients as in the Beatson West of Scotland Cancer Centre.

An appendix to the specification details that the HEPA filters meet EU12 standard (99.99% @ 0.3µm)

Advice for this was sought from Dr John Hood Consultant Microbiologist

Specification for rooms at WoS Cancer Centre

In the absence of definitive UK guidance on builds for severely immunocompromised patients the positive pressure side rooms are built to the CDC specification that is 12 air changes per hour and the rooms at a positive pressure to the corridor of 5-10 kPa.

Build process

Confirmation that the build was progressing as expected was sent to the clinical team on 9th December 2013 from Heather Griffin:

Thank you for your e-mail and also for your time in meeting with us the other day.
With regard to your query -

1. The spec for the Haemato-oncology area is as requested by John, in other words - hepa filtration positive to the rest of the hospital and all highly filtered air to H13 ie 99.95%. (Myra, refer to the plan I gave you).
2. The pentamidine treatment room is negatively pressured.

John is John Hood as described in the original specification above.

The expectation therefore was that the Haem-onc unit at SGUH was being built to the same standard as WoS Cancer centre.

Commissioning

The Infection control team was assured that all areas of the SGUH had been fully commissioned and validated from a Mechanical and Ventilation point of view. The details of the validation were not provided but that is not unusual as this is an

engineering specialism and ICPT's would only normally be involved in the event of significant failure. It is now apparent that Brookfield had not been required to undertake particle count test as part of their commissioning process.

Current deficiencies identified

1. HEPA Filtration for high risk patients	HEPA filtration in each room , 2 rooms verbally reported NOT to be HEPA filtered
2. Positive Pressure in each room 5-10 Pa in relation to corridor	No method of measuring pressure gradient is currently installed in any of the 4B rooms Verbally reported as 10 Rooms not sealed Not a solid ceiling, movement of ceiling tiles
3. Air exchanges required to be >12ph	Not yet achieved
4. Sealed room (0.5-sq ft leakage)	? Validation for leak testing
5) Particle counts 29 th June 960-579197	Current standard at WoS Cancer Centre <1000
6) negative pressure in the pentamidine room.	Not achieved

Conclusions

- 1) The original specification provided to Brookfield if delivered would have provided a safe environment for this vulnerable group of patients
- 2) Filter integrity/Particle counting would normally be required to validate areas provided with HEPA filtered air to ensure both the function of the HEPA filter and ensure the room seal. Expert Engineering advice should be sought to advise whether the commissioning process in this case was adequate. No validation data has to date been made available to the IPCT
- 3) In the light of the current provision of isolation facilities available to the Haem-Onc patients the IPCT support the return of these patients to WoS Cancer centre until the unit at the QEUH is provided to the required specification and appropriately validated

STATUS IN NHSSCOTLAND
BEST PRACTICE GUIDANCE

Health Building Note 00-07

Planning for a resilient healthcare estate

For queries on the status of this document contact
nss.hfsenquiries@nhs.net or telephone 0141207 1600

Status Note amended 14th October 2014

DOH Document Code Part - DOH Document Title and Name

This document must be read in conjunction with current Scottish Government Policy and NHSScotland Guidance, which take precedence. These include publications in both: www.sehd.scot.nhs.uk/ and www.hfs.scot.nhs.uk/publications-/ .

Specific updates for NHSScotland use:**Chapter 1**

The legal, regulatory and policy framework in Scotland can differ significantly from those in England referred to in this chapter, and must take precedence. However, best practice may be similar, given that the considerations and technical standards, European and British, are the same..

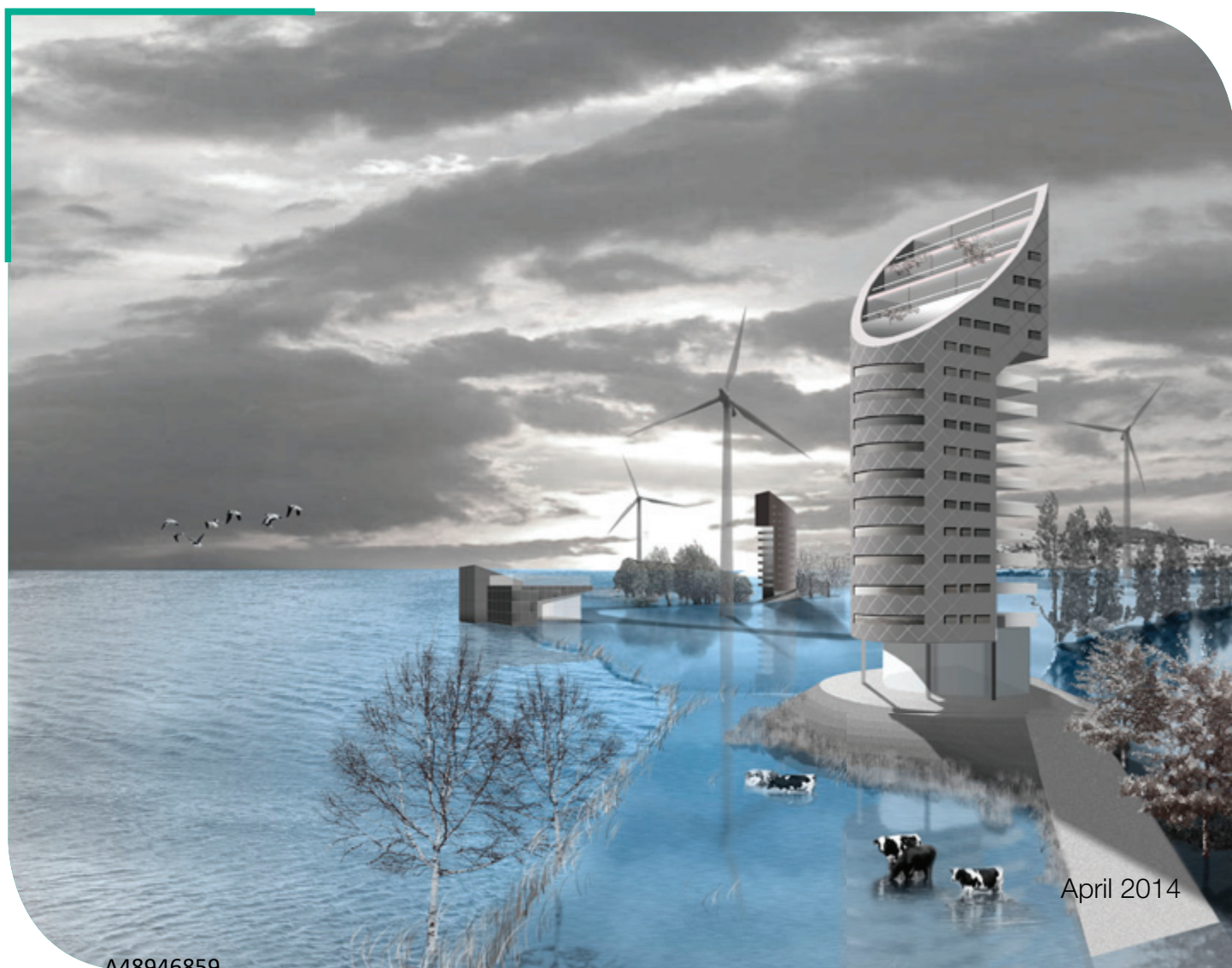


Department
of Health

Health Building Note 00-07

Planning for a resilient healthcare estate

2014 edition



April 2014

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This document is available from our website at www.gov.uk/government/collections/health-building-notes-core-elements

Front cover: The Long-term Initiatives for flood-risk Environments (LifE) project.
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Preface

About Health Building Notes

Health Building Notes give best practice guidance on the design and planning of new healthcare buildings and on the adaptation/extension of existing facilities.

They provide information to support the briefing and design processes for individual projects in the NHS building programme.

The Health Building Note suite

Healthcare delivery is constantly changing, and so too are the boundaries between primary, secondary and tertiary care. The focus now is on delivering healthcare closer to people's homes.

The Health Building Note framework (see next page) is based on the patient's experience across the spectrum of care from home to healthcare setting and back.

Health Building Note structure

The Health Building Notes have been organised into a suite of 17 core subjects.

Care-group-based Health Building Notes provide information about a specific care group

or pathway but cross-refer to Health Building Notes on generic (clinical) activities or support systems as appropriate.

Core subjects are subdivided into specific topics and classified by a two-digit suffix (-01, -02 etc), and may be further subdivided into Supplements A, B etc.

All Health Building Notes are supported by the overarching Health Building Note 00-01 in which the key areas of design and building are dealt with.

Example

The Health Building Note on accommodation for adult in-patients is represented as follows:

"Health Building Note 04-01:
Adult in-patient facilities"

The supplement to Health Building Note 04-01 on isolation facilities is represented as follows:

"Health Building Note 04-01:
Supplement 1 – Isolation facilities for
infectious patients in acute settings"

Health Building Note number and series title	Type of Health Building Note
Health Building Note 00 – Core elements	Support-system-based
Health Building Note 01 – Cardiac care	Care-group-based
Health Building Note 02 – Cancer care	Care-group-based
Health Building Note 03 – Mental health	Care-group-based
Health Building Note 04 – In-patient care	Generic-activity-based
Health Building Note 05 – Older people	Care-group-based
Health Building Note 06 – Diagnostics	Generic-activity-based
Health Building Note 07 – Renal care	Care-group-based
Health Building Note 08 – Long-term conditions/long-stay care	Care-group-based
Health Building Note 09 – Children, young people and maternity services	Care-group-based
Health Building Note 10 – Surgery	Generic-activity-based
Health Building Note 11 – Community care	Generic-activity-based
Health Building Note 12 – Out-patient care	Generic-activity-based
Health Building Note 13 – Decontamination	Support-system-based
Health Building Note 14 – Medicines management	Support-system-based
Health Building Note 15 – Emergency care	Care-group-based
Health Building Note 16 – Pathology	Support-system-based

Other resources in the DH Estates and Facilities knowledge series

Health Technical Memoranda

Health Technical Memoranda give comprehensive advice and guidance on the design, installation and operation of specialised building and engineering technology used in the delivery of healthcare (for example medical gas pipeline systems, and ventilation systems).

They are applicable to new and existing sites, and are for use at various stages during the inception, design, construction, refurbishment and maintenance of a building.

All Health Building Notes should be read in conjunction with the relevant parts of the Health Technical Memorandum series.

Activity DataBase (ADB)

The Activity DataBase (ADB) data and software assists project teams with the briefing and design of the healthcare environment. Data is based on guidance given in the Health Building Notes and Health Technical Memoranda.

For ADB technical queries only, contact the ADB Helpdesk. Telephone number: 01939 291684; email: support@talonsolutions.co.uk

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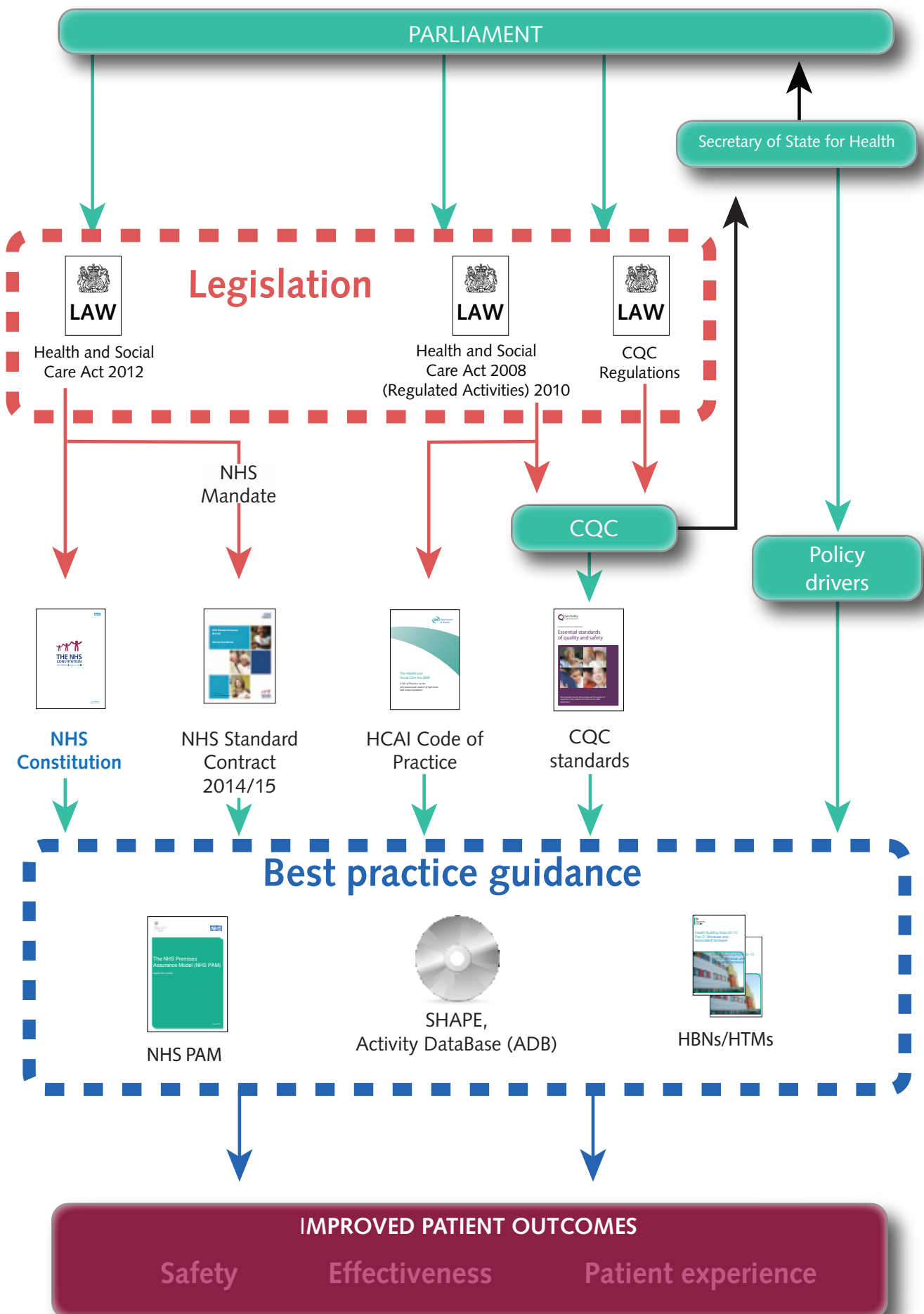
How to obtain publications

Health Building Notes are available from the UK Government's website at:

<https://www.gov.uk/government/collections/health-building-notes-core-elements>

Health Technical Memoranda are available from the same site at:

<https://www.gov.uk/government/collections/health-technical-memorandum-disinfection-and-sterilization>



Executive summary

Health Building Note (HBN) 00-07 provides guidance for NHS-funded providers on designing and planning for a resilient healthcare estate. It aims to help NHS-funded providers to determine appropriate levels of resilience for sites, buildings and installations against a wide range of emergencies, hazards and threats and their impacts and consequences including resilience to the impacts of climate change. This document focuses on:

- the strategic approach to resilience planning for healthcare estates;
- procuring resilient healthcare estates;
- design and planning considerations for a resilient healthcare estate;
- resilience of building services engineering.

It also embraces the move towards a whole-system approach to healthcare. The isolated approach of concentrating on the resilience of a single facility or organisation is no longer considered best practice. It is clear that this approach will affect building and services infrastructure requirements for the future and should be taken into account at the strategic planning stage for all new healthcare estates and facilities, and also when refurbishing or decommissioning the existing estate.

Relevance and audience

The guidance is relevant to the whole healthcare estate including private sector premises providing services to the NHS

(hereinafter referred to as “NHS-funded providers”); to those who advise and support them; and to associated supply chains.

It is applicable to new schemes, refurbishments, decommissioning and existing facilities. It takes into account the importance of resilience to ensure business continuity management (BCM) and aligns with the Integrated Emergency Management (IEM) model.

The HBN will be useful for a wide range of specialists, including (but not limited to):

- capital project teams;
- estates and facilities managers;
- healthcare engineers;
- architects and designers;
- healthcare planners;
- sustainability managers;
- IT and communication teams;
- local security management specialists (LSMS);
- accountable emergency officers (AEOs)/ head of resilience;
- emergency planning liaison officers and teams;
- clinician/medical teams involved with emergency planning;

- managers and directors including those executives with security and/or emergency planning portfolios.

It is essential that throughout the whole process of procuring and maintaining healthcare, the estates/facilities manager should communicate and work in close cooperation with the AEO (note: in some organisations this role may be carried out by the head of resilience). This will ensure that the resilience of the healthcare estate including climate change is integrated into the organisation's board-approved strategies, systems, training, policies and procedures.

Additional guidance for primary care and community care facilities is given in HBN 11-01 – 'Supplement A: resilience and emergency planning in primary and community care'.

The need for this guidance

This HBN has been revised to reflect the increasing long-term risks associated with climate change. HM Government's (2012) 'UK climate change risk assessment' (CCRA) shows that flooding is one of the largest risks for the UK. Therefore, this document has been updated to provide more guidance on adaptation measures to reflect this and other climate change impacts such as floods and heatwaves.

To assist in assuring compliance with relevant legislation and government policy, this HBN provides advice on the planning, design, construction, commissioning and operation of NHS-funded healthcare facilities. In particular, it has been developed to respond to the following key drivers:

- The CCRA identifies the key risks to the UK from climate change as being the first step towards development of the National Adaptation Programme (NAP) (HM Government, 2013). It acknowledges that building climate resilience is an ongoing investment and that a start needs to be made now, particularly for risks where

decisions have long-term consequences (for example, planning for a climate-resilient healthcare estate).

- The top risks for the UK identified in the CCRA are addressed in the 2013 NAP. This includes a health chapter for healthy and resilient communities, with this updated guidance specifically addressing health objective 12: "to promote climate resilience within the NHS, public health and care system to ensure continuity of services and resilient assets/estates, including the ability to deal with the increased demand for services associated with severe weather-related events".

Changes since the last edition

- This revision updates the HBN in line with new government policy, legislation and regulations and the reform of England's healthcare system including partnership working with Public Health England (PHE), NHS England and others.
- More guidance has been provided on the risks associated with climate change, and this is reflected in the specific advice given in the planning and design chapter.
- The resilience of engineering infrastructure has been expanded upon to reflect the critical nature of maintaining continuity of these services for healthcare delivery.
- The document still reflects the benefits of the IEM model, but the detail has been reduced and the reader has been signposted to other more relevant sources of information.
- It has revised, updated and incorporated the emergency planning and contingency sections that were in earlier editions of Health Technical Memorandum (HTM) 00 – 'Policies and principles of healthcare engineering'.

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Acknowledgements

The Department of Health would like to thank all those who have helped to develop and produce this guidance, including all those who commented and sent contributions during the consultation phase.

Acronyms

AEO	Accountable emergency officer	HBN	Health Building Note
BCM	Business continuity management	HTM	Health Technical Memorandum
BCP	Business continuity plan	IEM	Integrated Emergency Management
BIM	Building information modelling	KPIs	Key performance indicators
BMS	Building management system	LRF	Local resilience forum
CCRA	[UK] Climate change risk assessment [HM Government, 2012]	LSMS	Local security management specialist
CHP	Combined heat and power	NAP	National Adaptation Programme
CQC	Care Quality Commission	NHS PAM	NHS Premises Assurance Model
DCLG	Department for Communities and Local Government	PA	Public address
DH	Department of Health	PHE	Public Health England
EA	Environment Agency	SHAPE	Strategic Health Asset Planning Evaluation Tool
EPLO	Emergency planning liaison officer	SuDS	Sustainable drainage systems
FM	Facilities management	UPS	Uninterruptible power supplies
FRA	Flood risk assessment		

Definitions

For the purposes of this guidance the following definitions apply:

Adaptation – relates to changes made in readiness for, or in response to, the impacts of climate change.

Business continuity management – all activities undertaken to give NHS facilities the capacity to anticipate, prevent, prepare for, respond to and recover from disruptive challenges that would otherwise prevent the organisation from meeting its primary duties. The term subsumes resilience and resilience management.

Emergency – with regard to estates and facilities, this includes:

- a major incident;
- an unexpected event that gives rise to loss of, or damage to, facilities or services that may impact on the delivery of healthcare;
- an event or situation that threatens serious damage to the environment of a place in the UK, or war or terrorism which threatens serious damage to the security of the UK.

Hazards – non-malicious events including natural events, industrial accidents and industrial action.

Healthcare facility – all buildings, infrastructure, equipment, plant, embedded

systems and related items that support the delivery of healthcare and services of all types, irrespective of their ownership or operation by third parties.

Lockdown – lockdown refers to controlling the movement and access of people around a trust site or area in response to an identified risk, threat or hazard that might impact on the security of patients or assets.

Mitigation – relates to actions to limit the magnitude and/or rate of long-term climate change. Mitigation generally involves reductions in human-related emissions of greenhouse gases. Mitigation may be achieved by switching to low carbon energy sources such as renewable energy.

Recovery – the process of rebuilding, restoring or refurbishing a healthcare facility following an emergency, hazard or threat.

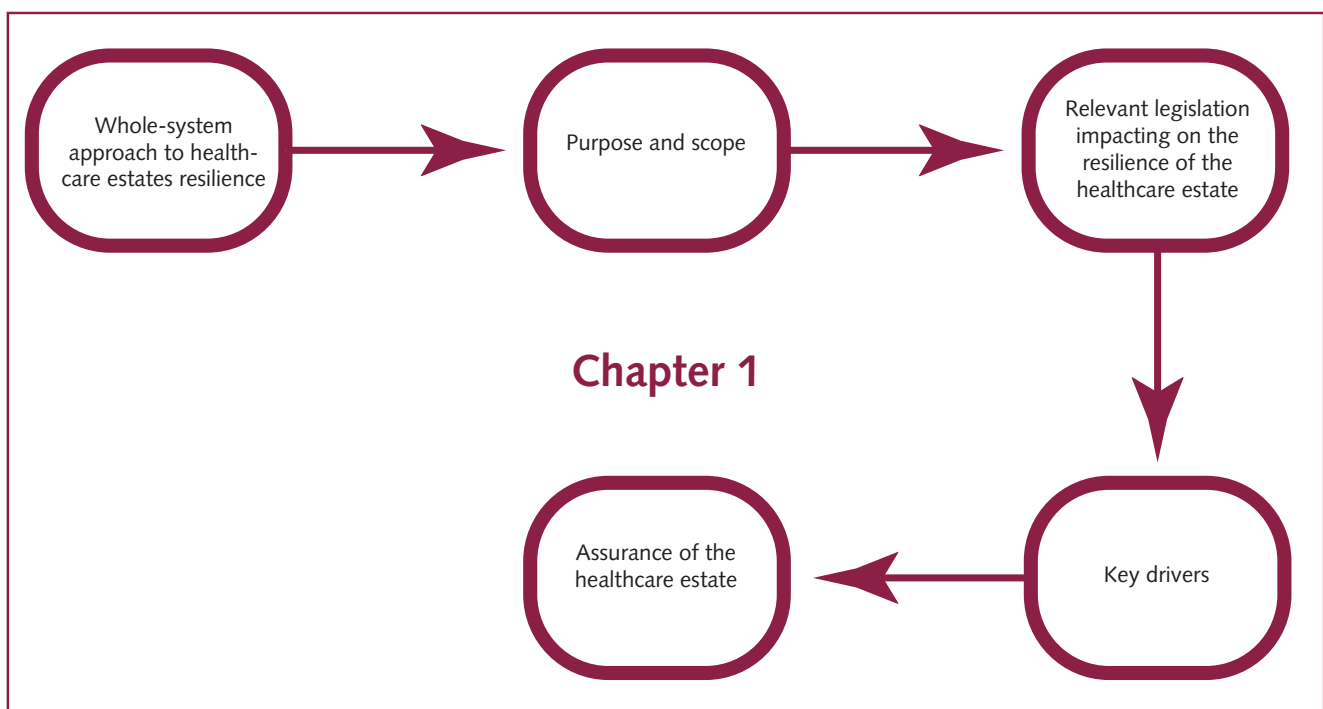
Resilience – the ability of an organisation to adapt and respond to disruptions, whether internal or external, to deliver organisationally agreed critical activities.

Surge capacity – the ability of a health service to expand beyond normal capacity to meet increased demand for clinical care. This is an important factor of resilience and emergency preparedness and should be addressed early in the planning process.

Threats – malicious attacks.

Whole system approach – any resilience planning should be integrated and take into account the whole healthcare system, including acute, community, primary and voluntary sectors. For example, not only do hospitals have to deal with the usual intake of patients during a severe event, but also with disaster-related patients and patients with chronic illnesses who are usually cared for at home, but who suddenly do not have access to the medical technologies they need.

1. Introduction



For the purpose of this document, resilience is defined as “the ability of an organisation to adapt and respond to disruptions, whether internal or external, to deliver organisationally agreed critical activities”. This builds on the definition of “resilience” in BS ISO 22301 and includes resilience to the impacts of climate change such as the increased extreme weather events of heatwaves and flooding.

Resilient facilities are those that have the following features:

- robustness – the system or facility should be able to absorb the effects of an event and continue to operate at the required level;
- redundancy – where robustness cannot be absolutely guaranteed, it is essential to provide more than one key facility or subsystem;
- reconfigurability – the unanticipated risk is often the most devastating. To be truly resilient, a system or facility should be adaptable to cope with the effects of an unexpected event, where practicable.

1.1 The resilience process aims to identify emergencies, hazards and threats, assess the associated risks, develop measures to mitigate those risks, and prepare plans for response to an emergency should it occur.

1.2 This document focuses on improving the resilience of the existing estate and its facilities management (FM) as well as new builds and refurbishments:

- For the existing estate and FM, resilience requires that plans are put in place to ensure that business continuity of healthcare is maintained no matter what the circumstances.
- Resilience should be considered early in the procurement/planning and design process/stages. Particular attention should be paid to flexibility in facility design in order to accommodate surge capacity and peaks in demand.

The whole system approach to healthcare estates resilience

1.3 Existing operational capability and resilience planning should take into account the whole healthcare system, including acute, community, primary and voluntary sectors. For example, hospitals have to deal not only with the usual intake of patients during a severe event, but also with the casualties caused by the disaster and those patients with chronic illnesses who are usually cared for at home but who suddenly do not have access to the medical technologies they need.

Purpose and scope

1.4 This document provides guidance on planning for a resilient healthcare estate. It aims to help NHS-funded providers to determine appropriate levels of resilience for sites, buildings and installations against a wide range of emergencies, hazards and threats and their impacts and consequences. The document provides guidance on:

- the strategic approach to resilience planning for healthcare estates;
- procuring resilient healthcare estates;
- design and planning considerations for a resilient healthcare estate;
- resilience of building services engineering.

1.5 This Health Building Note (HBN) is consistent with Department of Health (DH) policy and arrangements for planning for health emergencies. It complies with wider government plans for national and local emergencies as set out in the Cabinet Office's (2012) 'Emergency preparedness' and HM Government's 'Emergency response and recovery' guidance documents. It also embraces Public Health England (PHE) and NHS England's requirements for safeguarding healthcare services in England.

Relevant legislation that impacts on the resilience of the healthcare estate

1.6 The following main Acts and regulations are relevant to the resilience of the healthcare estate:

- The **Civil Contingencies Act 2004** requires NHS organisations, its subcontractors and providers of NHS-funded care to show that they can deal with such incidents and emergencies while maintaining services to patients.
- The **Climate Change Act 2008** established the target of reducing UK greenhouse gas emissions by at least 80% (from the 1990 baseline) by 2050. Reducing demand for energy, buildings and infrastructure will be more efficient and will reduce energy bills, but will also make organisations, and the country as a whole, more resilient through climate adaptation measures.
- The **Health and Social Care Act 2012** strengthens arrangements for emergency

response. It sets specific emergency duties for the Secretary of State for Health, NHS England and clinical commissioning groups.

Key drivers

1.7 To assist in assuring compliance with relevant legislation and government policy, this HBN is driven by:

- the National Adaptation Programme (NAP) health objective 12: “to promote climate resilience within the NHS, public health and care system to ensure continuity of services and resilient assets/ estates, including the ability to deal with severe weather-related events”;
- the UK climate change risk assessment (CCRA) (HM Government, 2012). This acknowledges that building resilience is an ongoing investment and that a start needs to be made now, particularly for those risks where decisions have long-term consequences (for example, planning for a resilient healthcare estate). The CCRA is the first step towards development of the NAP.

Assurance of the healthcare estate

1.8 Quality and fitness for purpose of the estate are assessed against a set of legal requirements and standards.

Regulatory requirements: essential standards of quality and safety for healthcare estates

1.9 The Care Quality Commission (CQC) regulates all providers of regulated health and adult social care activities in England. The CQC’s role is to make sure health and social care services provide people with safe, effective, compassionate, high-quality care that puts patients first, and to encourage care services to improve. The registration requirements are set out in the Care Quality Commission (Registration) Regulations 2009

(CQC Regulations) and include requirements relating to:

- safety and suitability of premises;
- safety, availability and suitability of equipment;
- cleanliness and infection control.

1.10 The CQC is responsible for assessing whether providers are meeting the registration requirements. Failure to comply with the CQC regulations is an offence and under the Health and Social Care Act 2008 (Regulated activities) Regulations 2010, CQC has a wide range of enforcement powers that it can use if the provider is not compliant. These include the issue of a warning notice that requires improvement within a specified time, prosecution and the power to cancel a provider’s registration, removing its ability to provide its regulated activities. The regulations stipulate that all premises and equipment used must be safe, clean, secure, suitable for the purpose for which they are being used, and properly used and maintained.

Note on amendment to the CQC Regulations

New regulations are due to come into effect during 2014 and will apply to all providers of health and social care that are required to register with the CQC.

The NHS Constitution

1.11 The NHS Constitution sets out the rights of patients, public and staff. It also outlines the pledges that the NHS is committed to achieve, together with responsibilities that the public, patients and staff owe to one another to ensure that the NHS operates fairly and effectively. All healthcare organisations are required by law to take account of the NHS Constitution in their decisions and actions. Healthcare organisations should “ensure that services are provided in a clean and safe environment that is fit for purpose, based on national best practice”.

In order to deliver this pledge, the NHS Constitution specifically advises NHS organisations to take account of:

- national best-practice guidance for the design and operation of healthcare facilities;
- the NHS Premises Assurance Model (NHS PAM).

1.12 The underlying principles of the NHS Constitution link to requirements for resilience in respect of the need to deliver a “positive experience of care and ensure that people are treated and cared for in a safe environment, protected from avoidable harm”.

The NHS Premises Assurance Model (NHS PAM)

1.13 With the support of DH, the NHS has developed the NHS Premises Assurance Model (NHS PAM). Its remit is to provide assurance for the healthcare environment and to ensure that

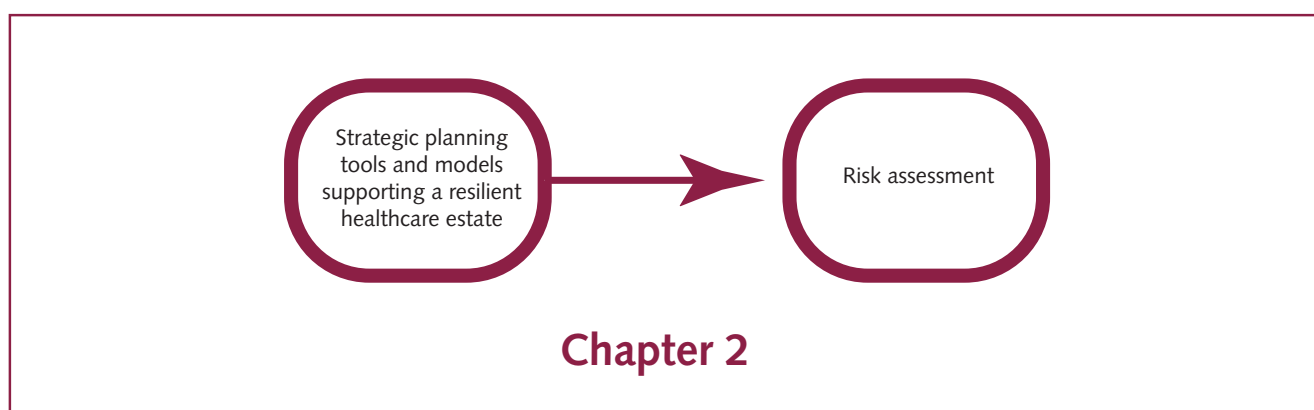
patients, staff and visitors are protected against risks associated with hazards such as unsafe premises.

1.14 Aimed at providing governance and assurance to boards of organisations, it allows organisations that provide NHS-funded care and services to better understand the effectiveness, quality and safety with which they manage their estate and facilities services and how that links to patient experience and patient safety.

1.15 Key questions are underpinned by prompt questions that require the gathering of evidence. Healthcare organisations should prepare and access this evidence to support their assessment of the NHS PAM.

1.16 The model also includes reference to evidence and guidance as a helpful aide-memoire to assist in deciding the level of NHS PAM assurance applicable to a particular healthcare organisation.

2. The strategic approach to resilience planning for healthcare estates



2.1 The healthcare sector's built environment and support services are the core element in an organisation's ability to maintain its business-prioritised activities.

2.2 Estates and facilities managers will need to consider a business continuity approach for buildings, infrastructure and services resilience, which needs to form part of the wider organisational approach to resilience. This is essential to maintain clinical services and should also take into account the need for surge capacity (that is, the ability of the health service to meet increased demand for clinical care).

2.3 Robust procedures should be prepared and tested for the following priority incidents as a minimum:

- unavailability of premises due to fire, flood, fuel shortages or other incidents;
- major problems relating to the transport infrastructure that affect access and

egress for healthcare professionals, patients and visitors;

- major electronic attacks or severe disruption to the IT network, systems and mobile telephony;
- loss of access to key resources, assets, utilities and fuel supply;
- theft or criminal damage that severely compromises the organisation's physical assets;
- significant chemical contamination of the working environment;
- loss of critical support services or the supply chain.

2.4 This support to business continuity is a key component towards compliance with the CQC's fundamental standards on cleanliness, safety and suitability of premises and equipment and good governance.

2.5 NHS-funded organisations will need to undertake regular risk assessment exercises appropriate to their facilities and services. For further guidance on business continuity management (BCM) and business continuity plans (BCPs), readers should refer to:

- chapter 6 of the Cabinet Office's (2012) 'Emergency preparedness';
- NHS England's:
 - 'Business continuity policy' (2013);
 - 'Business continuity management strategy' (2013); and
 - 'Business continuity management strategy toolkit' (2014).

2.6 BS ISO 22301 on BCM provides a generic framework that covers strategies in all phases before, during and after an incident.

Strategic planning tools and models supporting a resilient healthcare estate

2.7 Described below are a number of available tools and resources for use by NHS-funded providers as appropriate to their local needs and circumstances.

World Health Organization (WHO) tools and resources

Hospital emergency response checklist

2.8 WHO's (2011) 'Hospital emergency response checklist' is a tool for hospital administrators and emergency managers. The guidance and its checklists assist hospital-based emergency managers to respond effectively. The best practice guidance integrates priority actions required for rapid effective response to critical event-based all-hazard approaches.

2.9 It is structured according to a number of key components, each with a list of priority actions to support healthcare managers and

emergency planners in achieving the essentials for healthcare estates resilience:

- continuity of essential services;
- well-coordinated implementation of operations at every level;
- clear and accurate internal and external communication;
- swift adaptation to increased demands;
- the effective use of scarce resources;
- a safe environment for healthcare workers.

Hospital safety index

2.10 WHO's 'Hospital safety index' provides a rapid diagnosis of the safety, vulnerability and preparedness of hospitals. The results of the assessments inform decision makers about which hospitals could withstand the impact of hazards and deliver health services in emergency situations, and those which require remedial action to make them safe and operational in times of emergency.

The Strategic Health Asset Planning and Evaluation (SHAPE) tool

2.11 Produced by PHE, SHAPE is a web-enabled, evidence-based application that informs and supports the strategic planning of services and physical assets across a whole health economy. It links national datasets for clinical analysis, public health, primary care and demographic data with estate performance and facilities location and has a flood-mapping capability.

2.12 SHAPE enables interactive investigations by local area teams, clinical commissioning groups, GP practices and local authorities, and supports key policy initiatives such as the joint strategic needs assessment (JSNA).

2.13 Alongside SHAPE and in engagement with the Environment Agency (EA) locally, consideration should be given to using SMARTeST (Smart Resilient Technologies,

Systems and Tools) (www.floodresilience.eu). One of the key objectives of this is “climate proofing”, particularly of infrastructure.

The NHS Premises Assurance Model (PAM)

2.14 See paragraphs 1.13–1.16.

The Integrated Emergency Management (IEM) model

2.15 The IEM model is a holistic approach to preventing and managing emergencies that entails six key steps (see paragraph 2.16). Although there are other approaches to emergency management, the IEM model is adopted by this HBN not least because it:

- implements the common and consistent UK national model for the anticipation, assessment, mitigation and management of physical risks into the healthcare environment;
- defines a common set of words and processes, thereby minimising the risk of misunderstandings;
- facilitates the integration of site- and event-specific risk assessments and plans into the wider risk and emergency arrangements of other involved agencies;
- provides common ground for effective discourse between the organisations directly involved, the emergency services, and the many external agencies that may become engaged at different stages of any event or emergency and with varying degrees of intensity.

2.16 The IEM model describes a series of cyclical processes. It is essential to view the elements of the IEM as mutually-supporting processes and not as sequential steps, as the first four of the six are continuous, connected activities:

- a. anticipation;
- b. assessment;
- c. prevention;

- d. preparation;
- e. response;
- f. recovery.

2.17 For further details on the IEM model and these six steps, see the Cabinet Office’s (2012) ‘Emergency preparedness’ and HM Government’s ‘Emergency response and recovery’ guidance documents.

Risk assessment

2.18 For the estates and facilities manager, one of the main objectives of resilience is to undertake a risk assessment and to identify gaps in the overall capacity for managing the healthcare estate and to ensure the continued operation of its facilities, services and functions to maintain healthcare services during a crisis. The aim is to develop a plan of action to address those gaps and strengthen capacity. Follow-up assessments should be conducted at least every two years.

2.19 Every local situation will differ, but consideration should be given to how the building’s location, form and design could help in anticipating, preparing for, preventing, responding to, and recovering from disruptions whatever their source and whatever part of the business they affect.

2.20 Risk assessment plans should include a hazard-and-threat analysis as part of the decision-making process to take account of the issues addressed in Table 1.

2.21 Users will need to reference (among others):

- National Risk Register (<https://www.gov.uk/risk-assessment-how-the-risk-of-emergencies-in-the-uk-is-assessed>)
- Community Risk Register (<https://www.gov.uk/risk-assessment-how-the-risk-of-emergencies-in-the-uk-is-assessed>)

- UK Climate Impacts Programme (<http://www.ukcip.org.uk>).

See also the Cabinet Office's (2012) 'Emergency preparedness'.

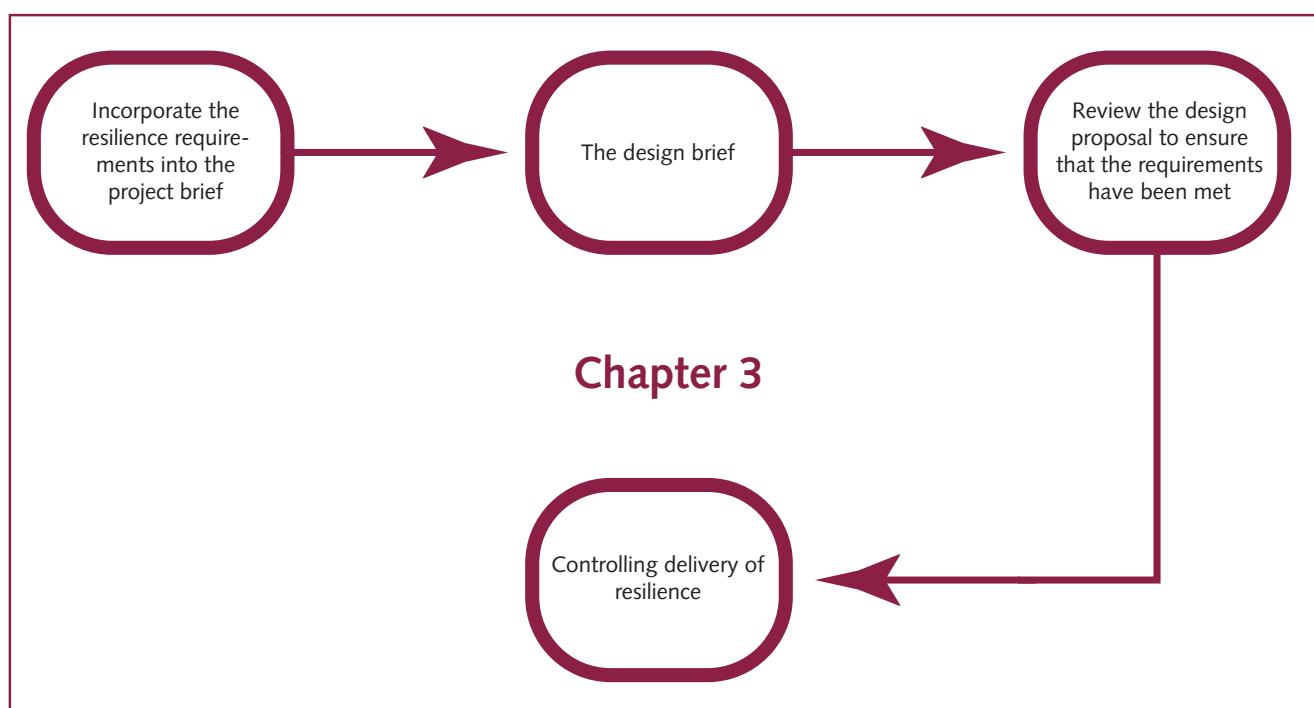
risks/threats to allow for any changes that may take place (for example, over time, a low risk may become a high-risk event). The review frequency should be linked to an automated email system, calendar or other bespoke software.

2.22 The risk assessment should be periodically reviewed across the whole range of

Utility supplies, that is, electricity, gas, water – how would healthcare be delivered without heating, cooling, gas and air handling, washing linen and dishes, cooking, powering blood banks, maintaining radiology services etc?
Water, drainage – loss of pumping mechanisms to provide clean water for drinking/hydration; water for cleanliness and control of infection.
Sewage treatment failure could lead to untreated/undertreated sewage potentially contaminating local waterways leading to public health concerns and clean-up costs at a later date.
Accessibility/transport – what would happen without transport to the facility (for example contractors maintaining essential services; equipment/supplies that could not be delivered)? Engage with transport coordinators.
Flood plans – engage with the local environment agency and local planners to continually review the local flood model and ensure plans take account of adjacent or neighbouring developments that may affect surface water drainage.
Extreme weather events – for example heavy snowfall and ice or windstorms can be very disruptive – how can this be mitigated?
Heatwave plan – ensure the design and layout allows for shading, temperature control and cool rooms for heat-distressed patients.
Cold weather plan – to support improved building design and increased energy efficiency, which can reduce carbon emissions, and improve and protect health (thereby potentially reducing pressure on health provision).
Winter pressures – can place more pressure on clinical services such as A&E services and acute care.
Infection prevention and control – can room availability and layouts contain the spread of airborne and waterborne viruses? Is there sufficient storage for necessary supplies and disposal of increased clinical/hazardous waste?
Extreme medical conditions – could the building facilitate lockdown of sections or rooms for containment?
Resilience for essential services – telecommunications, IT systems, utility services, medical gases and heating.
Supplies and procurement – how long can the organisation cope if supplies of drugs, food, medical equipment etc could not be delivered? What are the contingency plans for partner organisations to respond in times of emergency?
Fire/bomb threat – can the building be evacuated while maintaining care of the most critical patients?
Fuel shortages – how long would the facility function if fuel were in short supply?
Arson attacks
Civil aviation issues – Is the building located in a flight path: what would this mean for major incident planning if a major air accident occurred? Does the building require an air ambulance facility?
Theft and vandalism
Location – is the facility sited near to a chemical plant or other facility at risk of explosion etc?

Table 1 Issues to consider in a risk assessment plan (in no order of priority)

3. Procuring resilient healthcare estates



Introduction

3.1 If the strategic planning phase reveals that the facility needs to be redeveloped or relocated, the options for procuring this development should be appraised before a specific scheme is identified. These options will usually involve:

- no building work at all (including the decommissioning and the potential lease/sale or demolition of existing buildings);
- relocating or reassigning functions within the existing fabric of the building;
- refurbishing existing buildings;

- new developments.

3.2 This chapter explains how emergencies, hazards and threats can be dealt with throughout the procurement process to ensure that resilience is achieved.

3.3 In procuring a regulated healthcare facility and the services/equipment that are required within it, designers, planners and clients will need to be assured of meeting the CQC's standards of care, which stipulate that all premises and equipment used must be safe, clean, secure, suitable for the purpose for which they are being used, and properly used and maintained.

3.4 Estates and facilities resilience should not be planned in isolation. For large projects (particularly new builds), the threat part of the assessment may be produced at regional or national level, and may include input from other sources. At a local level, advice should be sought from the local resilience forum (LRF), police architectural liaison officer or crime prevention design adviser, and local police counter-terrorist security advisers.

Incorporating resilience requirements into the project brief

3.5 The project brief should communicate the client's requirement for resilience to emergencies, hazards and threats to the design team. This is equally important when occupying and/or leasing premises that are not owned by the healthcare organisation. This is the start of the continuous process of assessment that should be undertaken as part of the facility's lifecycle.

3.6 Resilience measures should not be discounted or compromised on the basis of costs, as the NHS-funded provider is the ultimate bearer of any risk to service provision. Therefore, the delivery mechanisms proposed for resilience should be scrutinised very closely and gauged against the overall benefits in the longer term.

3.7 To ensure that resilience is considered as a factor in the estates strategy, the following questions should be posed:

- How resilient is our estate? (What risks exist in our assessment that need to be addressed in the design?)
- How resilient should it be? (What risks are unacceptably high?)
- How can we improve our resilience? (What building or engineering measures can we apply to mitigate risks?)

The design brief

3.8 The design for resilience in any facility will depend on the assessed risk for that scheme at the time. Applying the guidance in this HBN to a particular scheme for a particular locality will require skilful risk assessment due to the variability and likelihood of emergencies, hazards and threats in different parts of the country. A risk assessment will be required for each business case, and this will need to address the design brief, geographical location and any other mitigating local factors.

3.9 The design brief should take account of future-proofing, adaptability and flexibility of the building. Further advice on future-proofing of healthcare facilities is provided in chapter 8 of HTM 07-07 – 'Sustainable health and social care buildings'.

Review the design proposal

3.10 Design proposals should be reviewed to assess whether the level of resilience meets the requirements set out in the project brief. In a simple facility purchase, this can be a straightforward review of the physical design, but where some form of leasing arrangement is proposed, the review should also include an operational assessment.

3.11 In terms of the current requirements, BCM and the IEM model described in [Chapter 2](#) should be used to enhance the project proposal as this is the point at which emergencies, hazards and threats can be prevented or prepared for.

Controlling delivery of resilience

3.12 Measuring resilience need not be complicated. In fact, the system should be as simple and unequivocal as possible. In common with other requirements stated in the project brief, the requirements should be tested and measured in the delivered project against the original output specification.

3.13 In a facility where service provision has been outsourced, responsibilities need to be clear. A useful mechanism to control and monitor the delivery of resilience requirements is to incentivise the contract with the use of performance monitoring tools such as key performance indicators (KPIs). This mechanism is of particular value to identify the requirements, since they are not products that are delivered but capabilities that are expected to be available. When considering contracts,

see NHS England's 'NHS standard contracts' (updated each year to reflect the requirements of the NHS operating framework).

Measuring resilience – an example

3.14 The following is an example of one type of risk that could be considered as part of a local risk management process when service provision has been outsourced.

The requirement

"Provision is to be made for an electricity supply system that is capable, in the absence of mains electricity, of sustaining the essential load of the facility for a period of X hours."

Assessing whether the proposal satisfies the requirement

The measure is not just in the physical presence of a suitably-sized generator (or alternative), but also in the presence of:

- sufficient fuel for X hours' running;
- the necessary breakdown/maintenance cover;
- trained personnel to operate the generator system;
- proof that the system works in its design condition (that is, under continuous full load, not just that it starts).

Clarifying responsibilities

If the organisation owns the generator and the contractor is responsible for maintaining and operating it, where does responsibility lie for ensuring business continuity if it fails to start?

(Note: ultimately, no matter how the contract is written, the risk of loss of power lies with the NHS-funded provider; therefore, ownership of the risk has not been transferred.)

Where the entire supply mechanism (generator, maintenance, operation) is outsourced, responsibilities are easier to define and less likely to produce gaps from which failures tend to arise, although there is a need to clarify and be confident of contingency plans and arrangements with suppliers.

Using key performance indicators

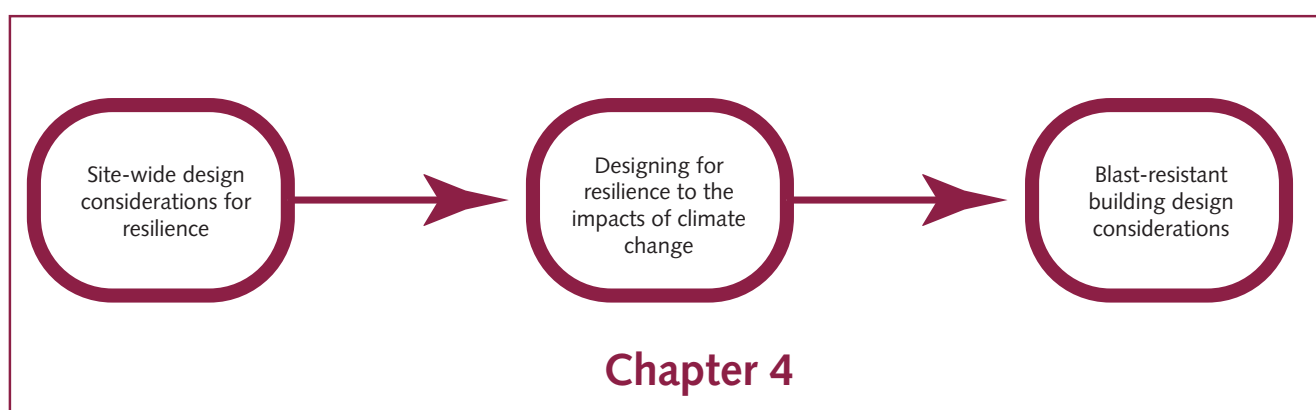
Negative KPIs (penalty or reduced payments):

- number of days when the standby generator was unavailable due to maintenance failure;
- number of days when trained personnel were unavailable.

Positive KPIs (bonus payments):

- a successful periodic test run of the generator under load;
- successful completion of a periodic test exercise.

4. Design and planning considerations for a resilient healthcare estate



Introduction

4.1 Planning and designing for resilience whenever the opportunity arises – that is, when new sites/buildings or departments are being considered and when major refurbishments are taking place – is a key responsibility of the organisation or board of directors.

4.2 Clear requirements should be provided by the healthcare organisation at the planning and design stage to enable an appropriate level of resilience to be built in. For this purpose, close liaison should take place between the organisation's AEO and the estates and facilities professionals, local planning authorities, and police architectural liaison officers/crime prevention design advisers. LRFs and emergency preparedness, resilience and response (EPRR) teams may also be able to advise on specific cases.

4.3 Local plans should take account of climate change over the longer term, including factors such as flood risk, coastal change, water supply and changes to biodiversity and landscape. New developments should be planned to avoid increased vulnerability to the range of impacts

arising from climate change. When a new development is brought forward in vulnerable areas, care should be taken to ensure that risks can be managed through suitable adaptation measures, including the planning of green infrastructure.

Note on Building Information Modelling (BIM)

The government's mandate is that the public sector will deliver centrally procured projects using BIM by 2016. BIM can be used for effective management of information throughout a project's lifecycle – from earliest concept, design, build, operation and through to ultimate demolition. BIM also has the capability to accurately model the building and its energy performance. In addition, it can be applied in the design and analysis of a building in terms of resilience to climate change as different design parameters can be modelled and tested. It may be extremely valuable in the creation, storage and retrieval of data essential for resilience.

Site-wide design considerations for resilience

Site selection

4.4 Resilient design starts with the site option appraisal process as a means of selecting the most appropriate site. Adjacency to other buildings/types should also be considered as part of this process.

4.5 Site location, orientation and accessibility issues are also paramount. Project teams will need to engage with the EA, local authority and local highway authority to assess local conditions, for example:

- the likelihood of flood risk in the area whether due to the proximity of a floodplain or increased impact from neighbouring developments;
- proximity and potential for impact from COMAH (Control of Major Accident Hazards) sites.

Engagement through the wider community LRF will also be key.

4.6 Although hospitals and medical facilities are not often targets for terrorist attacks, other neighbouring facilities may be. Therefore, siting a prospective new-build near to a potential terrorist target (government, commercial or domestic building) may increase the risk of becoming involved in an incident. (Note that city centres themselves, because of their symbolic nature or the potentially large number of people, have also been attacked.)

4.7 It may also be beneficial to consider the resilience of key utilities where an adjacent incident may impact on the proposed site. Designers should look at the wider national infrastructure from which a proposed development will draw services to evaluate any additional need for on-site resilience. SHAPE may be useful here (see [paragraphs 2.11–2.13](#)).

Grounds and site layout

4.8 Having selected a site, the nature of the grounds and the layout of the facility should be considered to take advantage of natural geographical features or to determine how best to enhance them to withstand natural hazards (for example, by providing better drainage, such as sustainable drainage systems (SuDS), to avoid disruption caused by floods etc). Boundary fencing to control the flow of foot and vehicle traffic should also be considered.

Radon controls

4.9 Designers need to consider the implications of radon contamination within buildings. This is determined by various factors including the geology of the ground, construction details and factors such as the methods of heating and ventilation.

4.10 In outline, basic radon protective measures involve the fitting of a gas-tight ground barrier to protect against radon ingress. This, which also acts as a damp-proof membrane, should cover the whole building footprint and be lapped to the damp-proof course in the walls and sealed around service penetrations. Full radon protective measures require the radon-proof ground barrier, together with a sump in the foundation, to be designed and constructed such that a suitable extraction system can be installed if high levels of radon are detected after occupancy. See also the Department for Communities and Local Government's (DCLG) (2013) 'Revision of building regulation policy on radon: impact assessment'.

Road and vehicular accessibility

4.11 For resilience and to maintain business continuity, it is essential to ensure adequate access and egress routes to healthcare facilities are kept open and functional.

4.12 Depending on location and likelihood of emergencies, hazards and threats, the following will need to be taken into consideration:

- **Roads:** balance the need for easy access for emergency vehicles against the perceived need for access. Limit the maximum possible approach speeds of vehicles by implementing traffic calming measures such as bends, humps and chicanes and consider the use of barriers as a final line of defence.
- **Accessibility in adverse weather:** consider the cost benefits of having access to a snow plough, de-icing vehicles or vehicles capable of transporting key personnel in a snowstorm to maintain business continuity at a time when there is increased need for healthcare facilities due to slips, trips, falls, accidents and injury.
- **Car parking:** careful management of the car park will be required to reduce any risk. Siting car parks in basements beneath tall buildings, where the effects of a flood, fire or a confined explosion would be much greater, will require significant additional structural engineering effort (and hence expense) to ensure that the building would safely withstand the impacts.
- **Vehicle bomb:** the best defence against such devices is distance; therefore, where such a threat is considered credible, precautions should be designed to maintain a stand-off distance by controlling vehicular approaches.
- **Loading bays:** these present a particular vulnerability to the structure since trucks need to approach right up to the building to deliver supplies. The risk can be minimised by siting them away from high-occupancy areas such as wards, canteens or sensitive areas such as laboratories. Access to the loading bays should be controlled; where the threat is deemed high enough, barriers covered by a CCTV and intercom arrangement should be considered, to deny entry until the validity of the delivery is assured.

4.13 Unexpected changes in risk and threat may mean that additional measures will need to be imposed to control vehicular access. Having a flexible management strategy in place will help to deal with new risks and threats as they become known.

4.14 The design team should consider provision of space for eventual introduction of further restrictions on vehicular access, denial of access to certain areas altogether and the introduction of enhanced parking restrictions.

Space for additional facilities

4.15 Space may need to be allocated on the proposed site for additional emergency facilities to deal with specific eventualities. Facilities such as chemical, biological, radiological and nuclear (CBRN) decontamination units, temporary water and/or fuel tanks and logistic stockpiles may be included in the project brief, and need space to be allocated to them. If the public parking area is designated for this, an alternative plan will be needed to allow visitors access to the site, and perhaps a shuttle bus-service could be considered.

4.16 If an emergency occurs, it may not be possible for waste disposal vehicles to come to site to remove healthcare waste. Most healthcare sites do not have the space to store waste for more than 24 hours. If this happens, for example, at a time of pandemic influenza, clinical/hazardous waste will build up more rapidly. Steps will need to be taken in discussion with the EA and infection prevention and control teams to avoid problems that could result. Consideration should also be given to the build-up of combustible materials which create a fire hazard. See HTM 07-01 – ‘Safe management of healthcare waste’. See also [paragraphs 5.64–5.67](#).

Control of pedestrians

4.17 Within the grounds, hard landscaping features such as footpaths and planted areas can be used to mark areas that are part of the design requirements for resilience. Smooth

building lines and well-designed, well-maintained footpaths/grounds will improve pedestrian flow while minimising the effects of weather events.

Pedestrian entrances

4.18 Designers should consider:

- limiting the number of entrances into a building or facility to the smallest number commensurate with the anticipated (and desired) flow of patients, staff and visitors;
- including space at the entrance to incorporate an influx of patients/personnel seeking aid or a personnel search facility if required;
- ensuring that access can be further restricted as necessary without excess impact on operational efficiency;
- access control (for example, swipe-card access and other controls), separating staff and visitor entrances and incorporating positive access control on using keys or electronic pass systems;
- allowing space for a decontamination area to be set up to receive contaminated casualties. External or adjacent land – car parks, playing fields, open areas etc – should be considered as potential decontamination locations using tents for cover. The draught lobby space or commercial areas could also be used for this;
- making the entrance robust against potential civil disturbances, if required, by selecting suitable street furniture and landscaping materials to ensure that the opportunity for aggravated disturbance is minimised.

Separation of patient access areas from other parts of healthcare premises

4.19 HTM 05-02 (Firecode) – ‘Guidance in support of functional provisions for healthcare premises’ provides guidance on the separation of patient access areas from areas considered

to be a fire hazard or risk and the development of appropriate evacuation strategies. In most healthcare buildings that provide in-patient accommodation, the fire evacuation strategy is based on progressive horizontal evacuation, where people are moved progressively away from a fire through fire-resisting walls. This approach may not be appropriate for non-fire emergencies. Therefore, alternative strategies may need to be developed through the normal user group consultation.

4.20 The ‘Heatwave plan for England’ (PHE, 2013) includes the requirement for internal room temperatures to be monitored and to ensure sufficient flexibility of room design and function such that vulnerable patients/people can be relocated to cool areas or zones within facilities when necessary.

High-density sites

4.21 In city-centre or other high-density sites, where pressure for space will always be high, designers should consider potentially radical options for reusing space to ensure that the impact of an event is reduced to an acceptable level (for example, adapting office accommodation or non-clinical areas for use as treatment areas). This should be done in consultation with key advisers such as local fire officers and AEOs.

Redundancy

4.22 Depending on the risk or threat level, organisations should consider whether any of the site-wide design considerations listed above should exist in duplicate or have an alternative. For example, access roads and entrances from the public highway may need an additional temporary route.

Protective security

4.23 Security covers many areas, most of which are described as robustness measures throughout this document. Additionally, the hazard and threat assessment may indicate that the areas described below are also examined.

4.24 Perimeter controls, such as fencing, while not popular, do offer the ability to control foot and vehicle traffic and enable accurate surveillance by channelling visitors into areas covered by CCTV and making a suspicious intent more obvious earlier. This can improve the general security of the facility as well as improving resilience by reducing the likelihood of a threat materialising.

4.25 When considering general security and crime prevention, see also the Association of Chief Police Officers' (2005) 'Secured by design' for additional guidance.

Lockdown

4.26 The need to seal off a facility from the outside or to isolate it internally may arise as a result of an intrusion, civil disturbance, terrorist attack or outbreak of an infectious disease. Selection of appropriate doors, barriers and locks as well as the use of electronic locks and identity/authority verification systems such as card readers, PIN codes and biometrics can then be used to enforce a policy. Appropriate signage and wayfinding strategies may also be used to support the enforcement of lockdown (see NHS Protect's (2009) 'Lockdown guidance').

4.27 Lockdown may be imposed from either an internal or an external authority, and may have as its role either the prevention of entry or the prevention of exit. The precise form the lockdown takes will depend on a number of variables, including:

- duration;
- reason;
- direction of movement to be controlled;
- local circumstances;
- availability of personnel to administer;
- suitability of facility to be locked down;
- physical environment and orientation of the site;

- lockdown zoning.

4.28 Design teams should consider the necessary architectural elements which make the implementation of lockdown easier to perform – in essence, those elements which define discrete zones within a facility and which limit access to those zones, with particular reference to external interfaces and interfaces to areas of high sensitivity or threat potential. This should be carried out in consultation with the local security management specialist (LSMS).

4.29 With regard to the measures for managing threats, project teams should read the Cabinet Office's (2013) 'HMG security policy framework' and bear in mind the advice in the Association of Chief Police Officers' (2005) 'Secured by design', which defines a series of baseline measures for security-conscious design.

Detection systems

4.30 There are a number of electronic options to assist security staff in detecting intruders and managing incidents. These may include:

- intruder detection systems (burglar alarms), which provide an excellent method of backing up an access control system by guarding entrances that are not normally in use (fire escape doors, windows etc); and
- CCTV, which allows more efficient deployment of security manpower and allows verification of alarm incidents remotely. CCTV may prove particularly useful in isolation units as it will allow staff to maintain protection around an area without needing to enter it. CCTV would also assist where buildings have a period of low occupancy or use.

4.31 In a new project, access control, intruder detection, CCTV (high definition and low light) and audio capability could be integrated into a security management system.

Note

See also the Centre for the Protection of National Infrastructure's website (www.cpni.gov.uk).

Screening

4.32 Where there is a particularly high risk to a facility, permanent installation of screening equipment to examine incoming goods and mail may be indicated. Even where it is not, it may be prudent to allow space and services for its installation in the future.

Mail rooms

4.33 Mail rooms should be sited to minimise the distance that unchecked mail has to travel through a building. Rooms should have at least one outside wall to allow a blast to vent, and should be robust enough not to pose a threat to the remainder of the structure.

Personnel screening

4.34 The precise screening measures required will depend on the risk assessment and may include the provision of security staff at entry and exit points on a part- or full-time basis.

4.35 Additional detection/search facilities may be required in high-risk areas at times of heightened alert. Where required, these should take place outside of a protected space. Consideration should be given to the space required not only to carry out the searches but also for queues of waiting people. If the threat is one of explosives, physical protection of the rest of the facility from the screening area should be addressed. Thought should also be given to how persons screened but found unsuitable for access should be directed away from site in a secure manner.

4.36 It should be noted that any imposition of an airport-style regime would severely impact on the functionality of the building and how this eases or impedes the flow of people in and out of any facility. Each line would require at least

three persons to administer it – one screening, one searching and one keeping oversight of all activity.

Designing for resilience to the impacts of climate change

Introduction

4.37 The built environment's response to climate change is organised around two main types of intervention:

- **adaptation** – the need for climate resilience in building type, form and layout needs to be planned and designed appropriately to meet projected healthcare demands and to protect the health of the patients, staff and visitors within these buildings (paragraphs 4.38–4.63 focus on this type of intervention);
- **mitigation** – the amount of energy generated (carbon footprint) which contributes to climate change, requiring buildings to be energy-efficient in design, location and service function (see HTM 07-02 – 'Encode').

4.38 The impact of climate change on a building will depend on how early and well organisations have planned for, and adapted their facilities to cope with, the impacts of climate change. For example, health impacts during heatwaves can be reduced by the effective planning and provision of appropriate temperature controls such as using green roofs and planting trees and zoning of healthcare buildings. The earlier adaptation measures are introduced, the lower the overall financial impact is likely to be on an organisation in the longer term and the better equipped they will be to deal with the predicted changes in climatic conditions.

4.39 Generic adaptation measures appropriate for healthcare infrastructure could include the following:

- The increased use of SuDS to provide a more sustainable approach to draining

Summary of specific responsibilities related to climate change

- The Climate Change Act 2008 requires a quinquennial CCRA – first published in 2012 – to identify the risks and opportunities related to climate change (HM Government, 2102). The Act also sets a framework for dealing with the top risks identified in the CCRA through the UK NAP (HM Government, 2013).
- The UK NAP (also a requirement of the Climate Change Act 2008) provides a framework for action. Adaptation planning is an opportunity to ensure a cohesive approach to current and future planning. The process of developing these plans should integrate with the development and refinement of emergency preparedness and BCPs to prepare for the current and future impacts of climate change.
- The EA's "climate ready service" provides tools and information to help businesses and other organisations live with the changing climate, now and in the future.
- The 'National flood emergency framework for England' (Department for Environment, Food & Rural Affairs, 2013) sets out the Government's strategic approach against flooding and is intended for use by all those involved in planning for and responding to flooding from the sea, rivers, surface water, groundwater and reservoirs.
- The Natural Hazards Partnership (NHP) (<https://www.gov.uk/government/policies/improving-the-uks-ability-to-absorb-respond-to-and-recover-from-emergencies>) brings together expertise from across the UK's leading public sector agencies with the aim of drawing on scientific advice in the preparation, response and review of natural hazards. Partners include the EA and PHE. Among its activities, the NHP publishes a daily hazard summary assessment, which is issued to stakeholders and currently covers some of the following hazards:
 - flooding;
 - geological hazards, such as landslides;
 - weather;
 - wildfires;
 - windstorms.

surface water (for example, a forecourt made from permeable material will allow water to drain away easily). Drainage systems need to be able to cope with the predicted increased frequency of heavy bursts of rainfall.

- Raising flooring in new-build properties to guard against flooding due to increased heavy downpours. Repositioning of power points further up the wall to guard against flood damage.

- Well-designed green spaces to help reduce the urban heat island effect, protect against flooding, promote healthy lifestyles and provide health co-benefits. Plants can be selected for resistance to drought. Trees can provide natural shading and their transpiration helps to mitigate the urban heat island effect.
- Double-glazed windows provide both insulation and natural ventilation, while screens protect against biting insects and vector-borne diseases.

- Roofs could be “green” (to help with the urban heat island effect, reduce water run-off and help biodiversity) or “white” (to reflect heat from the sun) or fitted with solar panels or micro wind turbines to generate electricity.

Note

Load-bearing properties of the roof will need to be carefully calculated to safeguard against potential overloading at times of heavy or prolonged rainfall when the green roof will absorb and retain moisture.

- Innovative building designs will be needed to ensure buildings remain resilient and fit for purpose over time.
- Heat pumps are able to extract heat from the air, ground or water sources (such as rivers or lakes) within the curtilage of a healthcare building and are an energy-efficient way to replace or supplement heating provided by fossil fuels or conventional electric heating methods. They can also be reversed to extract heat from the building when internal cooling is required.
- Road surfaces can be made from materials that are able to cope with hotter temperatures and more intense rainfall.

Floods

4.40 This document incorporates an increased focus on flood risk because the CCRA shows this is one of the largest increasing risks for the UK. ‘Report on the lessons learned from the summer 2007 flooding experiences from an estates and facilities perspective’ (DH, 2007) demonstrates the importance of being resilient to floods and the consequences of not being resilient.

4.41 Developments should be located outside areas of flood risk. Where this is not feasible, DCLG’s ‘National planning policy framework for England and planning practice guidance’

website contains useful guidance (<http://planningguidance.planningportal.gov.uk>).

Important flood risk factors to consider which will influence the design include:

- flood mechanisms (how the site would flood);
- predicted flood level;
- duration;
- frequency;
- velocity of flood water;
- depth; and
- amount of warning time before flooding.

4.42 Where assessment shows that there are no suitable alternative sites available in lower flood-risk areas and development is required, a detailed site-specific flood risk assessment (FRA) should be carried out.

4.43 A range of construction measures can be used to reduce the flooding risk at a site:

- **Flood avoidance:** where it is not possible to locate a building in an area of lower flood risk, constructing a building and its surrounds (at site level) to avoid it being flooded (for example, by raising it above flood level).
- **Flood resistance:** constructing a building to prevent floodwater entering the building and damaging its fabric.
- **Flood resilience:** constructing a building to reduce the impact of floodwater entering the building (so that no permanent damage is caused, structural integrity is maintained and drying and cleaning are facilitated).
- **Flood repairable:** constructing a building so that elements that are damaged by floodwater can be easily repaired or replaced.

4.44 Residential areas may contain a variety of land uses, including dwellings, vehicle and pedestrian access, parking areas, shops,

schools, healthcare and other community facilities. Layout should be designed so that the most vulnerable uses are restricted to higher ground at lower risk of flooding, with more flood-compatible development (parking, open space etc) in the highest-risk areas.

4.45 In designing site layout, the use of low-lying ground in waterside areas for recreation, amenity and environmental purposes can provide important flood conveyance and storage as well as providing connected green spaces with consequent social and environmental benefits. This green infrastructure has the potential to raise the profile and profitability of a development and contribute to other sustainability objectives.

4.46 Landscaping of public access areas subject to flooding should allow for easy access to higher land as flood waters rise and should avoid local features that could become isolated islands. Fences, hedges and walls should be designed and implemented so that they do not cause obstructions to escape routes.

4.47 Any essential structures, such as shelters and seats, should be designed to be flood resilient and firmly attached to the ground. The planning permission should make provision for future management of such areas through planning conditions or Section 106 agreements, with particular regard to safety signing, permitted and prohibited structures and the management of vegetation.

4.48 Buildings should be designed to withstand the effects of flooding. In areas of high velocity water, buildings should be structurally designed to withstand the expected water pressures, potential debris impacts, erosion and undercutting that may occur during a flood event. Particular care should be taken in the design of any building located in a rapid inundation zone. This should also apply to any architectural features within the grounds.

4.49 The final step in the flood risk management hierarchy is to mitigate through building design. This represents the least-

preferred option for new development as although buildings can be designed for reducing the impacts of flooding, hazards still remain, particularly for access and utility supply (see also DCLG's (2007) 'Improving the flood performance of new buildings: flood resilient construction').

Flood risk assessment (FRA) and consequence reports

4.50 FRA and consequence reports should be commissioned to address local authority planning requirements and the need to understand the nature of potential flood risks. Reports should include consideration of the likely effects of climate change (such as increased rainfall). For new developments, areas of permeable and impermeable ground cover should be pre-calculated. All possible relevant flood sources should be covered, including rivers, coastal inundation, surface water, groundwater, sewers and reservoir failure.

4.51 Consultation should be undertaken with regulators, including local authority drainage engineers where appropriate. Risk assessment and consequence reports can be used to meet the requirements of the following guidance by DCLG:

- 'National planning policy framework for England and planning practice guidance' (<http://planningguidance.planningportal.gov.uk>), when considering a planning application or for a healthcare provider to influence an emerging local plan;
- 'Code for sustainable homes' (particularly the environmental issues "Sur 1: management of surface water run-off from developments" and "Sur 2: Flood risk").

4.52 For properties located close to, or within, an EA fluvial or tidal flood risk zone, it is recommended that reports include EA data on flood levels; a data request will provide modelled flood elevations. The SHAPE tool also

has flood-mapping capability (see [paragraphs 2.11–2.13](#)).

4.53 Reports should clearly identify who or what is at risk and may include solutions to limit such risk. They are based on factual interpretation, addressing areas of concern and assessing flood risks to the site from rivers, run-off and groundwater, and also consider potential issues from the regulatory perspective. They can include traffic-light risk ratings and preliminary risk assessment in line with best practice and regulatory guidance such as DCLG's 'National planning policy framework for England and planning practice guidance' (<http://planningguidance.planningportal.gov.uk>).

4.54 Reports should be obtained:

- for the clarification of risk for insurance purposes;
- when validating planning requirements when submitting a planning application;
- to meet planning conditions;
- for land and property purchase;
- for the sale or divestment of a site;
- for due diligence purposes;
- as required for external organisations when new facilities are procured from non-NHS organisations (for example, the requirement of a bank or other funding institution financing the project);
- as part of the business risk assessment.

4.55 Reports should reference:

- customer-supplied information (for example, site location plans, proposed development plans, walkover surveys and recent site photographs);
- the local strategic FRA;
- preliminary risk assessment of flood to the site from all potential sources;

- assessment of flood risks off-site due to new developments and the latest UK environmental datasets:

- flood risks from rivers, surface water run-off and groundwater;
- sewer flood risk if the site is in a built-in area;
- historic flood maps;
- solid and drift geology;
- rainfall assessment.

4.56 When commissioning FRA and consequence reports from specialists, it is prudent and cost-effective to consider obtaining additional reports to assess other environmental matters such as SuDS (identifying site constraints and potential sustainable drainage solutions including run-off and storage volumes), geo-hazards and contaminated land (which may include landfill sites and burial grounds).

Note

The Floods and Water Management Act 2010 establishes a Sustainable Drainage Systems Approving Body in unitary or county councils. This body must approve drainage systems in new developments and redevelopments before construction begins.

Heatwave risks/drought: specific adaptation measures

4.57 Extended periods of dry weather leading to drought could:

- cause increased levels of dust, haze and fog;
- lead to land instability; and
- cause wildfires, which can culminate in one or more of the following:
 - loss or significant reduction in water supplies;

- slowed rate of sewage flow through the system, leading to public health concerns;
- increased risk of vermin above ground;
- reduction in water quality;
- loss or reduction of capacity in the electrical supply network;
- potential impact/closure of primary transport routes;
- possible closure of some businesses;
- increased demand for water supplies from all infrastructure sectors including health, agriculture, energy and emergency services;
- increased demand for emergency power;
- increased demand for health and emergency services.

The dynamics and implications on the built environment and its resilience are illustrated in research by Short et al (2012). The challenge of reducing carbon emissions and energy demand is amplified by the health implications of a changing climate.

The 2003 heatwave led to 15,000 excess deaths in Northern France. The UK heatwave of June/July 2006 is thought to have led to an increase in deaths over baseline mortality of 4%, and there were approximately 300 excess summer deaths after the 2009 heatwave between 30 June and 2 July.

Individuals sensitive to high temperatures are likely to be present at all times in hospitals, including those with compromised thermoregulatory systems (older people, the chronically and severely ill and those on certain medications that impair perspiration) as well as those who cannot take action in the face of high temperatures (small children, those patients who are confined to bed and

patients with mental health problems). However, very few existing buildings within the NHS estate were designed to be air-conditioned; indeed, many are poorly insulated and often over-glazed, leading to increased risk of summertime overheating, even in recently completed buildings.

The paper concludes that refurbishment, in particular to curb the heat lost through uncontrolled leakage of ventilation air from the building, could reduce energy demands and maintain or even improve the internal environment in the current climate. The five refurbishment options researched also offer the opportunity to increase the resilience of the building in a warming climate while saving energy. It concludes that relatively modest interventions could achieve substantial savings while achieving future resilience.

Excessive cold – snow and ice

4.58 PHE's 'Cold weather plan for England' builds on existing measures taken by DH, the NHS and local authorities to protect individuals and communities from the effects of cold weather and to encourage community resilience.

4.59 Coordinated multi-agency long-term planning and commissioning for cold weather is essential to:

- protect people and infrastructure from the effects of cold weather and thus reduce excess winter illness and death and the burden on health and social care sectors;
- support improved building design and increased energy efficiency which can improve and protect health (thereby potentially reducing pressure on health provision) and reduce carbon emissions;
- improve insulation properties of buildings in order to retain heat and minimise energy usage (note: insulation values need to be evaluated along with temperature controls).

Case study: Winter freeze/thaw, December 2010

This case study details a review undertaken by the Sustainable Development and Engineering Branch of the Health Estates Investment Group (Northern Ireland) into the resilience of the Health and Social Care estate in Northern Ireland subsequent to the extreme cold weather events of December 2010 and thaw of January 2011.

The main problems encountered by the trusts during the extreme cold weather event of December 2010 and January 2011 included:

- Buildings were designed to a standard and performed to that standard, but were unable to cope with prolonged temperatures of -10°C .
- Failure of frost coils in air handling units (AHUs). The short-term solution was to divert warm plantroom air into the AHU inlets. The reduction of air flow, where possible, also helped.
- An excess of natural ventilation in newer buildings gave problems in lifting air temperatures.
- In fully air-conditioned buildings, the AHUs were the only source of heating. This gave rise to a single point of failure.
- Pipes that were stressed by being frozen burst under pressure.
- Reverse osmosis plant in some instances could not operate due to being in an unheated space.
- In multi-storey facilities, loss of water pressure caused problems.
- Contingency plans did not cover a complete loss of both electricity and water supply.
- Lack of a dedicated point of contact within Northern Ireland Water (the water supplier).
- Lack of a formal structure for emergency contacts with Northern Ireland Water.

The full report of the investigations into the freeze/thaw incident can be found on the Northern Ireland Executive website (http://www.northernireland.gov.uk/consolidated_report_-_freezethaw_2010-11_incident.pdf).

Wildfires

4.60 The CCRA (HM Government, 2012) identified an increase in the incidence of wildfires as an emerging risk associated with climate change. Severe wildfire is included in the 'National risk register of civil emergencies' (Cabinet Office, 2013). It is anticipated that LRFs will review and consider the severe wildfire risks, as will the fire and rescue service, through their integrated risk management plan process. The Forestry Commission and the UK Forestry Standard should be consulted as part of the

contingency planning for any development whose location may be prone to such risks.

Windstorms (storms and gales)

4.61 Severe windstorms around the UK have become more frequent in the past few decades. The vulnerability of healthcare buildings in windstorms is a function of the strength of the building envelope components and their connections. Designers should use wind damage and impact prediction models to

take account of the increase in the frequency of windstorms and in average wind speeds.

See also HTM 07-04 – ‘Water management and water efficiency’.

Case study

In 2013 a storm brought disruption to the whole of South Yorkshire, and gale-force conditions cut off the power supply to Barnsley District General Hospital, which was obliged to cancel out-patient appointments while operating on emergency standby generators. The hospital issued a statement to reassure people that patients in the hospital were safe. Power was recovered and normal service resumed later that same day. The incident demonstrates the need to maintain business continuity through implementation of contingency plans and concomitantly the importance of good strategic communications – reassuring the public and mitigating risk.

Water resources

4.62 Increasing pressure on water resources is a growing risk. Buildings will need to become more water-efficient due to the predicted changes in water availability. Climate change and population growth may ultimately lead to less reliable supply conditions or restrictions on abstraction licences for those healthcare organisations with their own borehole supplies.

4.63 Adaptation and mitigation measures would include:

- close cooperation and communication with local water companies to conserve water;
- water conservation measures to collect and store water for non-patient use;
- installing water monitoring systems and water management plans for early detection and repair of leaks;
- checking and regular monitoring of water-pipe capacity and capability at planning/design stage and regularly thereafter.

Blast-resistant building design considerations

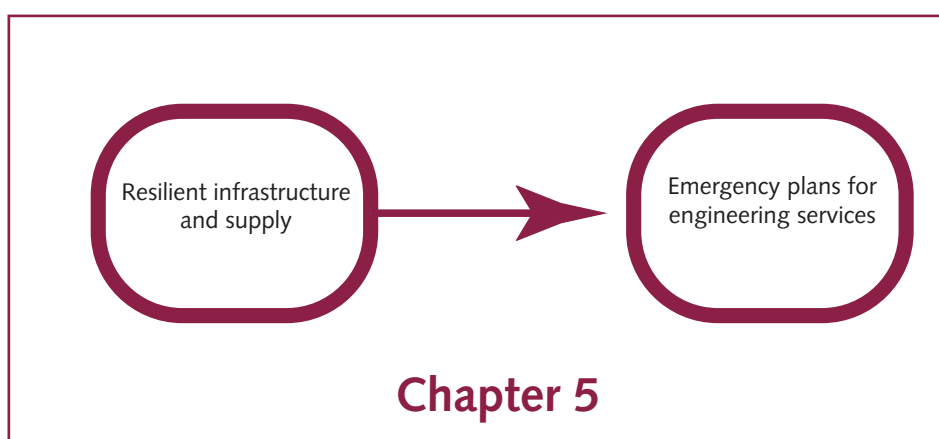
4.64 If a risk assessment (see [paragraphs 2.18–2.22](#)) identifies a high likelihood of threat from terrorism or a bomb, the following will need to be considered to maintain the structural design of buildings to resist blast effects caused by explosions:

- Use a framed construction in either structural steel or reinforced concrete that has the “degree of robustness” required by the relevant British Standards, whatever the number of storeys (that is, all buildings less than five storeys high should be designed as a five-storey building for robustness only).
- Provide “protected spaces” (previously known as bomb-shelter areas). This may be achieved by careful planning of the internal building (not necessarily reinforced concrete) or by the provision of a robust basement construction. In a healthcare environment these areas may need to be extended to wards if patients cannot be evacuated.
- Have ground- and first-floor slabs constructed of in-situ reinforced concrete, with slabs designed as suspended so that they can withstand the removal of one or more structural columns beneath them.
- Have floor slabs tied down to their structural supports to allow for the load reversal that occurs in an upward blast.
- Have a roof slab that is of similar construction to that of a typical floor.
- Have a cladding system that will not become an additional shrapnel hazard if separated from its supports and that can be repaired without removing undamaged panels.

Access to documentation

4.65 During an extreme event, the emergency services may request to see up-to-date electronic and paper copies of site plans, engineering services diagrams and other relevant documents. Senior managers should ensure that these are readily available and accessible.

5. Resilience of building services engineering



Resilient infrastructure and supply

5.1 Many medical technologies and modern communications are reliant on a reliable energy source. Therefore, in planning and designing any healthcare facility, the energy supply not only has to be adequate, but also robust and resilient. Single points of failure should be eliminated.

5.2 The location of hospitals requires careful consideration to ensure that they are built within low-risk areas so that disruption of infrastructure, including energy supplies, is minimised or prevented (see [Chapter 4](#)). Once operational, the systems and equipment providing the source of energy require regular maintenance with the prioritisation of the replacement of old equipment and the use of new and emerging technologies to mitigate the effects of age-related failure of systems and equipment (Klinger et al, 2014).

Electricity

5.3 Electricity is probably the most vital of all infrastructure services; without it, most of the other services will not function. The entire electricity distribution system, both within the facility and the external provision from the supply network, should therefore be designed to be as resilient as possible. This can be achieved by applying the principles of robustness, redundancy and reconfigurability to the system as the design progresses in accordance with HTM 06-01 – 'Electrical services: supply and distribution'. See also 'Report on the lessons learned from the summer 2007 flooding experiences from an estates and facilities perspective' (DH, 2007).

Mains electricity supplies

5.4 Designers should consider how a secure electricity supply can be ensured. Priority allocation of the site should be carried out with the network supplier for the site. Where

practical, consideration should be given to having two or more sources of supply from the supplier. A supply at high voltage (HV) from one or more primary network substations may have a higher initial cost, but will be more resilient against load-shedding in times of high demand or extreme events.

5.5 It is important that NHS-funded providers establish a formal working relationship with the electricity supplier. This may mean registering as a priority user. Normally this will be with a nominated client manager.

Robustness

5.6 The distribution system, including all of the non-electrical components such as substation buildings, emergency fuel supplies, cable ducts and other containment, should be robust enough to survive design hazards and threats. Where facilities are not duplicated, or where potential for a single point of failure exists (for example, where the standby generator is in the same building as the intake substation), robustness is doubly vital as the last line of defence. Consideration should be given to designing such facilities as protected spaces. Action should also be taken to eliminate the single point of failure as a matter of good practice and to ensure maximum robustness.

Redundancy

5.7 The electricity distribution system within the facility is best protected by having multiple sources of supply at all levels. Normal electrical system design, including the requirements and recommendations made in HTM 06-01 – ‘Electrical services: supply and distribution’, recommends the degree of redundancy in an electrical system which may need to be enhanced once credible threats are included in the risk management process.

Control

5.8 Building management (or other control) systems need to give an indication as to the state of the electricity supply. When the mains

supply fails or is subjected to cyber attack, actions need to be triggered such as:

- the preparation of maintenance responses;
- automated responses such as the shutting down of a computer server on activation of a UPS;
- isolation of non-essential loads;
- the ability to initiate manual overrides.

Reconfigurability

5.9 The ability to reconfigure a faulty or failed electricity supply system, or to reconfigure it should demand increase, can be designed into a system at the outset:

- Ring circuits rather than radial feeders provide two possible sources of supply and therefore provide a degree of resilience against damage and failure. Critical ring mains in HV networks can be made “closed” rather than “open” for maximum security of supply, albeit at greater expense, provided that adequate protection arrangements are installed.
- Interconnectors between node points on the network can be positioned to increase options for supply and to allow for bypass of damaged areas or failed components.
- Spare capacity in switchrooms and substations is essential to allow on-site engineering staff options to re-establish supplies after a failure. If access to the busbar is available (for example, by installing sockets and suitable interlock systems), a portable generator can be coupled to the system to replace a failed mains supply, or a new cable can be run out to a temporary facility. When refurbishment projects are being designed in existing facilities, it is good engineering practice to ensure spare capacity remains and, if necessary, install new switchgear.

- Sensing and control: developments in building management and automatic control systems are making it increasingly possible to design-in the ability to automatically sense failures and reconfigure the network accordingly. Business-critical facilities should consider using this technology.

Standby generation

5.10 Generators will provide an additional level of redundancy for essential loads. HTM 06-01 – ‘Electrical services: supply and distribution’ gives guidance on the number of generators that may be appropriate; the hazards and threats identified in the design brief will indicate whether it is appropriate to site standby generation in the same physical location as the power supply it replaces.

5.11 Standby generators should not be sited in basement areas or low-lying areas that are at risk of flooding.

5.12 Standby generators should be subjected to regular full-load testing. This will also ensure that the automated changeover from the mains supply to the standby generator functions correctly. Full-load testing can be achieved using load banks if required, but this on its own will not replicate the correct operation at a time of full mains failure.

Combined heat and power (CHP)

5.13 Where a CHP system is being considered, there is scope to consider this as a secondary form of standby generation provided that its other operating capabilities will be met. If the CHP system is provided on a leased arrangement, the maintenance and emergency repair response times should be considered and stated as contractual requirements, as should regular testing and availability criteria.

Uninterruptible power supplies (UPS)

5.14 Critical loads may require a UPS (static or rotary) to be installed. Currently, battery technology and space requirements generally

limit these devices to providing power for a short period or to a controlled closedown rather than to continue operating indefinitely. An exception to this is where a UPS is used to cover the break in supply while a standby generator starts or to support critical care and essential supplies while alternative supplies are made available.

5.15 For more information regarding management and operation of electrical systems, see the HTM 06 series of guidance, in particular HTM 06-02 – ‘Electrical safety guidance for low voltage systems’ and HTM 06-03 – ‘Electrical safety guidance for high voltage systems’.

Lighting

5.16 Consideration should be given to robust exterior lighting systems for all public access. These systems need to be suitable for extreme weather events (for example, high winds and flooding). External lighting may need to be fixed to the building structure in key locations.

5.17 LED lighting technology is increasingly being used in healthcare settings, principally because of their efficiency and low power consumption. It is possible to supply LED lighting via a dc power source so in an extreme power loss situation it is possible to supply LED lighting systems via battery banks.

Water

5.18 The continued availability of clean and safe hot and cold water supply is vital for healthcare premises, which are dependent on water to maintain hygiene, hydration and a comfortable environment for patients and staff.

5.19 Interruptions in mains water supply – whether planned or unplanned (such as a burst water main, low mains pressure, electrical supply failure, pump failure or concerns relating to water quality) – can disrupt healthcare activities. The design of systems must ensure that sufficient reserve water storage is available to minimise the consequence of disruption, while at the same time ensuring an adequate

turnover of water to prevent stagnation in storage vessels and distribution systems.

5.20 Mitigating the risk of having a single source of supply should be considered, and the possibility of acquiring a second source should be investigated. This could take the form of a second mains water supply, fed from a separate network to reduce reliance on a single network, or alternatively the utilisation of a private borehole or other alternative source. Should the private borehole be identified as being specifically for emergencies, obtaining or retaining an abstraction licence may be easier.

Note

It is important that NHS-funded providers establish a formal working relationship with the water supplier. This may mean registering as a priority user. Normally this will be with a nominated client manager. The two parties should work together to establish, as a minimum:

- potential mains water supply risks and how these risks can be mitigated;
- provision of water supply in the event of mains water failure (for example, provision of water tankers/bowsers, bulk bottled water);
- leakage prevention strategies to prevent contamination of the water distribution system within the healthcare provider's estate from lack of integrity of the on-site potable water distribution system.

5.21 Designers should consider not only how a secure supply can be guaranteed but also how its potable quality can be assured. Client organisations should advise the designer on whether the risk of using non-potable supplies for certain tasks (such as laundry services and cleaning) is acceptable.

5.22 Where potable water is required from secondary or alternative sources, on-site water treatment options (see paragraphs 5.26–5.31)

can help mitigate the loss of mains potable water.

5.23 The designer should consider the integration of bowser/tanker connections so that tankered water supplies can be efficiently discharged into the healthcare building's water storage system. The local water supplier should be able to assist in the provision of tankered water supplies and this will help ensure that the quality of the water delivered in this manner is through an appropriate quality control system.

5.24 HTM 04-01 – 'The control of *Legionella*, hygiene, "safe" hot water, cold water and drinking water systems' and its addendum give comprehensive advice and guidance to healthcare management, design engineers, estate managers and operations managers on the legal requirements, design applications, maintenance and operation of hot and cold water supply, storage and distribution systems in all types of healthcare premises. It is equally applicable to both new and existing sites.

5.25 With respect to risks associated with flood and fire, designers should also refer to:

- Chapter 8 on flood risk in HTM 07-04 – 'Water management and water efficiency';
- 'Report on the lessons learned from the summer 2007 flooding experiences from an estates and facilities perspective' (DH, 2007);
- HTM 05-02 (Firecode) – 'Guidance in support of functional provisions for healthcare premises' (so that requirements for fire-fighting are also met).

Water treatment

5.26 Where a need for on-site water treatment is identified, the required final water quality will determine the treatment required.

5.27 Where the healthcare provider has its own on-site borehole, if this is already being used for the provision of potable water, it should already

be registered with the local authority and compliant with the Private Water Supplies Regulations 2009. Depending on the borehole's characteristics, filtration and disinfection may be required, but in most cases the borehole supply is solely subjected to disinfection.

5.28 Where the on-site borehole is suspected of being contaminated by floodwater or other contaminants, the borehole should be removed from service and expert advice sought before it is returned to service.

5.29 Where it is identified that treatment of alternative water sources is required, packaged potable water treatment plants are available. These are likely to be either reverse osmosis plants or filtration plants. Both require a disinfection process before the water enters the healthcare building's water distribution system and will need to be compliant with the Private Water Supplies Regulations 2009.

5.30 Disinfection may take the form of chlorine-based chemical disinfection, ozone disinfection (via an ozone generator) or ultraviolet disinfection using specialist lamps. As properly controlled chemical dosing with chlorine-based compounds can maintain a residual disinfectant level in the treated water, it is the preferred solution.

Note

There may be the need to consider remineralisation following treatment.

All chemicals used in the disinfection process should be BS/EN accredited.

5.31 For further guidance on water treatment, see HTM 04-01 – 'The control of *Legionella*, hygiene, "safe" hot water, cold water and drinking water systems'.

Bulk stocks

5.32 The quantity of water that is held in storage on-site should be decided. The key factor affecting the decision will be the

anticipated length of time that the mains water supply may fail and the time that would be required to establish an alternative (for example bowser/tanker delivery) supply route. This should also be balanced against the costs associated with maintaining the stock in a potable condition.

5.33 When bulk supply of bottled water is carried out, the pallets of bottled water should be suitably stored to prevent external contamination of the bottles. They should also be stored at room temperature and away from direct sunlight.

5.34 A suitable arrangement for the supply of bottled water should be in place with the healthcare provider's water supplier or other suitable organisation that is able to respond accordingly.

Sewage

5.35 Although certain healthcare premises may have their own sewage treatment facilities, most will dispose of their sewage and trade effluent through the municipal sewerage network. However there are instances where this normally reliable disposal route may break down. A combination of aging sewer networks and the restriction of sewers due to the build-up of fat deposits and other media can lead to capacity problems within the network. In certain instances this will manifest itself as a complete blockage of the network.

5.36 Owing to the increased use of macerators to dispose of bedpan waste and food waste, this effect can also occur within a healthcare organisation's own sewage disposal network if care is not exercised in the correct risk assessment, selection and monitoring of macerators and the on-site sewage disposal network.

5.37 The lack of capacity within the sewer network can be exacerbated during times of heavy or prolonged rainfall, a particular concern during extreme weather events, leading to the backing up of the sewage within the network

and/or surface water flooding. Both can result in flooding of premises or land with water contaminated to a greater or lesser degree with sewage effluent.

5.38 Consideration of the age and condition of the local sewage and surface water disposal networks should form part of the decision-making process when:

- selecting a site for a new facility;
- planning construction of additional buildings on an existing site.

5.39 This is particularly pertinent for facilities built in flood-prone areas, where the risk of sewage inundation as well as flooding should be assessed.

Note

As with water, it is important that NHS-funded providers establish a formal working relationship with the water company that provides their sewage and trade effluent services. This will normally be with a nominated client manager and may be the same person/team providing the point of contact for water services. The two parties should work together to establish, as a minimum:

- potential sewage and trade effluent disposal risks and how these risks can be mitigated or removed;
- provision of waste water tankering services or temporary sewage treatment facilities in the event of sewer collapse, sewerage system failure etc;
- remediation services to assist with promptly returning services to normal following contamination due to sewage or sewage-contaminated flood water.

5.40 The loss of the ability to dispose of sewage and trade effluent is a critical infrastructure vulnerability, and due attention

should be paid to close liaison with local providers at the design stage to ensure that the relevant local sewerage infrastructure is fully understood in terms of its resilience and reliability. As part of risk mitigation, NHS-funded providers may need to consider provision of alternative disposal facilities, perhaps at a far lower flow rate, to allow continued operation of at least part of the facility under condition of failed sewerage arrangements.

5.41 Healthcare organisations that have their own on-site sewage treatment facilities should ensure they have robust plans in place that outline how they will continue to ensure the safe treatment and disposal of sewage during adverse conditions, including returning the treatment facility to correct operation after inundation during flooding events.

5.42 Water UK's (2011) 'National guidance for healthcare waste water discharges' strongly recommends that NHS-funded providers prepare an emergency plan that includes:

- spillages;
- loss of water supply; and
- drainage plans on which drains are suitably marked (for example, "red for foul water sewer" and "blue for surface water sewer").

Fuel

5.43 Fuels should be selected to ensure continuity of supply as well as to satisfy economic and environmental concerns. Primary and secondary fuel arrangements (for example natural gas/diesel dual-fuel options for boilers) are necessary to reduce reliance on sole suppliers and to improve resilience of the supply chain in the event of disruption. Prior engagement and communication with the supplier will:

- better ensure supply in case of emergency; and

- reduce the need for high volume local storage (which mitigates possible theft, contamination and degradation).

5.44 Bulk stocks of fuel should be held to span gaps in supply, but these bulk stocks may also present an attractive target to potential thieves or attackers and should be physically protected. Redundancy can be achieved by ensuring that a number of smaller tanks are held in more than one location, but the fuel, generator and mains transformer should not be aggregated into the same space. Security is important, including the use of lock and key.

5.45 Piped supplies of gas should be discussed with the regional gas transporter to ensure that they are noted as “priority user” and will be maintained/restored as priorities in the event of network difficulties.

5.46 Where off-site fuel storage is considered (oil, solid fuel etc), plans should be made for alternative routes of access in case of blocked roads.

Critical cooling

5.47 Cooling is a particular concern during periods of high temperature. A number of areas and equipment within healthcare facilities have a critical requirement for cooling. These include drug and blood banks, mortuaries, food and prepared meal stores, critical care areas, theatres and diagnostic imaging equipment. Related facilities include business-critical server data centres and high-powered diagnostic equipment.

5.48 In addition to ensuring that the cooling systems have adequate arrangements to power them, adequate redundancy within the system should be provided. This could be achieved by installing a common type of plant across a site to enable cannibalisation of equipment if required.

5.49 Monitoring systems to provide warning of cooling or power failures should be provided, and arrangements or plans made such as:

- data centres being able to hand over to a third party’s backup facility;
- high-priority items such as drugs and blood stocks being moved to other temperature-controlled stores;
- letting enabling contracts for the provision of temporary facilities such as refrigerated ISO containers (that is, shipping containers compliant with ISO standards);
- provision of temporary refrigeration units (if refrigerated mortuary facilities are required).

Piped medical gases

5.50 Healthcare facilities that have a significant requirement for medical gases may consider the benefits of providing a vacuum-insulated evaporator (VIE) and a piped distribution system rather than individual bottles an economically attractive option. In such circumstances, the following factors should also be considered alongside the guidance given in HTM 02-01 – ‘Medical gas pipeline systems’:

- A single VIE for each nature of gas presents a vulnerability to interruption of supply. Provision of two smaller (and physically separated) tanks may not be as economic but will improve resilience with respect to supply chain and deliveries. Monitoring of stock levels within the storage vessels via telemetry to the supplier will also provide additional resilience in supply chain management.
- Regardless of the storage method selected, cylinder storage facilities should be available as a last resort, since the supply of these can be assured from a number of sources (see [paragraphs 5.53–5.54](#)).
- The location of storage tanks should be very carefully considered as they represent a significant hazard in their own right, regardless of any additional threats. The tanks should have good physical protection from unauthorised access and

be sited away from high-occupancy areas. Where space considerations prevent a reasonable separation, a protective wall or bund should be considered.

- The engineering infrastructure to generate medical air and vacuum should be as resilient as the supply of other gases. Compressors and vacuum pumps require a source of electrical power to operate, and standby vacuum devices that operate on the venturi principle need a working supply of medical air.

5.51 Additionally, the piped medical gas distribution systems should include features to prevent gases such as oxygen contributing to a fire or explosion in the event that they become damaged (for example, numerous and easily accessible isolation valves should be provided).

5.52 NHS-funded providers should ensure that continuous access to reliable oxygen supplies (be they via bulk storage systems or individual cylinder provision) is available at all times. This is particularly pertinent during the winter period when pressures on the healthcare system may coincide with extreme wintry weather and associated logistics issues.

Cylinder gases

5.53 Healthcare facilities will need to ensure safe and secure storage for bottled and cylinder gases. In the event of a fire, this can lead to an exclusion zone being set up around the site by the fire and rescue service. This can seriously disrupt services and access, and should be taken on board when choosing a site.

5.54 For both piped and cylinder gases, ensuring priority user status with the supplier will:

- better ensure supply in case of emergency; and
- reduce problems of storage and fire safety.

Ventilation systems

5.55 Ventilation systems are installed throughout healthcare premises to fulfil a number of purposes, some of which have resilience implications. Factors such as smoke clearance for fire protection are already well understood and documented.

5.56 Hazards and threats that may be considered credible in a healthcare facility might include the spread of:

- airborne infections;
- waterborne infections;
- chemical or biological contaminants brought in on casualties;
- a contaminant deliberately released in a healthcare facility. Such a contaminant need not be in itself dangerous – but the impact of a cloud of coloured vapour in a crowded reception may be significant.

5.57 Designers should be briefed that as well as the guidance in HTM 03-01 – ‘Specialised ventilation for healthcare premises’, they should consider ventilation schemes across the entire facility and make an assessment of the flow of air based on developed pressure differentials. This is already commonplace in smaller areas of hospitals such as operating suites, but holistic consideration of the ventilation profile will enable better assessment of likely contamination routes and – if properly designed and commissioned – will provide an additional obstacle to the spread of contamination.

5.58 Good practice dictates the positioning of air intakes out of easy reach and the provision of facilities for immediate shut-down and isolation of discrete zones within the healthcare facility from a central location.

5.59 HTM 03-01 stresses the importance of ensuring that systems are correctly designed, installed, commissioned and maintained. Resilience requirements do not detract from these, but do reinforce the need for stringent maintenance including regular testing,

inspection and cleaning to ensure that systems are operating as designed and will deliver the required function in the event of an incident.

5.60 Owing to the higher running costs associated with generating the pressure differentials, it may be felt appropriate that systems have a “normal” (low-pressure) mode and an “isolation” (high-pressure) mode. If such a method is chosen, the control of how the modes are changed should be carefully designed – both in engineering and management terms – to ensure that it is activated at the appropriate times and remains active until no longer required. Both engineering and clinical staff need to be aware of the modes and the consequences of operation.

5.61 Risk assessment may indicate the filtration of supply air either full-time or temporarily in times of heightened threat. Consideration should be given to the development of safe changing routines in the event that contamination has occurred.

5.62 The three resilience principles (robustness, redundancy and reconfigurability) should be applied to designs to ensure that the ventilation system is:

- **robust** enough to withstand hazards and threats;
- **redundant** in order to allow continued operation in the event of component failure; and
- **reconfigurable** in the event of damage – although in such a case, this may be limited to the provision of dampers to ensure that damaged areas are isolated and that pressure gradients can be maintained.

5.63 Due consideration should be given to whether ventilation systems should be kept on or turned off during incidents (see also HTM 03-01 – ‘Specialised ventilation for healthcare premises’ and HTM 05-02 (Firecode) – ‘Guidance in support of functional provisions for healthcare premises’).

Note

Sealing buildings to increase energy efficiency may lead to a decrease in indoor air quality and/or overheating (unless suitable ventilation is maintained).

Waste disposal

5.64 The ability to remove waste from a facility is a critical logistical concern. Site restrictions and hygiene requirements will preclude the storage of waste for any significant length of time. Healthcare facilities typically require a means to dispose of three separate types of waste (see paragraph 5.65). The area where waste is stored should be secure and well-lit. It should also be sited away from flood risk and contamination sources.

Infectious/clinical/hazardous waste

5.65 When deciding how infectious/clinical waste will be disposed of, consideration should be given to emergency arrangements. Where it is proposed that disposal be outsourced, the issue becomes one of supply chain resilience, but the consequences of this failure may be such that contingency arrangements over the normal contractual arrangements will be required (for example, the provision of a temporary refrigerated store (including body store) or facility). Note that any such temporary arrangements should only be undertaken in full consultation with the EA. See also HTM 07-01 – ‘Safe management of healthcare waste’.

Refuse/recyclables

5.66 Refuse removal is traditionally outsourced to a municipal or other contractor, thus requiring an assessment of supply chain resilience that may indicate that an area for refuse storage needs to be set aside or an alternative standby arrangement made, which may include an alternative supply chain.

5.67 For further guidance on waste disposal, see HTM 07-01 – ‘Safe management of healthcare waste’.

IT and communication systems

5.68 Particular care needs to be considered for the electricity supply and cooling systems needed to support IT systems and communication systems/networks (including wireless systems) as these may be critical during an emergency. For example, if the electricity supply should fail, what impact would this have on:

- access to patients' records, patient data and telemedicine;
- electronically held policy and procedure manuals;
- telephones (including voice over internet protocol (VOIP) systems);
- pagers/cardiac pagers;
- printing;
- building management systems (BMS)/site alarms;
- pneumatic tube systems;
- internal communications (for example, email);
- or other essential systems (that is, those used for the ordering of supplies and medications)?

IT systems

5.69 IT resilience should ensure that suppliers plan, deliver and have the capacity to continually improve IT services aligned to business requirements and industry-standard best practice. Suppliers need to have a monitoring procedure to reduce risks of adverse impact on the business through system failures (for example, cyber attacks). Back-up systems and procedures need to be planned and periodically tested to ensure that essential records (such as patient care records) and data are not lost and to ensure that the building management system (or other systems) are not compromised.

IT service continuity management

5.70 Suppliers should communicate their own resilience plans to NHS-funded providers to enable integration into BCPs and to ensure system resilience is able to meet the level of service availability and business requirements. This should include mitigating any risks accordingly and supporting service improvements. NHS-funded providers should ensure appropriate monitoring of service availability is deployed by suppliers.

Telecommunications

5.71 In designing new, or proposing changes to existing, systems, designers should ensure that consideration is given to the requirements of emergency plans and communication-service resilience before decisions are taken.

5.72 Telecommunications systems should be considered from two perspectives:

- the systems themselves may be business-critical (for example in an IT data centre); or
- they may provide a vital function in managing an emergency (for example public address, telephone and paging systems, the Airwave mobile telecommunication system).

5.73 Where the system is business-critical, the resilience principles should be applied to it and any supporting subsystems.

5.74 For both business-critical and emergency situations, designers of telecommunications systems should consider:

- emergency switching of telephones: fall-back telephones should be sited to guarantee the availability of internal communications to all planned refuges and control centres. The public mobile telephone networks should not be relied on in any emergency communications plan, since extreme external events may overload them or force them to be shut down. Unless specific provision has been

made for availability of a reduced mobile telephone service for specific individuals and handsets, this service should not be solely relied upon in emergency planning;

- public address (PA) and alarm systems: PA and alarm systems provide the primary means to communicate with service users. In addition to providing systems throughout a facility, consider extending the system (or making provision for extension) into the car park or other waiting areas. PA systems should be on the essential services power supply and should also allow input into the system from multiple locations;
- use of dedicated two-way radios as back-up system (as networks are not always reliable during some incidents (for example, suspected terrorism) when networks may be switched off or lost);
- use of corporate screensavers for post-incident bulletin updates;
- paging and wireless data systems: similarly, these systems may need to be receivable in spaces adjacent to the site that are designated for emergency use;
- in an emergency, the media will be extremely keen to gather information. The security of data links, including audio, should be considered. Some form of encryption may be prudent to enable positive control of information release and protect personal or sensitive information;
- automated meter reading of bulk oxygen or fuel supplies via telemetry systems to the supplier (failure in the system will require manual intervention).

5.75 Digital communication and information is vital to business continuity, and specific plans need to be in place to mitigate any loss of service (see the Cabinet Office's (2011) 'UK cyber security strategy – protecting and promoting the UK in a digital world'). Where the system is business-critical, the resilience

principles should be applied to it and any supporting subsystems.

5.76 Home/mobile communication systems will be needed for key staff with whom contact will be required in the event of an emergency or adverse incident.

5.77 Special note should be taken of the need to ensure that batteries of all essential communications equipment are serviceable and fully charged to meet the needs of a prolonged power failure.

Emergency plans for engineering services

5.78 To be resilient, healthcare organisations should be able to restore engineering systems to normal as soon as practicable after an emergency. This will take the form of an emergency plan that will need to be regularly tested and updated, internally as well as with suppliers, to meet changing circumstances.

Note

In all aspects of emergency and resilience planning, NHS-funded providers should ensure engagement with the AEO, LSMS and emergency planning liaison officer (EPLO).

5.79 Healthcare organisations may encounter such scenarios as:

- unplanned interruption to a utility supply (gas, water, electricity, telecommunications etc);
- unexpected equipment and service distribution failures (telephones, water pipework, medical gases etc);
- a civil incident (act of terrorism, civil disturbance etc);
- an environmental incident (floods, storm damage, overheating or other extreme weather event);

- failure of transport infrastructure leading to the loss of external supplies or facilities that support the healthcare organisation.

5.80 Emergency and resilience planning cannot be carried out in isolation; all arrangements should be agreed through consultation and dialogue (internally and externally).

5.81 Individual services or departments should be encouraged to accept responsibility for contingency arrangements. This is particularly important for services provided through associated contracts (via PFI partners, commercial businesses, service level agreements etc).

Creating an emergency plan supported by resilience capability

5.82 It is important to define the area to which the plan will apply. This may be by site rather than individual buildings to avoid repetition and to embrace the wider service issues. All the estates services and facilities that exist in the range of buildings on-site should be considered. This plan should be considered in conjunction with the risk assessment described in [paragraphs 2.18–2.22](#).

5.83 [Table 2](#) gives a broad list of suggested topics for consideration. It is not a comprehensive list and may not be applicable to all sites, but it should act as a prompt to establish the “services list” for a particular healthcare organisation.

5.84 All plans should be documented and supported by relevant information. This should be kept up-to-date and under constant review. See NHS PAM for further assistance ([paragraphs 1.13–1.16](#)).

Testing the plan

5.85 Plans should be exercised in order to familiarise staff and to test procedures. Duty to exercise plans is contained in ‘NHS Commissioning Board core standards for emergency preparedness, resilience and response (EPRR)’ from NHS England (2013).

5.86 Larger and more wide-ranging exercises should be carefully planned and coordinated through the AEO or the EPLO.

5.87 These approaches should engage all staff involved in resilience planning for the healthcare organisation so that all lessons learned can be shared across all services and used to update the plans.

5.88 Maintaining services is an essential function of the emergency plan. Alternative sources of catering, laundry, waste disposal, transport, energy etc need to be confirmed, and all lines of communication and supply chains regularly tested and reviewed.

5.89 It is also necessary to discuss and establish the priorities of clinical services within the plan. These will include life-critical functions (operating theatres, critical and special care areas, neonatal intensive care units, emergency care etc); diagnostic services (imaging, laboratories etc); and clinical support functions (blood, sterile services, pharmaceutical supplies, medical gases, transport etc).

5.90 Particular consideration needs to be given to the services supporting critical and special patient requirements. This could include, for example, positive/negative ventilation for immuno-suppressed/infectious patients, intensive care, patient mobility and community care. These examples are not exhaustive, and a comprehensive assessment undertaken by a multidisciplinary group should take place and be maintained, to inform the emergency plan.

5.91 Prioritised but flexible, estate and facilities services which underpin clinical priorities will provide a good platform for the organisation to cope with the impact of emergencies, hazards and threats and speed up recovery to provide normal business continuity.

External impact

5.92 External influences are perhaps the most difficult element to incorporate into emergency plans due to the wide range of scenarios that could be presented. Consequently, scenario

System	Services	External influence
Mains electricity supply Standby generators CHPs UPS + other batteries Emergency lighting Mains water Hot water Treated water (renal etc) Heating, ventilation and air-conditioning Steam Pneumatic air tube systems Building management system Drainage Surface/foul/waste Fuel supplies Gas/oil/other fuels Communications, including wireless systems: • telephones (fixed) • mobile • paging CCTV Burglar alarms Door interlocks (access and ingress) IT and patient information systems Nurse call systems Lifts Sterilization and decontamination Piped and cylinder medical gases Fire alarms Refrigeration (food, mortuary, blood supplies, pharmacy equipment etc) Medical equipment Building structure Architectural design features	Catering – patients and staff Key clinical departments (A&E, theatres, critical care etc) Clinical support (pathology/radiology etc) Estates & facilities management (including engineering staff such as Authorised Persons and Competent Persons) Transport Portering Administration support Patient information Cleaning Waste disposal Laundry Medical supplies Fuel supplies Water drainage Security Parking	Mains water contamination Air pollution/quality Flooding Mains sewage treatment failure Transport routes and infrastructure Infestation Civil disturbance Explosion Excavation Terrorism incidents Communications Other severe/extreme weather conditions: • high temperatures/heatwaves • extreme cold weather/ice and snow • high winds (windstorms) Fires from adjacent properties Fauna and flora damage

Table 2 Suggested systems and services and building for consideration when creating an emergency plan

planning for every eventuality is very unlikely and unnecessary; a generic response framework can address most scenarios.

5.93 However, some of the most likely scenarios and the key issues arising should be examined, evaluated and tested to ensure that some form of response is in place for that eventuality (for example, loss of a major utility or external communication links).

Staff functions

5.94 The structure of different organisations will mean that staff with varying levels of experience and expertise could be called on to deal with estates and facilities emergencies; hence, there is a need to ensure that regular training and exercises take place involving all staff groups that may be called upon.

5.95 Written emergency operational procedures should be easily understood by those people expected to use them. For example, emergencies associated with engineering services should always be handled by qualified, competent and experienced engineers, as the emergency operational procedure may be highly technical.

5.96 In many cases, however, standby staff who may be the first to attend an emergency will not have the technical knowledge to make appropriate decisions. If this is the case, emergency operational procedures should be detailed and specific, and should include instruction on where and how to seek assistance from a more experienced colleague at any stage. This instruction should normally include more than one route and more than one level of management (that is, it should have some communication resilience).

Appendix 1: Design proposal review

Impacts of loss of power, water, drainage, sewage and transport – giving example questions to mitigate the impacts on healthcare organisations

This appendix gives examples of the questions that should be asked by the reviewers of a design proposal.

The list of questions given should not be taken as exhaustive; it is intended as a guide to show how to gauge the level of resilience in a proposal.

Understanding the impacts outlined in [Table A1](#) on the ability to deliver healthcare will inform the design team and direct the questions to ask during the planning process.

Scenario 1 – Mains water supply fails for three days

When considering safe water supplies, consideration needs to be given to:

- the Health and Safety Executive's 'Legionnaires' disease: the control of legionella bacteria in water systems – Approved Code of Practice and guidance on regulations' (commonly known as L8); and
- HTM 04-01 – 'The control of *Legionella*, hygiene, "safe" hot water, cold water and drinking water systems'.

- 1 What arrangements exist in the design for supplying water?
- 2 How will a failure in the supply be detected?
- 3 Are emergency stocks held in tanks?
 - 3a How much stock?
 - 3b How was this figure arrived at?
 - 3c Is this based on normal rates of consumption or rationed?
 - 3d How will the water in these tanks be kept potable so that it is ready for use immediately?
 - 3e What arrangements exist for turning over the stock?
- 4 Is there space in the grounds for collapsible temporary tanks?
 - 4a How long will it take to provide this capability (that is, how much notice is required)?
 - 4b Does the volume of tank stock allow sufficient time to construct these temporary tanks?
 - 4c Will they require pumping arrangements to feed into the existing distribution system?

Power outage	Results in reduced ability or inability to maintain critical care which may result in patients being either transferred to unaffected areas or evacuated to other designated facilities. Lifts, hoists and pneumatic air tube systems not working – severely restricting access to full healthcare facilities. Fire safety alarms, CCTV, burglar alarms and associated equipment not working – extreme risk of patient safety and safeguarding the infrastructure. IT, internet and computers going down, therefore limiting access to medical records – can have severe repercussions on patient care. Refrigeration – some medication needs temperature-controlled storage in a medical refrigerator. Impact on continuing patient treatment. Also, if food refrigeration is not available, food will be spoiled; this may affect patients' dietary requirements. Communication systems – patients unable to contact emergency services; impact on mobile phone networks; inability to recharge mobile phones or portable/cordless phones and two-way radios. No electricity to recharge essential equipment. Lighting inadequate or in some instances not provided – inability to deliver patient care (for example operating theatre lists); safety and security issues; impact on patients with visual impairment; impact on people with mental health problems or those with dementia. The ability to maintain essential equipment in limited lighting. Emergency lighting – (as above). Heating, cooling and ventilation – loss of any of these systems creates a poor care environment with patients too cold in winter or suffering heat exhaustion in summer or respiratory conditions through poor ventilation. Washing machines, dishwashers and catering equipment cannot be used – adequacy of linen supplies and availability of disposable paper plates/plastic utensils etc. Impact on increased waste, storage and cost of disposal. Pumping stations, booster pumps and monitoring mechanisms may not work at their optimum level, causing disruption to water, drainage and sewage – hydration, cleanliness, hygiene, contamination issues (see below).
Water, drainage, sewage	Power is necessary for pumping and booster pumps and monitoring mechanisms – loss of clean drinking water, hot water for bathing, washing, cleaning and hygiene. Poor drainage leads to back-up water in the pipes – contamination and potential public health issues. Sewage treatment failure – could lead to untreated/undertreated sewage being added directly to streams and water courses, leading to contamination, public health issues and clean-up measures and costs in the future.
Transport	Transport is dependent on fuel and reliant on electricity – that is, fuel pumps. If transport cannot get to and from the site, it is likely to result in issues around: • patients' inability to get to hospital for healthcare • patients calling emergency services for help • staff accessing patients in the community • staff ability to get to hospital to provide an adequate care service • staff on duty not able to go home, leading to stress and exhaustion.
Community health effects	Loss of home care, that is, oxygen or dialysis units. Lack of home care because staff not able to deliver community service. Loss of power in the community impacts on loss of lighting and therefore increase in accidents; loss of cooking and refrigeration affecting ability to have wholesome nutritional meals, hot drinks etc. Adverse mental health reactions to loss of services, that is, trauma, anxiety, depression. The impact means a greater demand on hospital healthcare services.

Table A1 Impacts of power outages and their implications on water, drainage, sewage, IT and transport and the ability of NHS-funded providers to maintain healthcare

- 5 Could a borehole and private supply be provided (that is, one procured outwith that supplied by the local water vendor)?
- 5a Will this be for emergency use only (may be easier to get an abstraction licence)?
- 6 What engineering controls will be in place if water rationing is part of the response plan?
- 7 Will non-essential supplies be shut off? Manually or automatically (by the BMS)?
- 8 What impact will the loss of water or imposition of rationing have on other services?
 - steam boiler/generator plant;
 - centralised sterile services department, operating theatre air-conditioning plant and other medical users;
 - catering, cleaning and other support users.
- 9 What will be the effect of reduced flow on the sewerage system?
 - simple trap-water seals may evaporate and allow gases/airborne bacteria to backflow;
 - reduced effectiveness in clearing pipework, build-up of sludge, blockages.
- 10 What is the possibility of using non-potable water from borehole or other source to flush systems?
- 2 What external services require mains electricity for delivery?
- 3 Will the local water undertaking be able to deliver water (pump failure?)
- 4 Outsourced suppliers, for example sterile supplies: is there sufficient space allocated within the facility to hold stocks for the anticipated duration of the failure? Will the provider be prepared to invest sufficient capital to hold these stocks?
- 5 What arrangements exist for emergency supply of electricity (that is, temporary generators, quick connections)?

Standby generator

- 6 Is the engine rated for continuous running? (Certain generators are only rated for non-continuous operation, for example 8 hours in a 24-hour period.)
- 7 How much fuel is held? Is there a need for a fuel bowser?
- 8 Is there adequate cooling for the generator to operate for extended periods in midsummer?
- 9 What if the generator is down for servicing on the day?
- 10 Has provision been made in the design for connection of another generator during maintenance?
- 11 Who will provide this additional generator and where will it be sourced from?
- 11a Is there an additional competent person available to supervise the running of the generator while under load?
- 12 Who owns the standby generator: the provider or a subcontractor?
- 12a If it is a subcontractor, how quickly are emergency repairs carried out?

Scenario 2 – Mains electricity fails for 24 hours

When considering this scenario, consideration will need to be given to prioritisation strategies with suppliers.

- 1 Is the normal supply at HV or LV?

- 12b** Consider the implications of a wide-scale incident on this subcontractor's ability to deliver.

Combined heat and power (CHP) plant used as a standby generator

When considering this aspect, refer to HTM 06-01 – 'Electrical services: supply and distribution'.

- 13** What arrangements exist for dumping excess heat in case of low demand? (If this needs water, consider a cascade failure.)
- 14** Does the design use the hospital heating system? (Consider the effect of possibly having to turn on the heating in midsummer to allow the generator to operate.)
- 15** What is the impact of internal failure, for example if a substation or distribution board fails?
- 15a** Can supply be re-routed from somewhere else?
- 15b** Is it possible to attach a portable generator?
- 15c** Who will provide the generator, service it etc?
- 16** What impact will the loss of the non-essential supply have on facility operations?
- 17** How long will it take to recover and clear any backlog of non-essential work?

Scenario 3 – Loss of telephone communications for up to five days

- 1** Which systems use the telephone network?

Internet connection and data centres

When considering this aspect, undertaking a cost/benefit analysis would be necessary to

determine the best options to realistically pursue.

- 2** Can supplier orders and deliveries still be tracked?
- 3** Are stock levels of critical supplies sufficient to last for the loss of service, or will manual monitoring of stock levels be required?
- 4** Where will the manpower for manual monitoring come from?

Building management system

- 5** Are satellite sites controlled and monitored from a remote location?
- 6** Could loss of the telephone network and data centres make remote operation impossible?
- 6a** Will systems have to be manually operated (manpower provision, costs)?
- 6b** Will systems/plant and equipment operate in less economical modes (increased running costs)?

Plant monitoring systems

- 7** Leased/hired generators and CHP plant often have a telephone connection to the manufacturer to report faults, allow for remote fault-finding, and identify routine maintenance requirements.
- 7a** How will a fault be reported if found?
- 7b** Will the estates department be aware?

CCTV and security systems

- 8** Remote monitoring of CCTV at an off-site security centre may be a financially viable option for a provider to consider.
- 8a** Will this system continue to operate if the telephone network and data centres fail?
- 8b** What vulnerabilities would be exposed by this failure?

Appendix 2: Case study. Ysbyty Ystrad Fawr local general hospital

The site for the new 276-bed Ysbyty Ystrad Fawr local general hospital is located on a floodplain. During the various stages of design, proposals were developed to ensure that the hospital remains in operation during any extreme flood event. Thus, the main hospital concourse is located one floor above the floodplain with parking arranged at the lower ground level. Patient and staff areas are sited around a series of enclosed and semi-enclosed

courtyards at both the lower ground and upper ground levels.

Extensive flood modelling was undertaken to understand the impact of a flood with regard to the hospital site. In addition, the flood-modelling exercise determined the broader impacts of flooding and displacement on the wider community.



Aerial view of Ysbyty Ystrad Fawr. ©Bam Construction Limited



View showing the car park below the elevated building. ©Philip Handforth Professional Photos



Further view showing elevated building ©Philip Handforth Professional Photos

References

Note

This HBN was prepared for publication in April 2014. Readers should ensure that they use the latest or new editions of all legislation, British/European Standards and guidance that post-date the publication of this document.

Acts and regulations

Care Quality Commission (Registration) Regulations 2009. SI 2009 No. 3112. HMSO, 2009.

<http://www.legislation.gov.uk/ukxi/2009/3112/made>

Civil Contingencies Act 2004. HMSO, 2004.

<http://www.legislation.gov.uk/ukpga/2004/36/contents>

Climate Change Act 2008. HMSO, 2008.

<http://www.legislation.gov.uk/ukpga/2008/27/contents>

Floods and Water Management Act 2010.

<http://www.legislation.gov.uk/ukpga/2010/29/contents>

Health and Social Care Act 2008 (Regulated Activities) Regulations 2010.

SI 2010 No. 781. HMSO, 2010.

<http://www.legislation.gov.uk/ukxi/2010/781/contents/made>

Health and Social Care Act 2012. HMSO, 2012.

<http://www.legislation.gov.uk/ukpga/2012/7/contents/enacted>

Private Water Supplies Regulations 2009. SI 2009 No. 3101.

<http://www.legislation.gov.uk/ukxi/2009/3101/note/made>

DH publications

Health Building Notes

Health Building Note 00-01. General design guidance for healthcare buildings.

<https://www.gov.uk/government/collections/health-building-notes-core-elements>

Health Building Note 00-08. Estatecode.

<https://www.gov.uk/government/publications/guidance-for-infection-control-in-the-built-environment>

<https://www.gov.uk/government/collections/health-building-notes-core-elements>

Health Building Note 11-01 Supplement A. Resilience and emergency planning in primary and community care.

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/148510/HBN_11-01_Supp_A_Final.pdf

Health Technical Memoranda

Health Technical Memorandum 00. Policies and principles of healthcare engineering.

<https://www.gov.uk/government/publications/guidance-policies-and-principles-of-healthcare-engineering>

Health Technical Memorandum 02-01. Medical gas pipeline systems.

<https://www.gov.uk/government/publications/medical-gas-pipeline-systems-part-a-design-installation-validation-and-verification>

Health Technical Memorandum 03-01. Specialised ventilation for healthcare premises.

<https://www.gov.uk/government/publications/guidance-on-specialised-ventilation-for-healthcare-premises-parts-a-and-b>

Health Technical Memorandum 04-01. The control of *Legionella*, hygiene, “safe” hot water, cold water and drinking water systems.

<https://www.gov.uk/government/publications/hot-and-cold-water-supply-storage-and-distribution-systems-for-healthcare-premises>

Health Technical Memorandum 04-01: Addendum. *Pseudomonas aeruginosa* – advice for augmented care units.

<https://www.gov.uk/government/publications/addendum-to-guidance-for-healthcare-providers-on-managing-pseudomonas-published>

Health Technical Memorandum 05-02 (Firecode). Guidance in support of functional provisions for healthcare premises.

<https://www.gov.uk/government/publications/guidance-in-support-of-functional-provisions-for-healthcare-premises>

Note

Health Technical Memorandum 05-02 is being revised and is due for publication in 2014.

Health Technical Memorandum 06-01. Electrical services: supply and distribution.

<https://www.gov.uk/government/publications/guidance-on-electrical-services-supply-and-distribution-within-healthcare-premises>

Health Technical Memorandum 06-02. Electrical safety guidance for low voltage systems.

<https://www.gov.uk/government/publications/electrical-safety-guidance-for-low-voltage-systems-in-healthcare-premises>

Health Technical Memorandum 06-03. Electrical safety guidance for high voltage systems.

<https://www.gov.uk/government/publications/electrical-safety-guidance-for-high-voltage-systems-in-healthcare-premises>

Health Technical Memorandum 07-01. Safe management of healthcare waste.

<https://www.gov.uk/government/publications/guidance-on-the-safe-management-of-healthcare-waste>

Health Technical Memorandum 07-02. Encode.

<https://www.gov.uk/government/publications/encode-guidance-on-the-procurement-and-management-of-energy-in-the-nhs>

Health Technical Memorandum 07-04. Water management and water efficiency.

<https://www.gov.uk/government/publications/water-management-and-water-efficiency-best-practice-advice-for-the-healthcare-sector>

Health Technical Memorandum 07-07. Sustainable health and social care buildings.

<https://www.gov.uk/government/publications/sustainable-health-and-social-care-buildings-planning-design-construction-and-refurbishment>

Other DH documents

(The) NHS Constitution. The NHS belongs to us all.

<http://www.nhs.uk/choiceintheNHS/Rightsandpledges/NHSConstitution/Documents/2013/the-nhs-constitution-for-england-2013.pdf>

NHS Premises Assurance Model (NHS PAM).

<https://www.gov.uk/government/publications/nhs-premises-assurance-model-launch>

Report on the lessons learned from the summer 2007 flooding experiences from an estates and facilities perspective.

http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_087103?IdcService=GET_FILE&dID=170858&Rendition=Web

British Standards

BS ISO 22301:2012. Societal security. Business continuity management systems. Requirements. British Standards Institution, 2012.

Cabinet Office publications

Emergency preparedness (2012).

<https://www.gov.uk/government/publications/emergency-preparedness>

HMG security policy framework (2013).

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/299556/HMG_Security_Policy_Framework_v11.0_doc.pdf

National risk register of civil emergencies (2013).

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/211867/NationalRiskRegister2013_amended.pdf

UK cyber security strategy – protecting and promoting the UK in a digital world (2011).

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/60961/uk-cyber-security-strategy-final.pdf

HM Government publications

Emergency response and recovery: non statutory guidance accompanying the Civil Contingencies Act 2004. [updated 2013]

<https://www.gov.uk/government/publications/emergency-response-and-recovery>

(The) National Adaptation Programme 2013.

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/209866/pb13942-nap-20130701.pdf

UK Climate Change Risk Assessment: Government Report 2012.

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/69487/pb13698-climate-risk-assessment.pdf

DCLG guidance

Code for sustainable homes.

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/5976/code_for_sustainable_homes_techguide.pdf

Improving the flood performance of new buildings: flood resilient construction.

http://www.planningportal.gov.uk/uploads/br/flood_performance.pdf

National planning policy framework for England and planning practice guidance.

<http://planningguidance.planningportal.gov.uk/>

Revision of building regulation policy on radon: impact assessment.

<https://www.gov.uk/government/publications/revision-of-building-regulation-policy-on-radon>

NHS England publications

Business continuity policy (2013).
<http://www.england.nhs.uk/wp-content/uploads/2013/08/pol-bus-cont.pdf>

Business continuity management strategy (2013).
<http://www.england.nhs.uk/wp-content/uploads/2013/08/pol-bus-cont-man-strat1.pdf>

Business continuity management strategy toolkit (2014).
<http://www.england.nhs.uk/wp-content/uploads/2014/01/toolkit-cover-doc.pdf>

NHS Commissioning Board core standards for emergency preparedness, resilience and response (EPRR).
<http://www.england.nhs.uk/wp-content/uploads/2013/03/epr-core-standards.pdf>

NHS standard contract 2014/15.
<http://www.england.nhs.uk/nhs-standard-contract/>

PHE resources

Cold weather plan for England (2013).
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/252838/Cold_Weather_Plan_2013_final.pdf

Heatwave plan for England (2013).
<https://www.gov.uk/government/publications/heatwave-plan-for-england-2013>

Strategic Health Asset Planning and Evaluation (SHAPE).
<http://shape.dh.gov.uk/>

Other publications

Association of Chief Police Officers (ACPO) (2005). **Secured by design – hospitals**.
http://www.securedbydesign.com/pdfs/SBD_Hospitals_110405.pdf

Department for Environment, Food & Rural Affairs (Defra) (2013). **National flood emergency framework for England**.

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/254292/pb14033-national-flood-emrgency-framework.pdf

Health & Safety Executive (2013). **Legionnaires' disease: the control of legionella bacteria in water systems – Approved Code of Practice and guidance on regulations**. HSE Books, Sudbury.
<http://www.hse.gov.uk/pubns/books/l8.htm>

Information Commissioner's Office (2008). **CCTV code of practice**. ICO, Wilmslow.
http://ico.org.uk/~media/documents/library/Data_Protection/Detailed_specialist_guides/ICO_CCTVFINAL_2301.pdf

Klinger, C., Landeg, O. and Murray, V. (2014). **Power outages, extreme events and health: a systematic review of the literature from 2011–2012**. PLOS Currents Disasters. No. 1, January.
<http://currents.plos.org/disasters/article/power-outages-extreme-events-and-health-a-systematic-review-of-the-literature-from-2011-2012/>

The NHS Protect (2009). **Lockdown guidance**. [Only available via NHS Protect's secure extranet.]

Short, C.A., Lomas K.J., Renganathan, G. and Fair, A.J. (2012). **Building resilience to overheating into 1960s UK hospital buildings within the constraint of the national carbon reduction target: adaptive strategies**. Building and Environment. Vol. 55, pp. 73–95.
<http://dx.doi.org/10.1016/j.buildenv.2012.02.031>

Water UK (2011). **National guidance for healthcare waste water discharges**. London.
<http://www.water.org.uk/home/policy/publications/archive/industry-guidance/wastewater-from-hospitals/national-guidance-hospital-discharges-april-2011-v1.pdf>

World Health Organization (WHO) (2011).
Hospital emergency response checklist.
WHO, Copenhagen.
<http://www.euro.who.int/en/health-topics/emergencies/disaster-preparedness-and-response/publications/2011/hospital-emergency-response-checklist>

World Health Organization (WHO) (2008).
Hospital safety index. Pan American Health Organization, Washington, DC.
<http://www1.paho.org/english/dd/ped/SafeHospitalsChecklist.htm>



Ventilation Systems Policy

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1.0 Introduction

- Ventilation is used extensively in healthcare premises to closely control the environment and air movement of the space that it serves. This is for both the comfort of occupants in buildings and to contain, control and reduce hazards to patients, staff and visitors from airborne contaminants including, dust and harmful micro-organisms.
- This Policy sets out the detailed requirements for the maintenance and safe operation of all air conditioning and ventilation plant as stated in SHTM 03-01 Parts A & B. These will be maintained so that they do not present a risk to persons either in the vicinity of the plant, in areas served by the plant, or a statutory compliance risk to NHS Greater Glasgow & Clyde.
- This Policy requires that all ventilation and air conditioning equipment is installed, inspected, serviced and maintained in accordance with all Statutory Instruments, NHS Guidelines and Scottish Health Technical Memorandums (SHTM's) to ensure that such equipment does not pose a health or operational risk to either, staff, patients or visitors

2.0 Scope

- This Policy applies to all staff, service users and contractors associated with the NHS Greater Glasgow & Clyde. Those persons with defined responsibilities should read this policy, and where applicable, read and understand the ventilation procedures manual.
- This Policy covers all maintenance activities on ventilation and air conditioning plant within NHS Greater Glasgow & Clyde, and any sites which NHS Greater Glasgow & Clyde is responsible for the maintenance of ventilation equipment. This will include, but not limited to, local room extraction plants up to full air handling and conditioning systems.
- The Ventilation policy makes reference to SHTM 00 Best Practice Guidance for HealthCare Engineering with regards to dealing with emergencies e.g. Loss of utilities, failure of a main component and storm damage (relevant if AHU's and chillers are located on roofs).
- This policy will need to be reviewed annually or subject to and industry or government guidance, SHTM `s and best practice updates.

3.0 Duties and responsibilities

3.1 Clear lines of managerial responsibility should be in place so that no doubt exists as to who is responsible for the safe operation and maintenance of the equipment.

3.2 A periodic review of management systems should take place in order to ensure that the agreed standards are being maintained.

3.3 Persons required for inspecting, verifying or maintaining ventilation equipment will need to show that they are competent to do so. As a minimum they should have sufficient knowledge of its correct operation to be able to recognise faults. They should have attended CP (V) training.

3.4 Designated staff functions

A person intending to fulfil any of the staff functions specified below should be able to prove that they possess sufficient skills, knowledge and experience to be able to perform safely the designated tasks.

3.5 Management

Management is defined as the owner, occupier, employer, chief executive, general manager or other person who is ultimately accountable for the safe operation of premises.

3.6 Chief Executive

The Chief Executive has the overall authority and responsibility for ensuring ventilation services and systems are properly operated, maintained and repaired throughout NHS GG&C in line with SHTM 03-01. The Chief Executive's specific responsibilities are to ensure that NHS GG&C appoint the Designated Person in writing.

3.7 Designated Person (DP)

This person provides the essential senior management link between the organisation and professional support. The Designated Person should also provide an informed position at board level. They are also responsible for ensuring that there are sufficient and suitable resources available to enable all systems associated with ventilation systems are operated, maintained and repaired safely and effectively.

3.8 Authorising Engineer (Ventilation), AE(V)

The AE (V) is defined as a person designated by Management to provide independent auditing and advice on ventilation systems and to review and witness documentation on validation.

The AE will act as an independent, professional advisor to the healthcare organisation. The AE should be appointed by the organisation with a brief to provide services in accordance with the SHTM guidance.

The AE will act as an assessor and make recommendations for the appointment of AP's, monitor the performance of the service and provide an annual audit to the DP. To carry out this effectively, particularly with regard to audit, it is preferable that the AE remains independent of the operational structure of the NHS board.

3.9 The Compliance Manager

Has an administrative role in ensuring compliance for Ventilation systems across NHS GG&C is managed effectively.

3.10 Authorised Person – Lead (Ventilation), AP (V/L)

The Lead Authorised Person is a site specific role, they will direct all other AP's in their daily duties and control and manage the Ventilation systems on the site. They will be responsible for the practical implementation and operation of Management's safety policy and procedures relating to the engineering aspects of ventilation systems.

3.11 Authorised Person (Ventilation) AP (V)

The AP(V) will be an individual possessing adequate technical knowledge and having received appropriate training, appointed in writing by the Designated Person (in conjunction with the advice provided by the AE(V)), who is responsible for the practical implementation and operation of Management's safety policy and procedures relating to the engineering aspects of ventilation systems. There is currently no requirement for AP refresher training however there is a requirement for an AE (V) to interview AP (V) every 3 years.

3.12 Competent Person (Ventilation) CP (V)

The CP (V) is defined as a person designated by Management to carry out maintenance, validation and periodic testing of ventilation systems. Who, further to CP Ventilation training and assessment by their AP (V) , should be appointment as a CP (V) in writing.

3.13 Competent Person with limitations (Ventilation) CP (V*)

All persons carrying out work on ventilation systems are to be appointed as a CP (V) in writing by the AP (V) for the level and complexity of work undertaken.

3.14 Infection Control Officer

The Infection Control Officer (or consultant microbiologist if not the same person) is the person nominated by management to advise on monitoring the infection control policy and microbiological performance of the systems.

Major policy decisions should be made through an infection control committee. The infection control committee should include representatives of the user department and estates and facilities or their nominated representative (that is, the AP (V)).

4.0 Records

A record should be kept of those appointed to carry out the functions listed above. The record should clearly state the extent of the post holder's duties and responsibilities, and to who they are to report.

5.0 Training

Routine inspection and maintenance procedures can cause risks to the health of staff carrying out the work and those receiving air from the plant. All those involved should be made aware of the risks, and safe systems of work should be agreed. Suitable safety equipment should be provided as necessary, and training in its use should be given.

Any training given should be recorded, together with the date of delivery and topics covered.

Training in the use of safety equipment and a safe system of work will need to be repeated periodically in order to cater for changes in staff

6.0 Ventilation Systems

6.1 All ventilation systems should be subject to but not limited to one visual inspection annually.

6.2 The purpose of the inspection is to establish that:

- The system is still required; the AHU conforms to the minimum standard set out in (SHTM 03-01 part B Section 3);
- The fire containment has not been breached;
- The general condition of the system is adequate for purpose;
- The system overall is operating in a satisfactory manner.

6.3 The 40 point check sheet (Appendix B) should be used to record the result of the inspection.

- 6.4 All critical ventilation systems should be inspected quarterly and verified at least annually. In some circumstances the verification may need to be carried out more frequently.
- 6.5 The quarterly inspection should be as detailed in paragraphs 6.1 – 6.3.
- 6.6 The purpose of the annual verification will be to ensure additionally that the system:
- Unless otherwise specified below, the ventilation system should achieve not less than 75% of the design air-change rate given in SHTM03-01 Part A Appendix 1, or its original design parameters.
 - The pressure regime should achieve not less than 75% of the design value given in SHTM03-01 Part A Appendix 1, or its original design parameters; and the pressure gradient relationships with regards to surrounding areas must be maintained.;
 - Is operating to an acceptable performance level;
 - Remains fit for purpose.

Definition of a critical system

- 6.7 Ventilation systems serving the following are considered critical:
- Operating theatres of any type, including rooms used for investigations (for example catheter laboratories);
 - Patient isolation facility of any type;
 - Critical care, intensive treatment or high-dependency unit;
 - Neonatal unit; SHTM 03-01: Part B: Operational management and performance verification Version 1: October 2011 Page 26 © Health Facilities Scotland, a Division of NHS National Services Scotland
 - Category 3 or 4 laboratory or room;
 - Pharmacy aseptic suite;
 - Inspection and packing room in a sterile services department;
 - MRI, CAT and other types of emerging imaging technologies that require particularly stable environmental conditions to remain within calibration;
 - Any system classified as an LEV system under the COSHH Regulations;
 - Any other system that clearly meets the definition.

7.0 Estates alerts and operational restrictions

Estates alerts and operational restrictions related to ventilation systems on site(s) may be issued by various means, such as

- Health and Safety Alerts
- NHS Estates
- Health Facilities Scotland (HFS)
- Competent Persons reports
- Safety Information Bulletins issued by NHS
- Manufactureres of ventilation installation equipment and components
- Asbestos Register (Shine). The Board has ducting with asbestos mastic and rope seals throughout its estate.

8.0 Equipment Release Certificate

8.1 This is a safety document, for use in Critical Ventilation plant, which is a form signed by the user, countersigned signed and issued by an AP (V) to the CP (V) in charge of work to be carried out. It defines the scope of the work to be undertaken and makes known exactly what areas are affected.

8.2 The AP (V) will ensure all CP(V)`s and Test Specialists working on ventilation systems carry out their duties in a safe and efficient manner in accordance with SHTM 03-01 and best practice. All work will be conducted in accordance with written instructions.

9.0 Emergency Procedures

In the event of System failure the AP (V) will notify the User (Critical System) and the site infection control team, who shall collectively consider the implications of the failure and the continued use of the Area served by the Critical System, to decide whether or not to recommend closure of the facility to the respective Management Team. All decisions should be formally recorded and issued to the General Managers for their records.

10.0 Business Continuity Plans

Departments and users should develop business continuity plans for loss of critical ventilation services in the event of system failure or conditions outside of the systems operating envelope.

11.0 Monitor & Review

The ventilation services policy shall be reviewed annually with regards to procedures, incidents and the competence of staff for their assigned duties by the DP. An agreed minute of the review meeting shall be presented by the DP to the Chief executive for their consideration before being passed to the relevant persons and line managers for action, thereafter the document is to be placed in the operational procedures manual / file.

12.0 References

H&S at Work 1974.
 Provision And Use of Work Equipment regulations 1998.
 Management of H & S at Work Regulations.
 SHTM 00 - Best Practice Guidance for Healthcare Engineering.
 SHTM 03-01 - Ventilation Services.
 SHTM 04-01 - The control of Legionella in healthcare premises
 – a code of practice.
 HSE ACOP L8 (Control of Legionella in healthcare water systems).
 The Pressure Systems Safety Regulations 2000
 SHTM 08-08 Pressure systems: policies and guidance
 NHS GG&C Pressure System Policy.

APPENDIX A – SCHEDULE OF VENTILATION SYSTEMS

Ventilation systems include (but are not restricted to) the following summary:

System / Type	Typical Area of Use
General (Extract)	Operating theatres Hospital wards and departments Toilets Bathrooms Kitchens Mortuary
General (Supply)	Operating theatres Hospital wards and departments
Ultra Clean Ventilation Systems	Operating theatres
Local Cooling / Refrigeration Units	Laboratories Clinical areas Specialist areas
Local Exhaust Ventilation (LEV)	Operating theatres (exhaled gas) Laboratories Dental Mortuary Workshops Specialist areas
Fume Cupboards	Pharmacy Laboratories
Microbiological Safety Cabinets	Pharmacy Laboratories

APPENDIX B – 40 Point Check Sheet

Competent Person (Ventilation) Air Handling Unit (AHU) Routine Inspection

Note: Critical ventilation systems should be inspected quarterly. Non-critical ventilation systems should be inspected annually.

GENERAL CONDITION

End of useful life. This should be clear from the condition of the AHU and its associated services and plant. **Action: Urgent replacement indicated.** The main indicators will be:

1. Extensive internal and/or external corrosion of the AHU casing.
2. Failure of filter housings to prevent air bypass.
3. General corrosion of heater and cooling battery fins, attenuator surfaces etc.
4. Significant failure to meet minimum standards.
5. Associated plant services and controls in poor condition or not able to fulfil their purpose.
6. AHU aged 20 years or more.

Poor. Should be fairly apparent but would include an assessment of the degree of corrosion; cleanliness of coils and batteries; quality of filter mountings and their ability to prevent air bypass; fan and drive train condition; the control system elements' ability to fulfil their function; condition of the access doors and inspection covers. The age of the AHU is generally less important. **Action: Extensive refurbishment or programmed replacement indicated.**

Average. Some faults but generally free of significant corrosion, clean internally and conforming to minimum standards. **Action: Faults capable of correction at next maintenance period.**

Good. Conforming to the minimum standards, obviously cared for and subject to routine maintenance. **Action: Routine maintenance will preserve standard of the equipment.**

COMPLIANCE WITH MINIMUM STANDARDS (questions 2 to 23, 32 and 33)

Poor. More than three answers are negative. **Action: Management action required by estates/facilities department.**

Average. No more than three answers are negative. **Action: Maintenance action required.**

Good. No answers are negative, full compliance. **Action: None.**

MAINTENANCE QUALITY (questions 5, 12, 26 to 31 and 34 to 40)

Poor. More than three answers are negative. **Action: Management action required by estates/facilities department.**

Average. No more than three answers are negative. **Action: Maintenance action required.**

Good. No answers are negative. **Action: None.**

Hospital.....

Plantroom.....

Air Handling Unit.....

Age of unit.....

Area Served by unit.....

Date of survey.....

Name.....

Signature.....

General condition: End of useful life Poor Average Good

Compliance with minimum standards Poor Average Good
(Questions 2 to 23, 32 and 33)

Maintenance quality Poor Average Good
(Questions 5, 12, 26 to 31 and 34 to 40)

Serial	Survey Question	Yes	No	Comments
1	Plant running?			
2	Is the unit and its associated plant secure from unauthorised access?			
3	Is the unit safely accessible for inspection and maintenance?			
4	Is the air intake positioned to avoid short circuiting with extract or foul air from other sources such as gas scavenging outlets?			
5	Are all inspection lights operating?			

6	Are motorised dampers fitted to the intake and discharge?			
7	Are fan motor(s) outside of the air stream?			
8	Is the fan drive train visible without removing covers?			
9	Is the cooling coil located on the discharge side of the fan?			
10	Is an energy-recovery system fitted (state type)?			
11	Are condensate drainage systems fitted to all energy recovery systems, cooling coils and humidifiers in accordance with Chapter 3 of Health Technical Memorandum 03-01, Part B?			
12	Are drainage traps clean and filled with water? (see Table 3 in Health Technical Memorandum 03-01, Part B)			
13	Is the drain trap air break at least 15 mm?			
14	If a humidifier is fitted, state the type			
15	Is the humidifier capable of operation?			
16	Is there space to safely change the filters?			
17	Are there test holes in the principal ducts?			
18	Are the test holes capped?			
19	What is the general condition of the exterior of the AHU?			
20	Are the principal ducts lagged?			
21	What is the general condition of the associated control valves and pipework?			
22	Is the pipework adequately lagged?			
23	Is the system clearly labelled?			
24	Record prefilter differential pressure			

25	Record main filter differential pressure			
SWITCH PLANT OFF. FIT PADLOCK AND CAUTION SIGN TO ISOLATOR				
26	Did the motorised dampers close on plant shut-down?			
27	Is the vermin/insect screen clean?			
28	Is the intake section including the fog coil clean?			
29	Are the prefilters correctly fitted with no air bypass?			
30	Are all drive belts correctly aligned and tensioned?			
31	Is the cooling-coil matrix clean?			
32	Are all drip-trays fully accessible or capable of being removed for cleaning and have a fall to drain?			
33	Are the drainage trays stainless?			
34	Are the drainage trays clean?			
35	Are there any signs of water ponding in the AHU?			
36	Is the matrix clean for each heater-battery?			
37	Have the main filters been correctly fitted with no air bypass?			
38	Is AHU and its associated main ductwork clean internally?			
ENERGISE PLANT				
39	Did unit restart satisfactorily?			
Test automatic fan-motor change-over, if fitted				
40	Did automatic change-over operate satisfactorily?			



Hospital

Queen Elizabeth University Hospital (QEUEH)

Satellite Hospitals

Nil

Date(s) of Audit 14-15 Nov 16

Date(s) of Previous Audit 9-10 Dec 2015

Reference 161114-QEUEH-V-DGM-01

Site Address

1345 Govan Road,
Glasgow
G51 4TF

1. Terms of Reference

1.1 This audit was conducted in accordance with the following current reference documents:

- Scottish Health Technical Memorandum 00: Policies and principles of healthcare engineering.
- Scottish Health Technical Memorandum 03-01: Specialised ventilation for healthcare premises.

2. Executive Summary

2.1 Introduction. The purpose of this audit was to assess the compliance, operation and maintenance of the Safe System of Work at the Hospital(s) in accordance with the discipline specific Health Technical Memoranda, Acts, Regulations and HSE Guidance documents. The resulting Action Plan will be reviewed periodically. The appointments of the discipline specific Authorised Persons were also assessed during the audit.

2.2 Report Summary

- The Lead AP should review the action plan at the end of this report and produce his own action plan.
- A draft ventilation Standard Operating Procedure (SOP) was held on StaffNet. In addition to the SOP, a ventilation safety policy should be produced and ratified by the board.
- Due to the size and ongoing change at the hospital the APs were not always able to find the time to carry out their duties. The provision of APs (V) should be reviewed by senior management taking into consideration other duties the APs are liable for. Cyril Dowson is scheduled for his AP assessment in December 2016. Jim Guthrie and David Bratney should attend training before being assessed.
- CPs should be trained, assessed and appointed. Evidence of competency was held for two contractor CPs, letters of competency should be held for all contractor CPs.
- Task risk assessments were not held for in-house tasks. These must be produced and communicated to the in-house CPs.
- Permits to work were in use for the Lab Block but they were not in use across the rest of the estate. There were some minor errors on some of the permits to work issued which all APs should note.
- The Document Register was populated for the Lab Block. This should be extended to include the Adult & Children's and the retained estate. The Document Register should include a list of all ventilation assets.
- Planned maintenance was not carried out on the retained estate. The AHUs should be subject to planned maintenance, cleaning, quarterly inspections and annual inspections.
- Chilled beams should be cleaned 6 monthly and split air condition systems should be cleaned 3 monthly.
- The Lab Block AHUs were cleaned periodically but records were not retained. Cleaning records should be retained.

9. Not all critical systems were subject to annual verifications. Adult & Children's isolation rooms, critical care areas and MRI/CT suites should be verified annually. Retained estate neonatal and MRI/CT suites should be verified annually. When a critical system fails to meet the performance criteria set out in SHTM 03-01, Part B, the AP should notify the User (V)/Responsible Person and infection control in writing.
10. Most but not all LEVs had been subject to 14 monthly examinations under the COSHH Regulations. The mortuary dissection tables had not been examined and performance tested. Some MGPS AGSS had been tested but records had not been retained. The test reports for the Lab Block LEV systems were retained by individual departments. The AP should check that all LEVs in the Lab Block have been examined and tested at least every 14 months.

3. Conclusion

ASSESSMENT OF SAFE SYSTEM OF WORK	CONCLUSION
1. Assessment of the Management Policy.	Medium
2. Assessment of the Authorised Persons.	Medium
3. Assessment of the Competent Persons.	High
4. Assessment of Incidents, Accidents and Dangerous Occurrences.	Very Low
5. Assessment of the Safety Documentation.	Low
6. Assessment of the Operating Records.	Medium
7. Assessment of the Safety equipment & Access Control.	Low
8. Assessment of the Engineering Systems.	Medium
9. Assessment of the Engineering Work Spaces.	Medium

Is the system safe to continue?	Yes, under the supervision of the AE
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4. Next Audit Date

The next audit visit is planned to take place in

November 2017

Signature:



Date:

21-Nov-16

Name:

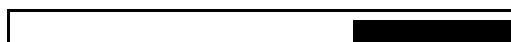
Duncan G Machell

Turner Facilities Management
Professional Engineering Services
65, Craigton Road
Govan
Glasgow G51 3EQ

E-mail:



Mobile Phone:



Key to Assessments:

<u>Safe System of Work Section Assessment</u>	<u>SCART Risk Grading</u>
1. Good.	Very Low
2. Satisfactory (Some minor or observation issues need to be resolved).	Low
3. Unsatisfactory (Some elements of major issues remain unresolved).	Medium
4. Hazardous (Major issues have started to be resolved).	High
5. Unsafe to continue with current practices/arrangements.	Very High
Not tested.	Untested
<u>Overall Safe System of Work Assessment</u>	
The system is safe to continue.	Yes
The system is safe to continue subject to caveats.	Yes, under the supervision of the AE
The system is unsafe to continue.	No

Distribution:

NHS Contract:

Ms Mary-Anne Kane	Interim Director of Facilities
Mr Alan Gallacher	General Manager (Estates)
Mr Gary Cullen	Compliance Manager
Mr Ian Powrie	Sector Estates Manager (South)
Mr David Bratney	Senior Estates Manager and Authorised Person (Ventilation) Designate
Mr Paul Allan	Estates Manager and Authorised Person (Ventilation)

Turner Facilities Management Ltd:

Mr C James	Interim Business Unit Manager
Mr D G Machell	Authorising Engineer (Ventilation)
Mrs D Halsey	AE Administrator
File	TIME

5	Very High
4	High
3	Medium
2	Low
1	Very Low

PREVIOUS ACTION PLAN

Serial	Rating	Reference	Action Required	Remarks
1	3	141208/1	The Ventilation Services Policy should be reviewed.	Ongoing, review at next audit.
2	3	141208/4	CPs should be occasionally monitored when carrying out works and a record of monitoring activities retained in the Documents Register.	Ongoing, review at next audit.
3	5	141208/6	In-house CPs should be trained, assessed and appointed. Certificates of appointment and evidence of training should be retained in the Documents Register.	Ongoing, review at next audit.
4	5	141208/7	Letters of competency should be obtained from the employers of contractor CPs and retained in the Documents Register.	Ongoing, review at next audit.
5	3	141208/8	A CP Register should be produced listing the contractor CPs and should be retained in the Documents Register.	Ongoing, review at next audit.
6	5	141208/9	Plant shutdown/make-safe risk assessments should be produced to identify the hazards associated with taking critical ventilation systems out of use and for work on LEVs that present a hazard to the maintainer. The risk assessments should be retained in the Documents Register.	Ongoing, review at next audit.
7	5	141208/10	Ensure task risk assessments are held for all works on ventilation systems. This documentation should be retained or referenced in the Documents Register.	Ongoing, review at next audit.
8	5	141208/12	Produce a schedule of ventilation systems to identify all systems as critical, non-critical or LEV in accordance with SHTM 03-01, Part B, Para 4.7. Retain the schedule in the Documents Register.	Ongoing, review at next audit.
9	3	141208/18	Display safety signs at the entrance to all plantrooms.	Ongoing, review at next audit.
10	3	141208/19	Display unique plantroom identity signs at the entrance to all plantrooms.	Ongoing, review at next audit.
11	3	141208/21	Repair/replace the dilapidated Neurosurgery external plant area access door.	Completed.
12	3	141208/22	Install task lighting and emergency lighting for the Neurosurgery external plant area.	Ongoing, review at next audit.

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13	5	141208/23	Implement a planned maintenance regime for emergency lights fitted in plantrooms.	Action updated, review at next audit.
14	3	141208/27	Monitor the condition of the corroded intake louvres on the Neurosurgery external AHUs.	Completed.
15	3	141208/31	Repair the inspection lights on Neonatal AHU 3 and Neurosurgery AHU 5.	Completed.
16	5	141208/33	Investigate and repair the Magnehelic gauges on the Old Maternity AHU and Neurosurgery AHU 5.	Action updated, review at next audit.
17	3	141208/34	Fit direction of flow labels to the discharge ductwork on the Old Maternity AHU.	Asbestos hazard prevents access. Action withdrawn.
18	5	141208/36	Carry out quarterly inspections on all critical ventilation systems in accordance with SHTM 03-01, Part B, Appendix 1.	Progress made, action updated and review at next audit.
19	5	141208/37	Carry out annual inspections on all non-critical ventilation systems in accordance with SHTM 03-01, Part B, Appendix 1.	Progress made, action updated and review at next audit.
20	2	141208/39	Reference the location of inspection reports and verification reports in the Document Register.	Completed.
21	5	141208/40	Test fire dampers in accordance with SHTM 03-01, Part B, Para 4.13.	Ongoing, review at next audit.
22	5	141208/41	Carry out a 14 monthly thorough examination and test of all AGSS in accordance with the COSHH Regulations requirement for LEVs.	Action updated, review at next audit.
23	2	141208/42	Oversee the 14 monthly examinations of LEVs to ensure all the LEVs listed in the schedule of ventilation systems are examined.	Ongoing, review at next audit.
24	3	151209/1	Assess and appoint Mr Cyril Dowson as an AP (V).	Ongoing, review at next audit.
25	3	151209/2	Assess and appoint David Bratney as an AP (V) when he has completed AP (V) training.	Ongoing, review at next audit.
26	3	151209/3	Arrange for David Bratney to attend AP (V) training and forward a copy of his training certificate to the AE on completion.	Ongoing, review at next audit.
27	3	151209/4	Forward a copy of David Bratney's first aid training certificate to the AE.	Ongoing, review at next audit.
28	3	151209/5	Forward a copy of Cyril Dowson's first aid training certificate to the AE.	Completed.
29	3	151209/6	Arrange for Paul Allan to attend first aid training by 30 Jun 16 and forward a copy of his training certificate to the AE on completion.	Action updated, review at next audit.
30	4	151209/7	Use permits to work when taking critical systems out of service and when carrying out intrusive maintenance on hazardous LEVs.	Ongoing, review at next audit.

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31	3	151209/8	Take remedial action to prevent the uncommanded shutdown of the AHU serving Theatre 8.	Completed.
32	3	151209/9	Only issue permits to work to appointed NHS CPs or contractor CPs listed in the CP Register.	Ongoing, review at next audit.
33	3	151209/10	Catalogue the ventilation system drawings for the Lab Block and Adults & Children's so they are readily available to the APs.	Completed.
34	5	151209/11	Populate the CAFM system (FM First) with planned maintenance tasks for all ventilation systems and retain records of all planned maintenance tasks carried out.	Ongoing, review at next audit.
35	3	151209/12	Calibrate the micro manometer and hand held anemometers annually and retain copies of calibration certificates in the document register.	Completed.
36	3	151209/13	Obtain copies of instrument calibration certificates used by all contractor CPs.	Completed.
37	5	151209/14	Rectify the unserviceable lighting on the Old Maternity 4th floor plantroom and install emergency lighting.	Ongoing, review at next audit.
38	3	151209/15	Fit identify signs or labels to the HEPA filter enclosures in the Adult and Children's Plantroom 21.	Ongoing, review at next audit.
39	5	151209/16	Provide a standby air handling unit for Ward 4b Haemato-oncology to allow for proper maintenance & verification and to provide redundancy in the system.	Action withdrawn.
40	3	151209/17	Fit access hatches to all AHU intake ductwork sections to allow inspections.	Ongoing, review at next audit.
41	3	151209/18	Fit glass drain traps to all Neurosurgery AHUs on the retained estate.	Progress made, action updated and review at next audit.
42	4	151209/19	Modify the drain trap arrangement on all AHUs in the Lab Block and Adult & Children's to ensure there is a 15mm air gap between the trap outlet and the drainage pipework.	Ongoing, review at next audit.
44	2	151209/21	Consider fitting inspection windows and internal lighting on all Lab Block AHU's.	Ongoing, review at next audit.
45	3	151209/22	Rectify the unserviceable lighting on retained estate Neonatal AHUs 1, 3 and 4.	Completed.
46	3	151209/23	Investigate and rectify the spurious bag filter readings on retained estate Neonatal AHUs 1, 3 and 4.	Ongoing, review at next audit.
47	4	151209/24	Rectify the collapsing pre-filters on the Old Maternity level 4 plantroom intake plenum and fit a pressure differential gauge/manometer.	Ongoing, review at next audit.

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48	3	151209/25	Fit direction of flow labels to the isolation room extract ductwork in the Adult & Children's Plantroom 21.	Ongoing, review at next audit.
49	5	151209/26	Carry out annual verifications on the retained estate Neonatal and SCBU ventilation systems.	Action updated, review at next audit.
50	3	151209/27	Carry out and record annual cleaning on all AHUs.	Action updated, review at next audit.
51	3	151209/28	Ensure verification reports for critical ventilation systems include a summary clearly stating whether a pass or a fail was achieved and that the reports also record noise levels.	Completed.
52	5	151209/29	Ensure that LEV examinations and tests are carried out on the Mortuary dissection tables every 14 months in accordance with the COSHH Regulations.	Ongoing, review at next audit.
53	5	151209/30	Obtain confirmation from Pharmacy that the Aseptic suite containment cabinets are subject to LEV examinations and tests every 14 months in accordance with the COSHH Regulations.	Completed.
54	5	151209/31	Survey the Clinical Research department to identify any LEVs. Subject all identified LEVs to examinations and tests every 14 months in accordance with the COSHH Regulations.	Ongoing, review at next audit.
55	3	151209/32	Critical ventilation systems that do not meet the performance criteria specified in SHTM 03-01 should be taken out of service. If the clinical requirement prevents this the User and infection control should be notified in writing by the AP.	Ongoing, review at next audit.

Additional Comments

Nil.

AP Training and Appointments Matrix

AP Name	Paul Allan	Cyril Dowson	Jim Guthrie	David Bratney	
Status	AP (V)	AP (V) Des	AP (V) Des	AP (V) Des	
Based at	QEUH	QEUH	QEUH	QEUH	
Appointment Certificate	GG&C V 07	Not yet	Not yet	Not yet	
Issue Date	05-Jan-15	N/A	N/A	N/A	
Expiry Date	04-Jan-18	N/A	N/A	N/A	
Sites covered	SGH	N/A	N/A	N/A	
Ventilation Training Expiry Date	30-Oct-17	27-Apr-18	TBA	TBA	
First Aid Expiry Date	Scheduled for 12 Dec 16	22-Jun-18	03-Mar-18	TBA	
Permit-to-work	0	40	0	0	
Number checked by AE	0	1	0	0	

Comments

Paul Allan should attend emergency first aid training by 12 Dec 16 as planned. He should forward a copy of his training certificate to the AE .

Jim Guthrie should attend AP (V) training and forward a copy of his training certificate to the AE on completion.

David Bratney should attend AP (V) training and forward a copy of his training certificate to the AE on completion. He should also attend emergency first aid training forwarding a copy of his certificate to the AE.

REPORT

Personnel

Duty Holder	Robert Calderwood	1
Designated Person	Mary-Anne Kane	1
Authorising Engineer	Duncan Machell	1
Authorised Persons	Paul Allan	2
	Cyril Dowson (Designate)	1
	Jim Guthrie (Designate)	3
	David Bratley (Designate)	4

1. Management Policy	Y/N	Comments	
Is there a Board Ventilation Safety Policy In place?	Y	NHS GG&C Ventilation Safety Policy.	1
Is the Ventilation Safety Policy approved at Board level?	Y	The policy was approved by Alex McIntyre (Director of Facilities).	1
Is the Board Ventilation Safety Policy reviewed periodically?	Y	The policy was first issued in October 2011 and reviewed in August 2012. The policy had been withdrawn from StaffNet for a review.	3
Is the Board Ventilation Safety Policy a controlled Document?	Y	The policy is a controlled document. A copy was held in the Document Register.	1
Are the Duty Holder (V) responsibilities clearly defined in the Policy?	Y	The policy states that the Duty Holder is responsible for ensuring the ventilation systems are operated, maintained and repaired in accordance with SHTM 03-01.	1
Is the Designated Person appointed in writing?	N	The Designated Person is shown as the Director of Facilities in the structure chart.	2
Does the Board Ventilation Safety Policy include emergency procedures?	N	Emergency procedures were not included in the policy.	3
Have the emergency procedures been validated or tested during the current audit period?	N/A	Not applicable.	
Has the Authorising Engineer (AE) (V) appointment been correctly made and is it in date?	Y	The AE's appointment expires on 31 Aug 17.	1

2. Authorised Persons (V)	Y/N	Comments	
Are all APs (V) currently certified?	N	Jim Guthrie, David Bratley and Cyril Dowson had not been appointed. Cyril Dowson will be assessed in December 2016.	4
Are the APs (V) due for refresher training in SHTM 03-01?	Y	Jim Guthrie and David Bratley should attend AP (V) training and forward copies of their training certificate to the AE on completion.	3
Are the APs (V) due for training in emergency first-aid?	Y	Paul Allan and David Bratley should attend emergency first aid training by 14 Feb 17 and should forward a copy of their training certificates to the AE on completion.	3

Are the APs (V) carrying out AP (V) duties on a regular basis?	N	Paul Allan and David Bratney were not using permits to work to control maintenance activities.	4
Are the APs (V) formally monitoring the work-in-progress and are they recording their observations?	N	CP Monitoring had not been carried out. Identified in previous audit.	3
Is the provision of APs (V) adequate?	N	When Jim Guthrie, David Bratney and Cyril Dowson are appointed this will provide four APs (V) for the campus. Comments were made by some APs that they struggled to find the time to carry out AP (V) duties on top of their other commitments.	3

3. Competent Persons (V)			
	Y/N	Comments	
Have the NHS CPs (V) been formally assessed and appointed by an AP (V)?	N	In-house CPs had not been assessed and appointed. Training certificates were held for two NHS CPs and a third was thought to have been trained but a certificate was not available. The remaining NHS CPs had not been trained.	4
Is evidence of the competency of Contractor CPs (V) held in the Document Register?	N	Evidence of competency was held for A Laughland and R Peel of Atlas Clean Air Ltd who carry out performance verifications on safety cabinets in the Laboratory building. Letters of competency or training certificates were not held for the CPs employed by H&V Commissioning Services Ltd and MAT Ltd.	3
Are the roles and responsibilities of Contractor CPs (V) defined in writing?	N/A	Not checked.	
Are records held in the Document Register of the site induction for the Contractor CPs (V)?	Y	The GG&C Contractor Control & Permit Register includes the issue of an identity card that listed the fundamental site rules and procedures.	1
Is there an up to date Register of CPs (V) appointed for the Trust included in the Document Register?	N	A CP Register was not held. Identified in previous audit.	3
Are the NHS CPs (V) carrying out their duties on a regular basis?	Y	In-house CPs and contractor CPs had been carrying out duties on a regular basis.	1

4. Incidents, Accidents and Dangerous Occurrences			
	Y/N	Comments	
Have there been any accidents, incidents, dangerous occurrences or "near misses" in connection with the ventilation systems?	Y	None reported.	1
Have the details of incidents, accidents or dangerous occurrences been properly recorded and reported?	N/A	Not applicable.	

5. Safety Documentation

Job Number:	Permit to work 81	Originating AP (V):	C Dowson
		Y/N	Comments
Was there a suitable & sufficient Risk Assessment to cover the work undertaken?	Y	23 May 16. Annual service of Labcaire PCR by Atlas Clean Air Ltd. Two risk assessments were held in the Document Register.	1
Was the permit-to-work completed by the AP (V) specifying the work to be carried out?	Y	The Hazardous/Not Hazardous option was not struck through at Part 1 of the permit to work.	3
Was the permit-to-work signed by the User (V) to allow the work to proceed?	N	The permit to work was not signed by the User (V).	3
Was the permit-to-work issued to a CP (V)?	Y	The permit to work was issued to A Laughland.	1
Was the permit-to-work cleared by a CP (V) and did they state that system was fit or unfit for use?	Y	No issues found.	1
Was the permit-to-work cancelled by an AP (V) and did they acknowledge that the system was fit or unfit for use?	Y	No issues found.	1
Did the User (V) acknowledge that the system should or should not be brought back into use?	Y	No issues found.	1
Were the site records up-dated on completion of the work?	Y	No issues found.	1

6. Operating Records

General	Y/N	Comments
Are the ventilation operating record documents kept in a secure location?	N	The ventilation documents were held in a secure office.
Do the APs (V) have access to copies of relevant SHTMs and other reference documents?	Y	An electronic copy was held.
Does the Document Register index include all of the subjects required by SHTM 03-01?	N	The Document Register was populated for the Laboratory Block only. The APs should either populate the Document Register with information for The Adult & Children's and the retained estates or populate individual document registers.
Is the working Ventilation Document Register periodically reviewed and out-of-date information transferred to the archive Ventilation Document Register?	N/A	The Document Register was in the process of being populated. Not assessed.
Is there a schedule of ventilations systems detailing which are critical, non-critical or LEVs?	N	Asset lists were held electronically covering the retained estate and Adult & Children's. The Lab Block asset list was held in the Document Register. A consolidated schedule of ventilation plant should be produced stating the classification (non-critical, critical or LEV) of the plant.

Are adequate technical drawings available to the APs?	Y	Drawings were held electronically (Zutec) for the Adult & Children's and the Lab Block. The drawings were well managed. Drawing ME/ZA/00/PL/524/518/21 dated 14 Jan 14 was checked with no issues found. Adequate drawings were not held for the retained estate neurosurgery theatres but these are due for refurbishment/replacement from mid 2017. Original drawings for the retained estate maternity theatres were reported to be held.	2
Are adequate O&M manuals available to the APs?	Y	O&M information was held electronically (Zutec) and on the shared drive for the Adult & Children's and the Lab Block. Original O&M information for the retained estate maternity theatres was reported to be held and was scheduled to be organised into a useable pack in 2017.	2
Are all of the ventilation systems included in the Trust's planned maintenance programme?	N	The Adult & Children's ventilation systems and the Lab Block ventilation systems were subject to planned maintenance. Good. Planned maintenance was not being carried out on the retained estate ventilation systems. Chilled/active beams were not subject to 6 monthly inspection & cleaning but this was being planned by the APs. Split air conditioning systems were not subject to quarterly hygiene inspections.	4
Are the planned maintenance records suitable, sufficient and accessible to the APs?	N	In-house maintenance was documented manually on check sheets. Service sheets were held for work carried out by contractor CPs. None of the maintenance was scheduled on FM First.	3
Are the results of the Trust's planned maintenance programme formally reviewed annually to establish trends and gaps? Are these reviews recorded?	N/A	Not checked.	
Inspection and Verification			
	Y/N	Comments	
Are critical ventilation systems being inspected quarterly?	N	The Adult & Children's critical systems were subject to quarterly inspections. Good. The retained estate critical systems were not subject to quarterly inspections.	3
Are non-critical systems being inspected annually?	N	Retained estate non-critical ventilation systems were not subject to annual inspections.	3

Are critical ventilation systems being verified annually?	N	All theatres were subject to a rolling programme of annual verifications. Good. Other critical systems in the Adult & Children's (isolation rooms, critical care and MRI) were not being verified annually but this requirement was under consideration by the APs. The retained estate ventilations systems serving Neonatal and MRI/CT were not subject to annual verifications.	3
Are the inspections and verifications being recorded as per SHTM 03-01, Part B, Appendices 1 & 2 and the records retained in the Ventilation Documents Register?	Y	Verification reports produced by H&V Commissioning Services Ltd provided an executive summary, air change rates, pressure differentials and noise levels. The quarterly inspections carried out on the Adult & Children's isolation rooms, MRI/CT and critical care areas did not conform fully to Appendix 1.	2
Are the main components in AHUs serving critical and non-critical areas being cleaned annually?	N	Annual cleaning of the AHUs in the Adult & Children's was being carried out. Good. The cleaning of Lab Block AHUs was not recorded. Retained estate non-critical AHUs had not been cleaned within the previous year.	3
Are the fire dampers being tested annually?	N	Fire dampers were not subject to annual testing. A list of the fire dampers in the Lab Block had begun to be populated.	5
Are the LEV systems being examined and tested by a competent person at least every 14 months?	N	All Lab Block safety cabinets and fume cupboards were reported to have had COSHH LEV performance tests carried out in the past 14 months. Records were held by individual departments. The Mortuary dissection table had not been subjected to a COSHH LEV test in the past 14 months. Some but not all Anaesthetic Gas Scavenging Systems (AGSS) had been re-commissioned annually. Adequate test records were not held for those systems that had been recommissioned. It was reported that the Clinical Research department may contain LEVs.	3
Are critical systems that are unable to meet the required standards being taken out of service after receipt of condemnatory reports?	N	The annual verification report produced by H&V Commissioning Services Ltd dated 5 May 16 recorded non-compliant air change rates and pressure differentials in Neuro Sciences Theatres 6 & 7 dirty utility. The User (V) had not been notified of the non-compliance.	3

7. Safety Equipment & Access Control		Y/N	Comments	
Do the APs (V) have sufficient isolation safety devices for the likely number of concurrent jobs?	Y	Adequate safety devices were held at the hospital.	1	
Do the APs (V) have sufficient safety signage for the likely number of concurrent jobs?	Y	Adequate safety signs were held at the hospital.	1	
Do the NHS CPs (V) have sufficient safety devices and signs for their routine work?	N/A	Not checked.		
Are records available of annual NHS safety and protective equipment inspections by an AP (V)?	N	The half masks issued to the CPs should be visually inspected annually by an AP and a record kept of the inspections.	3	
Do all NHS test instruments have in date calibration certificates?	Y	Micro Manometer 4902159510 and Anememomter13450118 were calibrated on 24 Feb 16. Good.	1	
Have contractors provided in-date calibration certificates for all of their test instruments and safety equipment?	Y	Copies of calibration certificates were provided for the test instruments used by H&V Commissioning Services Ltd who carry out annual verifications.	1	
Is there an effective and auditable system for the control of plantroom access in use?	Y	An access control procedure was held in the document register.	1	

8. Engineering Systems

Air Handling Units (AHUs)	Y/N	Comments	
Is each AHU clearly and uniquely labelled and does this label exactly correspond to the AHU Register?	N	The isolation room HEPA filter extract cabinets in Adult & Children's Plantroom 21 were not labelled.	3
Is the general condition of each AHU satisfactory?	Y	Those checked.	1
Is the AHU constructed according to the principles in SHTM 03-01, Part A, Figure 1?	Y	Those checked.	1
Are the automatic controls fitted to critical systems capable of being overridden in the event of a software failure?	Y	Those checked.	1
Are fresh air intakes sited correctly, constructed correctly and are access hatches or hinged louvres installed?	N	AHUs in the Adult & Children's Plantrooms 21 & 22 and in the Lab Block Cat 2 and Cat 3 plantrooms did not have access hatches fitted to the intake ducts to allow for inspection.	3
Are drainage systems installed for wet components and are the drainage systems properly constructed?	N	The traps fitted to the retained estate neurosurgery AHUs had no drainage pipework fitted. Drain traps on the AHUs in the Adult & Children's Plantrooms 21 & 22 were connected directly to drainage pipework with no air gap. Some drain traps were visibly dirty. The drain traps on the Lab Block AHUs were connected directly to drain with no air gap.	3

Are belt driven fan drives situated outside of the air stream?	N	Some fan drives were internal to the AHUs. No action required.	2
Is there adequate access around the AHU and are access doors provided for all major components?	Y	The Lab Block Cat AHUs had no inspection windows fitted.	2
Are inspection windows and internal lights provided for cooling coils and filters?	Y	Those checked.	1
Are the filters the correct grade and correctly fitted to minimise bypass?	N	Pre-filters were fitted to a walk-in plenum in the Old Maternity Level 4 plantroom. Several filters were not secure in the frame and the access door was open allowing complete bypass of the filters.	3
Are the filters provided with a means of checking the differential pressure across them?	N	Retained estate Neonatal AHUs 1, 3 and 4 bag filter Minihelic gauges were reading 0 Pascal's. There was no means of checking pressure differential on the pre filters fitted to the walk-in plenum in the retained estate Old Maternity Level 4 plantroom.	3
Is the direction of air flow clearly marked on all main and branch ducts?	N	The extract ductwork serving the isolation rooms in Adult & Children's Plantroom 21 did not have direction of flow labels fitted.	3
Are all air flow test-points properly located, clearly identified and is the size of the duct provided at each point?	Y	No issues found.	1

9. Engineering work spaces

Plantroom externals	Y/N	Comments	
Is there a legible and secure safety sign displayed at the entrance to the plantroom?	N	Adult & Children Plantrooms 21 & 22 and the Old Maternity 4th floor plantroom did not have warning signs displayed at the entrance doors.	3
Is the name of the plantroom exactly the same as the AHU Register?	N	Adult & Children Plantrooms 21 & 22 and the Old Maternity 4th floor plantroom did not have unique name signs displayed at the entrance doors.	3
Is the correct contact telephone number shown?	N/A	Not applicable.	
Plantroom security	Y/N	Comments	
Is the door soundly made and kept secure?	Y	No issues found.	1
Is there an emergency escape door and can it be opened from the inside?	N/A	Not checked.	
Is there a clear escape route outside the plantroom?	Y	No issues found.	1
Are adequate emergency communications systems available?	Y	Staff entering plantrooms carry either a mobile telephone or PDA.	1
Are there any unauthorised items stored in the plantroom?	N	No issues found.	1
If so, are the access arrangements to the plantroom adequately controlled?	N/A	Not applicable.	

Plantroom structure

Is the plantroom structure and condition satisfactory?	N	The Old Maternity 4th floor plantroom general lighting was unserviceable. Emergency lighting was not installed in the Old Maternity 4th floor plantroom.	3
Are posters and drawings displayed as required?	N/A	Not checked.	

Fire Precautions

	Y/N	Comments	
Is combustion equipment located in the plantroom?	Y	No issues found.	1
Are any rubbish or fire hazardous materials stored immediately outside the plantroom?	Y	No issues found.	1
Is there at least one suitable fire extinguisher provided in the plantroom and has it been inspected in the last 12 months?	Y	All fire extinguishers checked were serviced in April 2016.	1

I confirm that, where actions are required, a report has been submitted to the Designated Person



Duncan G Machell

(Signature of AE (V))

(Name)

SCART Risk Grades	
5	Very High
4	High
3	Medium
2	Low
1	Very Low

UPDATED ACTION PLAN

Serial	Rating	Reference	Action Required	Responsible Person	Date due
Action points carried forward from previous audit					
1	3	141208/1	The Ventilation Services Policy should be reviewed.	DP	08-Mar-15
2	3	141208/4	CPs should be occasionally monitored when carrying out works and a record of monitoring activities retained in the Documents Register.	All APs	08-Mar-15
3	5	141208/6	In-house CPs should be trained, assessed and appointed. Certificates of appointment and evidence of training should be retained in the Documents Register.	Lead AP	08-Jun-15
4	5	141208/7	Letters of competency should be obtained from the employers of contractor CPs and retained in the Documents Register.	Lead AP	08-Mar-15
5	3	141208/8	A CP Register should be produced listing the contractor CPs and should be retained in the Documents Register.	Lead AP	08-Mar-15
6	5	141208/9	Plant shutdown/make-safe risk assessments should be produced to identify the hazards associated with taking critical ventilation systems out of use and for work on LEVs that present a hazard to the maintainer. The risk assessments should be retained in the Documents Register.	Lead AP	08-Jan-15
7	5	141208/10	Ensure task risk assessments are held for all works on ventilation systems. This documentation should be retained or referenced in the Documents Register.	Lead AP	08-Jan-15
8	5	141208/12	Produce a schedule of ventilation systems to identify all systems as critical, non-critical or LEV in accordance with SHTM 03-01, Part B, Para 4.7. Retain the schedule in the Documents Register.	Lead AP	08-Jan-15
9	3	141208/18	Display safety signs at the entrance to all plantrooms.	Lead AP	08-Mar-15
10	3	141208/19	Display unique plantroom identity signs at the entrance to all plantrooms.	Lead AP	08-Mar-15
11	3	141208/22	Install task lighting and emergency lighting for the Neurosurgery external plant area.	Lead AP	08-Dec-15

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12	5	141208/23	Implement a planned maintenance regime for emergency lights fitted in plantrooms. Where DALI systems are installed a formal check of the automatic test results should be carried out.	Lead AP	08-Jan-15
13	5	141208/33	Investigate and repair the Magnehelic gauge on Neurosurgery AHU 5.	Lead AP	08-Dec-14
14	5	141208/36	Carry out quarterly inspections on the retained estate critical ventilation systems. Record all critical system quarterly inspections in accordance with SHTM 03-01, Part B, Appendix 1.	Lead AP	08-Mar-15
15	5	141208/37	Carry out annual inspections on the retained estate non-critical ventilation systems in accordance with SHTM 03-01, Part B, Appendix 1.	Lead AP	08-Mar-15
16	5	141208/40	Test fire dampers in accordance with SHTM 03-01, Part B, Para 4.13.	Designated Person	08-Mar-15
17	5	141208/41	At least every 14 months carry out a thorough examination and test (recommission) of all AGSS. Record the test results and a sketch of the systems.	Lead AP	08-Jan-15
18	2	141208/42	Oversee the 14 monthly examinations of LEVs to ensure all the LEVs listed in the schedule of ventilation systems are examined.	Lead AP	08-Mar-15
19	3	151209/1	Assess and appoint Cyril Dowson as an AP (V).	AE/DP	12-Mar-16
20	3	151209/2	Assess and appoint David Bratney as an AP (V) when he has completed AP (V) training.	AE/DP	12-Jun-16
21	3	151209/3	Arrange for David Bratney to attend AP (V) training and forward a copy of his training certificate to the AE on completion.	DP	12-Jun-16
22	3	151209/4	Forward a copy of David Bratney's first aid training certificate to the AE.	Lead AP	12-Jan-16
23	3	151209/6	Arrange for Paul Allan to attend first aid training by 14 Feb 17 and forward a copy of his training certificate to the AE on completion.	DP	30-Jun-16
24	4	151209/7	Use permits to work when taking critical systems out of service and when carrying out intrusive maintenance on hazardous LEVs.	D Bratney and P Allan	12-Jan-16
25	3	151209/9	Only issue permits to work to appointed NHS CPs or contractor CPs listed in the CP Register.	All APs	12-Jan-16
26	5	151209/11	Populate the CAFM system (FM First) with planned maintenance tasks for all ventilation systems and retain records of all planned maintenance tasks carried out.	DP	12-Jun-16
27	5	151209/14	Rectify the unserviceable lighting on the Old Maternity 4th floor plantroom and install emergency lighting.	Lead AP	12-Mar-16

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28	3	151209/15	Fit identify signs or labels to the HEPA filter enclosures in the Adult and Children's Plantroom 21.	Lead AP	12-Mar-16
29	3	151209/17	Fit access hatches to all AHU intake ductwork sections to allow inspections.	Lead AP	12-Dec-16
30	3	151209/18	Fit drainage pipework to the glass drain traps on the retained estate Neurosurgery AHUs.	Lead AP	12-Mar-16
31	4	151209/19	Modify the drain trap arrangement on all AHUs in the Lab Block and Adult & Children's to ensure there is a 15mm air gap between the trap outlet and the drainage pipework.	Lead AP	12-Jun-16
32	2	151209/21	Consider fitting inspection windows and internal lighting on all Lab Block AHU's.	Lead AP	12-Jun-16
33	3	151209/23	Investigate and rectify the spurious bag filter readings on retained estate Neonatal AHUs 1, 3 and 4.	Lead AP	12-Mar-16
34	4	151209/24	Rectify the collapsing pre-filters on the Old Maternity level 4 plantroom intake plenum and fit a pressure differential gauge/manometer.	Lead AP	12-Jun-16
35	3	151209/25	Fit direction of flow labels to the isolation room extract ductwork in the Adult & Children's Plantroom 21.	Lead AP	12-Mar-16
36	5	151209/26	Carry out annual verifications on the Adult & Children's isolation rooms, critical care and MRI ventilation systems. Carry out annual verifications on the retained estate Neonatal and MRI/CT ventilation systems.	Lead AP	12-Mar-16
37	3	151209/27	Record annual the annual cleaning of AHUs in the Lab Block. Carry out and record the annual cleaning of all AHUs in the retained estate.	Lead AP	12-Dec-16
38	5	151209/29	Ensure that LEV examinations and tests are carried out on the Mortuary dissection tables every 14 months in accordance with the COSHH Regulations.	Lead AP	12-Jan-16
39	5	151209/31	Survey the Clinical Research department to identify any LEVs. Subject all identified LEVs to examinations and tests every 14 months in accordance with the COSHH Regulations.	Lead AP	12-Mar-16
40	3	151209/32	Critical ventilation systems that do not meet the performance criteria specified in SHTM 03-01 should be taken out of service. If the clinical requirement prevents this the User and infection control should be notified in writing by the AP.	Lead AP	13-Mar-16
Action points from this audit					
41	3	161114/1	Produce a local action plan to address the actions raised in this report.	Lead AP	14-Dec-16

42	3	161114/2	Review the time available for APs to carry out AP (V) duties taking into consideration other disciplines they are responsible for.	DP	14-Feb-17
43	3	161114/3	Train, assess and appoint Jim Guthrie as an AP (V).	DP/AE	14-May-17
44	3	161114/4	Ensure all options are struck through on all permits to work	All APs	14-Dec-16
45	3	161114/5	Ensure the User (V) signs Part 2 of all permits to work.	All APs	14-Dec-16
46	3	161114/6	Populate the existing Document Register with information relating to the retained estate and Adult & Children's, or setup and populate individual document registers.	All APs	14-Feb-17
47	4	161114/7	Carry out planned maintenance on the retained estate AHUs. Carry out quarterly hygiene checks on split air conditioning units. Carry out 6 monthly chilled beam cleaning.	Lead AP	14-May-17
48	3	161114/8	Inspect the half masks issued to the CPs annually and retain a record of the inspections.	Lead AP	14-May-17

DP-Designated Person : AE- Authorising Engineer : AP- Authorised Person with Line Management Support

The **Designated Person** should sign this Action Plan to acknowledge the contents. The original copy should then be filed in the Document Register.

Signature: _____

Date: _____

Name: Mary-Anne Kane

I have the following comments/feedback on this report or the service I have received from Turner Facilities Management:

Appendix A**Reconciliation of Ventilation Safety Documents**

Site: Queen Elizabeth University Hospital **Board:** Greater Glasgow and Clyde
From (date): 09-Dec-15 **To (date):** 14-Nov-16

Ser	Authorised Person	<u>Ventilation / LEV</u>				Competent person	Comments
		Isolation Diagram (if needed)	Safety programme (if needed)	Permit-to-work	Permission for disconnection / Interruption		
1	Cyril Dowson	N/A	N/A	54 - 93	N/A	R Peel S Rennie A Laughland S Collins	Permit to work 8. The Hazardous/Not Hazardous option was not struck through at Part 1 of the permit to work. The permit to work was not signed by the User (V) at Part 2.



Hospital

Queen Elizabeth University Hospital (QEUH)

Satellite Hospitals

Nil

Date(s) of Audit 07 & 10 Nov 17

Date(s) of Previous Audit 14-15 Nov 2016

Site Address

1345 Govan Road,
Glasgow
G51 4TF

Reference 20171113-250-QEUH-V-JM-001

1. Terms of Reference

1.1 This audit was conducted in accordance with the following current reference documents:

- a. Scottish Health Technical Memorandum 00: Policies and principles of healthcare engineering.
- b. Scottish Health Technical Memorandum 03-01: Specialised ventilation for healthcare premises.

2. Executive Summary

2.1 Introduction. The purpose of this audit was to assess the compliance, operation and maintenance of the Safe System of Work at the Hospital(s) in accordance with the discipline specific Health Technical Memoranda, Acts, Regulations and HSE Guidance documents. The resulting Action Plan will be reviewed periodically. The appointments of the discipline specific Authorised Persons were also assessed during the audit.

2.2 Report Summary

1. The Lead AP should review the action plan at the end of this report and produce his own action plan.
2. Due to the size and on-going change at the hospital the APs were not always able to find the time to carry out their duties. The provision of APs (V) should be reviewed by senior management taking into consideration other duties the APs are liable for.
3. CPs should be trained, assessed and appointed. Evidence of competency was held for two contractor CPs, letters of competency should be held for all contractor CPs.
4. Task risk assessments were not held for in-house tasks. These must be produced and communicated to the in-house CPs.
5. The Document Register was populated for the Lab Block. This should be extended to include the Adult & Children's and the retained estate. The Document Register should include a list of all ventilation assets.
6. Chilled beams should be cleaned 6 monthly and split air condition systems should be cleaned 3 monthly.
7. The Lab Block AHUs were cleaned periodically but records were not retained. Cleaning records should be retained.
8. Work should continue to verify all critical systems. When a critical system fails to meet the performance criteria set out in SHTM 03-01, Part B, the AP should notify the User (V)/Responsible Person and infection control in writing before it is brought back into service.
9. Most but not all LEVs had been subject to 14 monthly examinations under the COSHH Regulations. The mortuary dissection tables had not been examined and performance tested.
10. Oil and combustible material should be removed from the Neonatal plant room ASAP.
11. Fire dampers must be tested for correct operation annually.

12. The use of authority for disconnection (permit to work) should be reintroduced to prevent unintentional loss of supplies to the theatres and critical equipment.

3. Conclusion

ASSESSMENT OF SAFE SYSTEM OF WORK	CONCLUSION
1. Assessment of the Management Policy.	4
2. Assessment of the Authorised Persons.	8
3. Assessment of the Competent Persons.	16
4. Assessment of Incidents, Accidents and Dangerous Occurrences.	1
5. Assessment of the Safety Documentation.	20
6. Assessment of the Operating Records.	16
7. Assessment of the Safety equipment & Access Control.	8
8. Assessment of the Engineering Systems.	20
9. Assessment of the Engineering Work Spaces.	20

Is the system safe to continue?	Yes, under the supervision of the AE
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4. Next Audit Date

The next audit visit is planned to take place in

November 2018

Signature:

[Redacted Signature]

Date:

13-Nov-17

Name:

Jamie Minhinnick

Turner Professional Engineering Services
Team Q Maintenance Ltd
Collier House
Mead Lane
Hertford SG13 7AX

E-mail:

[Redacted E-mail]

Mobile Phone:

[Redacted Mobile Phone]

Key to Assessments:

		<u>Severity</u>				
		INSIGNIFICANT	MINOR	MODERATE	MAJOR	EXTREME
<u>Likelihood</u>	ALMOST CERTAIN	5	10	15	20	25
	LIKELY	4	8	12	16	20
	POSSIBLE	3	6	9	12	15
	UNLIKELY	2	4	6	8	10
	REMOTE	1	2	3	4	5

NHS Contract:

Ms Mary-Anne Kane	Interim Director of Facilities
Mr Alan Gallacher	General Manager (Estates)
Mr Gary Cullen	Compliance Manager

Turner Professional Engineering Services:

Mr P Clinton	Coordinating Authorising Engineer
Mr J Minhinnick	Authorising Engineer (Ventilation)
Mrs D Halsey	AE Administrator
File	TIME

5	Very High
4	High
3	Medium
2	Low
1	Very Low

PREVIOUS ACTION PLAN

Serial	Rating	Reference	Action Required	Remarks
1	12	141208/1	The Ventilation Services Policy should be reviewed.	Reviewed Dec 16. Closed
2	8	141208/4	CPs should be occasionally monitored when carrying out works and a record of monitoring activities retained in the Documents Register.	On-going, review at next audit.
3	20	141208/6	In-house CPs should be trained, assessed and appointed. Certificates of appointment and evidence of training should be retained in the Documents Register.	On-going, review at next audit.
4	20	141208/7	Letters of competency should be obtained from the employers of contractor CPs and retained in the Documents Register.	On-going, review at next audit.
5	12	141208/8	A CP Register should be produced listing the contractor CPs and should be retained in the Documents Register.	On-going, review at next audit.
6	20	141208/9	Plant shutdown/make-safe risk assessments should be produced to identify the hazards associated with taking critical ventilation systems out of use and for work on LEVs that present a hazard to the maintainer. The risk assessments should be retained in the Documents Register.	On-going, review at next audit.
7	20	141208/10	Ensure task risk assessments are held for all works on ventilation systems. This documentation should be retained or referenced in the Documents Register.	On-going, review at next audit.
8	20	141208/12	Produce a schedule of ventilation systems to identify all systems as critical, non-critical or LEV in accordance with SHTM 03-01, Part B, Para 4.7. Retain the schedule in the Documents Register.	On-going, review at next audit.
9	8	141208/18	Display safety signs at the entrance to all plant rooms.	On-going, review at next audit.
10	8	141208/19	Display unique plant room identity signs at the entrance to all plant rooms.	On-going, review at next audit.
11	12	141208/22	Install task lighting and emergency lighting for the Neurosurgery external plant area.	Completed, closed.

12	16	141208/23	Implement a planned maintenance regime for emergency lights fitted in plant rooms. Where DALI systems are installed a formal check of the automatic test results should be carried out.	On-going, review at next audit.
13	20	141208/33	Investigate and repair the Magnehelic gauge on Neurosurgery AHU 5.	Completed, closed.
14	20	141208/36	Carry out quarterly inspections on the retained estate critical ventilation systems. Record all critical system quarterly inspections in accordance with SHTM 03-01, Part B, Appendix 1.	Completed, closed.
15	20	141208/37	Carry out annual inspections on the retained estate non-critical ventilation systems in accordance with SHTM 03-01, Part B, Appendix 1.	On-going, review at next audit.
16	25	141208/40	Test fire dampers in accordance with SHTM 03-01, Part B, Para 4.13.	On-going, review at next audit.
17	20	141208/41	At least every 14 months carry out a thorough examination and test (recommission) of all AGSS. Record the test results and a sketch of the systems.	Completed, closed.
18	8	141208/42	Oversee the 14 monthly examinations of LEVs to ensure all the LEVs listed in the schedule of ventilation systems are examined.	On-going, review at next audit.
19	8	151209/1	Assess and appoint Cyril Dowson as an AP (V).	Completed, closed.
20	8	151209/2	Assess and appoint David Bratney as an AP (V) when he has completed AP (V) training.	Overtaken by events. Closed.
21	8	151209/3	Arrange for David Bratney to attend AP (V) training and forward a copy of his training certificate to the AE on completion.	Overtaken by events. Closed.
22	8	151209/4	Forward a copy of David Bratney's first aid training certificate to the AE.	Overtaken by events. Closed.
23	8	151209/6	Arrange for Paul Allan to attend first aid training and forward a copy of his training certificate to the AE on completion.	Completed, closed.
24	20	151209/7	Use permits to work when taking critical systems out of service and when carrying out intrusive maintenance on hazardous LEVs.	On-going, review at next audit.
25	12	151209/9	Only issue permits to work to appointed NHS CPs or contractor CPs listed in the CP Register.	On-going, review at next audit.

26	20	151209/11	Populate the CAFM system (FM First) with planned maintenance tasks for all ventilation systems and retain records of all planned maintenance tasks carried out.	On-going, review at next audit.
27	20	151209/14	Rectify the unserviceable lighting on the Old Maternity 4th floor plant room and install emergency lighting.	On-going, review at next audit. Asbestos?
28	12	151209/15	Fit identify signs or labels to the HEPA filter enclosures in the Adult and Children's Plant room 21.	On-going, review at next audit.
29	8	151209/17	Fit access hatches to all AHU intake ductwork sections to allow inspections.	On-going, review at next audit.
30	4	151209/18	Fit drainage pipework to the glass drain traps on the retained estate Neurosurgery AHUs.	On-going, review at next audit.
31	16	151209/19	Modify the drain trap arrangement on all AHUs in the Lab Block and Adult & Children's to ensure there is a 15mm air gap between the trap outlet and the drainage pipework.	Completed, closed.
32	4	151209/21	Consider fitting inspection windows and internal lighting on all Lab Block AHU's.	On-going, review at next audit.
33	12	151209/23	Investigate and rectify the spurious bag filter readings on retained estate Neonatal AHUs 1, 3 and 4.	Completed, closed.
34	12	151209/24	Rectify the collapsing pre-filters on the Old Maternity level 4 plant room intake plenum and fit a pressure differential gauge/manometer.	On-going, review at next audit.
35	8	151209/25	Fit direction of flow labels to the isolation room extract ductwork in the Adult & Children's Plant room 21.	On-going, review at next audit.
36	20	151209/26	Carry out annual verifications on the Adult & Children's isolation rooms, critical care and MRI ventilation systems. Carry out annual verifications on the retained estate Neonatal and MRI/CT ventilation systems.	MRI is difficult to access, Isolations rooms 50% complete. On-going review at next audit.
37	12	151209/27	Record the annual cleaning of AHUs in the Lab Block. Carry out and record the annual cleaning of all AHUs in the retained estate.	On-going, review at next audit.
38	20	151209/29	Ensure that LEV examinations and tests are carried out on the Mortuary dissection tables every 14 months in accordance with the COSHH Regulations.	On-going, review at next audit.

39	20	151209/31	Survey the Clinical Research department to identify any LEVs. Subject all identified LEVs to examinations and tests every 14 months in accordance with the COSHH Regulations.	Completed, closed.
40	12	151209/32	Critical ventilation systems that do not meet the performance criteria specified in SHTM 03-01 should be taken out of service. If the clinical requirement prevents this the User and infection control should be notified in writing by the AP.	Theatres are taken out of service for 1 week. Any failures are rectified before recommission. Closed.
41	8	161114/1	Produce a local action plan to address the actions raised in this report.	Gary Cullen has taken this on.
42	12	161114/2	Review the time available for APs to carry out AP (V) duties taking into consideration other disciplines they are responsible for.	On-going, review at next audit.
43	12	161114/3	Train, assess and appoint Jim Guthrie as an AP (V).	Overtaken by events. Closed.
44	12	161114/4	Ensure all options are struck through on all permits to work	Overtaken by events. Closed.
45	12	161114/5	Ensure the User (V) signs Part 2 of all permits to work.	Overtaken by events. Closed.
46	12	161114/6	Populate the existing Document Register with information relating to the retained estate and Adult & Children's, or setup and populate individual document registers.	On-going, review at next audit.
47	16	161114/7	Carry out planned maintenance on the retained estate AHUs. Carry out quarterly hygiene checks on split air conditioning units. Carry out 6 monthly chilled beam cleaning.	On-going, review at next audit.
48	12	161114/8	Inspect the half masks issued to the CPs annually and retain a record of the inspections.	On-going, review at next audit.

Additional Comments

Nil.

AP Training and Appointments Matrix

AP Name	Paul Allan	Cyril Dowson			
Status	AP (V)	AP (V)			
Based at	QEUH	QEUH			
Appointment Certificate	GG&C V 07	GG&C V 16			
Issue Date	05-Jan-15	12-Dec-16			
Expiry Date	04-Jan-18	11-Dec-19			
Sites covered	QEUH	QEUH			
Ventilation Training Expiry Date	30-Oct-17	27-Apr-18			
First Aid Expiry Date	11-Dec-19	22-Jun-18			
Permit-to-work	0	0			
Number checked by AE	0	0			

Comments

Paul Allan should attend an AP refresher course.

Another AP (V) should be nominated to carry out training.

One of the AP (V) should be designated the lead AP.

REPORT

Personnel

Duty Holder	Robert Calderwood	1
Designated Person	Mary-Anne Kane	1
Authorising Engineer	Jamie Minhinick	1
Authorised Persons	Paul Allan	5
	Cyril Dowson	1

1. Management Policy	Y/N	Comments	
Is there a Board Ventilation Safety Policy In place?	Y	NHS GG&C Ventilation Safety Policy.	1
Is the Ventilation Safety Policy approved at Board level?	Y	The policy was approved by Alex McIntyre (Director of Facilities).	1
Is the Board Ventilation Safety Policy reviewed periodically?	Y	The policy was reviewed in Dec 16 and will be reviewed annually.	1
Is the Board Ventilation Safety Policy a controlled Document?	Y	The policy is a controlled document. A copy was held in the Document Register.	1
Are the Duty Holder (V) responsibilities clearly defined in the Policy?	Y	The policy states that the Duty Holder is responsible for ensuring the ventilation systems are operated, maintained and repaired in accordance with SHTM 03-01.	1
Is the Designated Person appointed in writing?	N	The Designated Person is shown as the Director of Facilities in the structure chart.	5
Does the Board Ventilation Safety Policy include emergency procedures?	N	Emergency procedures were not included in the policy.	8
Have the emergency procedures been validated or tested during the current audit period?	N/A	Not applicable.	
Has the Authorising Engineer (AE) (V) appointment been correctly made and is it in date?	Y	No issues found.	1

2. Authorised Persons (V)	Y/N	Comments	
Are all APs (V) currently certified?	Y	Jim Guthrie has left the hospital and David Bratney is due to retire. Another 2 AP V should be nominated and trained.	8
Are the APs (V) due for refresher training in SHTM 03-01?	Y	Paul Allan should attend AP (V) training and forward copies of his training certificate to the AE on completion.	8
Are the APs (V) due for training in emergency first-aid?	Y	No issues found.	1
Are the APs (V) carrying out AP (V) duties on a regular basis?	N	The APs are not using permits to control maintenance activities.	8

Are the APs (V) formally monitoring the work-in-progress and are they recording their observations?	N	CP Monitoring had not been carried out. Identified in previous audit.	12
Is the provision of APs (V) adequate?	N	Jim Guthrie has left and David Bratney is due to retire. Comments were made by some APs in previous audits that they struggled to find the time to carry out AP (V) duties on top of their other commitments. A further 2 APs (V) should be identified and trained.	16

3. Competent Persons (V)			
	Y/N	Comments	
Have the NHS CPs (V) been formally assessed and appointed by an AP (V)?	N	In-house CPs had not been assessed and appointed. Training certificates were held for two NHS CPs and a third was thought to have been trained but a certificate was not available. The remaining NHS CPs had not been trained.	16
Is evidence of the competency of Contractor CPs (V) held in the Document Register?	Y	Evidence of competency was held for A Laughland and R Peel of Atlas Clean Air Ltd who carry out performance verifications on safety cabinets in the Laboratory building. Letters of competency or training certificates were not held for the CPs employed by H&V Commissioning Services Ltd and MAT Ltd.	8
Are the roles and responsibilities of Contractor CPs (V) defined in writing?	N/A	Not checked.	
Are records held in the Document Register of the site induction for the Contractor CPs (V)?	Y	The GG&C Contractor Control & Permit Register includes the issue of an identity card that listed the fundamental site rules and procedures.	1
Is there an up to date Register of CPs (V) appointed for the Trust included in the Document Register?	N	A CP Register was not held. Identified in previous audit.	12
Are the NHS CPs (V) carrying out their duties on a regular basis?	Y	In-house CPs and contractor CPs had been carrying out duties on a regular basis.	1

4. Incidents, Accidents and Dangerous Occurrences			
	Y/N	Comments	
Sine the last audit has the site been free from any accidents, incidents, dangerous occurrences or "near misses" in connection with the ventilation systems?	Y	None reported.	1
Have the details of incidents, accidents or dangerous occurrences been properly recorded and reported?	N/A	Not applicable.	

5. Safety Documentation

Job Number:	Originating AP (V):	Y/N	Comments
Was there a suitable & sufficient Risk Assessment to cover the work undertaken?	n/a	No permits issued since last audit.	
Was the permit-to-work completed by the AP (V) specifying the work to be carried out?	n/a	No permits issued since last audit.	
Was the permit-to-work signed by the User (V) to allow the work to proceed?	n/a	No permits issued since last audit.	
Was the permit-to-work issued to a CP (V)?	n/a	No permits issued since last audit.	
Was the permit-to-work cleared by a CP (V) and did they state that system was fit or unfit for use?	n/a	No permits issued since last audit.	
Was the permit-to-work cancelled by an AP (V) and did they acknowledge that the system was fit or unfit for use?	n/a	No permits issued since last audit.	
Did the User (V) acknowledge that the system should or should not be brought back into use?	n/a	No permits issued since last audit.	
Were the site records up-dated on completion of the work?	n/a	No permits issued since last audit.	

6. Operating Records

General	Y/N	Comments
Are the ventilation operating record documents kept in a secure location?	Y	Gary Cullen is setting up an electronic ventilation operating record on Smart Sheet. As compliance officer ventilation, once proved this will roll out across to board.
Do the APs (V) have access to copies of relevant SHTMs and other reference documents?	Y	An electronic copy was held.
Does the Document Register index include all of the subjects required by SHTM 03-01?	N	This is a work in progress on Smart Sheet by Gary Cullen. This will be used in conjunction with a hard copy held by retained estates and be expanded to include all areas.
Is the working Ventilation Document Register periodically reviewed and out-of-date information transferred to the archive Ventilation Document Register?	N/A	The Document Register was in the process of being populated. Not assessed.

Is there a schedule of ventilations systems detailing which are critical, non-critical or LEVs?	N	Asset lists were held electronically covering the retained estate and Adult & Children's. The Lab Block asset list was held in the Document Register. A consolidated schedule of ventilation plant should be produced stating the classification (non-critical, critical or LEV) of the plant.	20
Are adequate technical drawings available to the APs?	Y	Technical drawings are held on Zutec. Can be difficult to navigate.	4
Are adequate O&M manuals available to the APs?	Y	O&M information was held electronically (Zutec) and on the shared drive for the Adult & Children's and the Lab Block. Original O&M information for the retained estate maternity theatres was reported to be held.	4
Are all of the ventilation systems included in the Trust's planned maintenance programme?	N	The Adult & Children's ventilation systems and the Lab Block ventilation systems were subject to planned maintenance. Chilled/active beams were not subject to 6 monthly inspection & cleaning but this was being planned by the APs. Split air conditioning systems were not subject to quarterly hygiene inspections.	12
Are the planned maintenance records suitable, sufficient and accessible to the APs?	N	In-house maintenance was documented manually on check sheets. Service sheets were held for work carried out by contractor CPs. None of the maintenance was scheduled on FM First.	12
Are the results of the Trust's planned maintenance programme formally reviewed annually to establish trends and gaps? Are these reviews recorded?	N/A	Not checked.	

Inspection and Verification		Y/N	Comments	
Are critical ventilation systems being inspected quarterly?	Y	PPM files were held for all critical AHU. Monthly and quarterly checks were retained.	1	
Are non-critical systems being inspected annually?	Y	PPM files were held for all non critical AHU. Monthly and quarterly checks were retained.	1	
Are critical ventilation systems being verified annually?	Y	All theatres were subject to a rolling programme of annual verifications. Other critical systems in the Adult & Children's such as isolation wards are in the process of being verified with 50% complete. The retained estate ventilations systems for MRI/CT were not subject to annual verifications.	8	
Are the inspections and verifications being recorded as per SHTM 03-01, Part B, Appendices 1 & 2 and the records retained in the Ventilation Documents Register?	Y	Verification reports produced by H&V Commissioning Services Ltd provided an executive summary, air change rates, pressure differentials and noise levels. The quarterly inspections carried out on the Adult & Children's isolation rooms, MRI/CT and critical care areas did not conform fully to Appendix 1.	5	
Are the main components in AHUs serving critical and non-critical areas being cleaned annually?	Y	Annual cleaning of the AHUs is now being carried out.	1	
Are the fire dampers being tested annually?	N	Fire dampers were not subject to annual testing. A list of the fire dampers in the Lab Block had begun to be populated.	25	
Are the LEV systems being examined and tested by a competent person at least every 14 months?	N	All Lab Block safety cabinets and fume cupboards have had COSHH LEV performance tests carried out in the past 14 months. Records were held by Estates. The Mortuary dissection table had not been subjected to a COSHH LEV test in the past 14 months.	8	
Are critical systems that are unable to meet the required standards being taken out of service after receipt of condemnatory reports?	Y	All critical AHU's verified in the last 12 months are performing to the required standard. Immediate reports are given to estates before H&V leave site allowing problems to be rectified in the shut down period.	1	

7. Safety Equipment & Access Control			
	Y/N	Comments	
Do the APs (V) have sufficient isolation safety devices for the likely number of concurrent jobs?	Y	Adequate safety devices were held at the hospital.	1
Do the APs (V) have sufficient safety signage for the likely number of concurrent jobs?	Y	Adequate safety signs were held at the hospital.	1
Do the NHS CPs (V) have sufficient safety devices and signs for their routine work?	N/A	Not checked.	
Are records available of annual NHS safety and protective equipment inspections by an AP (V)?	N	The half masks issued to the CPs should be visually inspected annually by an AP and a record kept of the inspections.	8
Do all NHS test instruments have in date calibration certificates?	N	Micro Manometer 4902159510 and Anemometer 13450118 were calibrated on 24 Feb 16. Certificates could not be located during this audit.	5
Have contractors provided in-date calibration certificates for all of their test instruments and safety equipment?	Y	Copies of calibration certificates were provided for the test instruments used by H&V Commissioning Services Ltd who carry out annual verifications.	1
Is there an effective and auditable system for the control of plant room access in use?	Y	An access control procedure was held in the document register.	1

8. Engineering Systems

Air Handling Units (AHUs)			
	Y/N	Comments	
Is each AHU clearly and uniquely labelled and does this label exactly correspond to the AHU Register?	N	The isolation room HEPA filter extract cabinets in Adult & Children's Plant room 21 were not labelled.	8
Is the general condition of each AHU satisfactory?	Y	Those checked.	1
Is the AHU constructed according to the principles in SHTM 03-01, Part A, Figure 1?	Y	Those checked.	1
Are the automatic controls fitted to critical systems capable of being overridden in the event of a software failure?	Y	Those checked.	1
Are fresh air intakes sited correctly, constructed correctly and are access hatches or hinged louvres installed?	N	AHUs in the Adult & Children's Plant rooms 21 & 22 and in the Lab Block Cat 2 and Cat 3 plant rooms did not have access hatches fitted to the intake ducts to allow for inspection.	8
Are drainage systems installed for wet components and are the drainage systems properly constructed?	N	Some of the traps fitted to the retained estate neurosurgery AHUs had no drainage pipework fitted. Some drain traps were visibly dirty. The drain traps on the Lab Block AHUs were connected directly to drain with no air gap.	8
Are belt driven fan drives situated outside of the air stream?	N	Some fan drives were internal to the AHUs. No action required.	4

Is there adequate access around the AHU and are access doors provided for all major components?	Y	The Lab Block Cat AHUs had no inspection windows fitted.	5
Are inspection windows and internal lights provided for cooling coils and filters?	Y	Those checked.	1
Are the filters the correct grade and correctly fitted to minimise bypass?	N	Pre-filters were fitted to a walk-in plenum in the Old Maternity Level 4 plant room. A number of pre-filters in plant room 21 had collapsed allowing bypass.	16
Are the filters provided with a means of checking the differential pressure across them?	Y	There was no means of checking pressure differential on the pre filters fitted to the walk-in plenum in the retained estate Old Maternity Level 4 plant room.	8
Is the direction of air flow clearly marked on all main and branch ducts?	N	The extract ductwork serving the isolation rooms in Adult & Children's Plant room 21 did not have direction of flow labels fitted.	8
Are all air flow test-points properly located, clearly identified and is the size of the duct provided at each point?	Y	No issues found.	1

9. Engineering work spaces

Plant room externals	Y/N	Comments	
Is there a legible and secure safety sign displayed at the entrance to the plant room?	N	Adult & Children Plant rooms 21 & 22 and the Old Maternity 4th floor plant room did not have warning signs displayed at the entrance doors.	8
Is the name of the plant room exactly the same as the AHU Register?	N	Adult & Children Plant rooms 21 & 22 and the Old Maternity 4th floor plant room did not have unique name signs displayed at the entrance doors.	8
Is the correct contact telephone number shown?	N/A	Not applicable.	
Plant room security	Y/N	Comments	
Is the door soundly made and kept secure?	Y	No issues found.	1
Is there an emergency escape door and can it be opened from the inside?	N/A	Not checked.	
Is there a clear escape route outside the plant room?	Y	No issues found.	1
Are adequate emergency communications systems available?	Y	Staff entering plant rooms carry either a mobile telephone or PDA.	1
Is the plant room free from any unauthorised items stored within?	N	Oil stored on top of and wood / cardboard leaning against the plant in the Neonatal Theatre No 2 plant room.	25
If so, are the access arrangements to the plant room adequately controlled?	N/A	Not applicable.	

Plant room structure			
Is the plant room structure and condition satisfactory?	N	The Old Maternity 4th floor plant room general lighting was unserviceable. Emergency lighting was not installed in the Old Maternity 4th floor plant room.	8
Are posters and drawings displayed as required?	N/A	Not checked.	
Fire Precautions		Y/N	Comments
Is the plant room free from combustion equipment?	Y	No issues found.	1
Is the plant room free from rubbish or fire hazardous materials stored inside or immediately outside the plant room?	N	An open bottle of lubricating oil and drip tray was observed on the top of Theatre No 2 AHU in the Neonatal plant room. Various wood and materials were leaning against the AHU.	25
Is there at least one suitable fire extinguisher provided in the plant room and has it been inspected in the last 12 months?	Y	All fire extinguishers checked were serviced in April 2017.	1

I confirm that, where actions are required, a report has been submitted to the Designated Person	
	Jamie Minhinick
(Signature of AE (V))	(Name)

SCART Risk Grades	
5	Very High
4	High
3	Medium
2	Low
1	Very Low

UPDATED ACTION PLAN

Serial	Rating	Reference	Action Required	Responsible Person	Date due
Action points carried forward from previous audit					
1	8	141208/4	CPs should be occasionally monitored when carrying out works and a record of monitoring activities retained in the Documents Register.	All APs	08-Mar-15
2	20	141208/6	In-house CPs should be trained, assessed and appointed. Certificates of appointment and evidence of training should be retained in the Documents Register.	Lead AP	08-Jun-15
3	20	141208/7	Letters of competency should be obtained from the employers of contractor CPs and retained in the Documents Register.	Lead AP	08-Mar-15
4	12	141208/8	A CP Register should be produced listing the contractor CPs and should be retained in the Documents Register.	Lead AP	08-Mar-15
5	20	141208/9	Plant shutdown/make-safe risk assessments should be produced to identify the hazards associated with taking critical ventilation systems out of use and for work on LEVs that present a hazard to the maintainer. The risk assessments should be retained in the Documents Register.	Lead AP	08-Jan-15
6	20	141208/10	Ensure task risk assessments are held for all works on ventilation systems. This documentation should be retained or referenced in the Documents Register.	Lead AP	08-Jan-15
7	20	141208/12	Produce a schedule of ventilation systems to identify all systems as critical, non-critical or LEV in accordance with SHTM 03-01, Part B, Para 4.7. Retain the schedule in the Documents Register.	Lead AP	08-Jan-15
8	8	141208/18	Display safety signs at the entrance to all plant rooms.	Lead AP	08-Mar-15
9	8	141208/19	Display unique plant room identity signs at the entrance to all plant rooms.	Lead AP	08-Mar-15
10	16	141208/23	Implement a planned maintenance regime for emergency lights fitted in plant rooms. Where DALI systems are installed a formal check of the automatic test results should be carried out.	Lead AP	08-Jan-15

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11	20	141208/37	Carry out annual inspections on the retained estate non-critical ventilation systems in accordance with SHTM 03-01, Part B, Appendix 1.	Lead AP	08-Mar-15
12	25	141208/40	Test fire dampers in accordance with SHTM 03-01, Part B, Para 4.13.	Designated Person	08-Mar-15
13	8	141208/42	Oversee the 14 monthly examinations of LEVs to ensure all the LEVs listed in the schedule of ventilation systems are examined.	Lead AP	08-Mar-15
14	20	151209/7	Use permits to work when taking critical systems out of service and when carrying out intrusive maintenance on hazardous LEVs.	D Bratney and P Allan	12-Jan-16
15	12	151209/9	Only issue permits to work to appointed NHS CPs or contractor CPs listed in the CP Register.	All APs	12-Jan-16
16	20	151209/11	Populate the CAFM system (FM First) with planned maintenance tasks for all ventilation systems and retain records of all planned maintenance tasks carried out.	DP	12-Jun-16
17	20	151209/14	Rectify the unserviceable lighting on the Old Maternity 4th floor plant room and install emergency lighting.	Lead AP	12-Mar-16
18	12	151209/15	Fit identify signs or labels to the HEPA filter enclosures in the Adult and Children's Plant room 21.	Lead AP	12-Mar-16
19	8	151209/17	Fit access hatches to all AHU intake ductwork sections to allow inspections.	Lead AP	12-Dec-16
20	4	151209/18	Fit drainage pipework to the glass drain traps on the retained estate Neurosurgery AHUs.	Lead AP	12-Mar-16
21	4	151209/21	Consider fitting inspection windows and internal lighting on all Lab Block AHU's.	Lead AP	12-Jun-16
22	12	151209/24	Rectify the collapsing pre-filters on the Old Maternity level 4 plant room intake plenum and fit a pressure differential gauge/manometer.	Lead AP	12-Jun-16
23	8	151209/25	Fit direction of flow labels to the isolation room extract ductwork in the Adult & Children's Plant room 21.	Lead AP	12-Mar-16
24	20	151209/26	Carry out annual verifications on the Adult & Children's isolation rooms, critical care and MRI ventilation systems. Carry out annual verifications on the retained estate Neonatal and MRI/CT ventilation systems.	Lead AP	12-Mar-16
25	12	151209/27	Record annual the annual cleaning of AHUs in the Lab Block. Carry out and record the annual cleaning of all AHUs in the retained estate.	Lead AP	12-Dec-16

26	20	151209/29	Ensure that LEV examinations and tests are carried out on the Mortuary dissection tables every 14 months in accordance with the COSHH Regulations.	Lead AP	12-Jan-16
27	5	151209/31	Survey the Clinical Research department to identify any LEVs. Subject all identified LEVs to examinations and tests every 14 months in accordance with the COSHH Regulations.	Lead AP	12-Mar-16
28	12	151209/32	Critical ventilation systems that do not meet the performance criteria specified in SHTM 03-01 should be taken out of service. If the clinical requirement prevents this the User and infection control should be notified in writing by the AP.	Lead AP	13-Mar-16
29	8	161114/1	Produce a local action plan to address the actions raised in this report.	Lead AP	14-Dec-16
30	12	161114/2	Review the time available for APs to carry out AP (V) duties taking into consideration other disciplines they are responsible for.	DP	14-Feb-17
31	12	161114/6	Populate the existing Document Register with information relating to the retained estate and Adult & Children's, or setup and populate individual document registers.	All APs	14-Feb-17
32	16	161114/7	Carry out planned maintenance on the retained estate AHUs. Carry out quarterly hygiene checks on split air conditioning units. Carry out 6 monthly chilled beam cleaning.	Lead AP	14-May-17
33	12	161114/8	Inspect the half masks issued to the CPs annually and retain a record of the inspections.	Lead AP	14-May-17

Action points from this audit

34	25	20171113/01	An open bottle of lubricating oil and drip tray was observed on the top of Theatre No 2 AHU in the Neonatal plant room. Various wood and materials were leaning against the AHU. These must be removed.	Lead AP	ASAP
35	25	20171113/02	Fire dampers were not subject to annual testing. This should be actioned at a strategic level.	DP	ASAP
36	8	20171113/03	Paul Allan should attend a AP (V) refresher course.	Lead AP	31-Mar-18
37	20	20171113/04	The number of AP (V) should be assessed against other workloads. A further 2 APs are recommended.	DP	31-Mar-18

38	20	20171113/05	The use of authority for disconnection (permit to work) should be reintroduced to prevent unintentional loss of supplies to the theatres and critical equipment.	Lead AP	ASAP
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DP-Designated Person : AE- Authorising Engineer : AP- Authorised Person with Line Management Support

The **Designated Person** should sign this Action Plan to acknowledge the contents. The original copy should then be filed in the Document Register.

Signature: _____

Date: _____

Name: Mary-Anne Kane

I have the following comments/feedback on this report or the service I have received from Turner Professional Engineering Services:

Appendix A**Reconciliation of Ventilation Safety Documents**

Site: Queen Elizabeth University Hospital **Board:** Greater Glasgow and Clyde
From (date): 14-Nov-16 **To (date):** 07-Nov-17

Ser	Authorised Person	<u>Ventilation / LEV</u>				Competent person	Comments
		Isolation Diagram (if needed)	Safety programme (if needed)	Permit-to-work	Permission for disconnection / Interruption		
1							



Hospital

Queen Elizabeth University Hospital (QEUH)

Satellite Hospitals

Nil

Date(s) of Audit 11-12 Dec 18

Date(s) of Previous Audit 07 & 10 Nov 17

Site Address

1345 Govan Road,
Glasgow
G51 4TF

Reference 20181212-250-QEUH-V-JM-002

1. Terms of Reference

1.1 This audit was conducted in accordance with the following current reference documents:

- a. Scottish Health Technical Memorandum 00: Policies and principles of healthcare engineering.
- b. Scottish Health Technical Memorandum 03-01: Specialised ventilation for healthcare premises.

2. Executive Summary

2.1 Introduction. The purpose of this audit was to assess the compliance, operation and maintenance of the Safe System of Work at the Hospital(s) in accordance with the discipline specific Health Technical Memoranda, Acts, Regulations and HSE Guidance documents. The resulting Action Plan will be reviewed periodically. The appointments of the discipline specific Authorised Persons were also assessed during the audit.

2.2 Report Summary

Steady good progress has been made at QEUH under the direction of the compliance manager and interim site manager (operational estates). Some issues remain unresolved and are placing the board at risk:

1. Fire dampers were not subject to annual testing.
2. Maintenance of ventilation systems is not planned and appears to be done on a reactive basis following planned inspections when faults are identified. The planned maintenance issued to NHS competent persons should be reviewed.
3. The schedule of ventilation assets should be extended to include LEV's, Split AC's, Cassette Units, FCU's, and ACB's.
4. The criticality of all ventilation systems should be reviewed with user groups to positively identify all systems that should be deemed critical. This should be recorded in the ventilation assets schedule.
5. Once identified, all critical systems should be subjected to performance verification at least annually and inspected every 3 months using the 40 point check or appropriate inspection template.
6. Split AC's, Cassette Units and FCU's should be subjected to 3m inspections and cleaning.
7. All Active Chilled Beams (ACB's) should be inspected on a 6m basis and cleaned as required.

3. Conclusion

ASSESSMENT OF SAFE SYSTEM OF WORK	CONCLUSION
1. Assessment of the Management Policy.	4
2. Assessment of the Authorised Persons.	8
3. Assessment of the Competent Persons.	9
4. Assessment of Incidents, Accidents and Dangerous Occurrences.	1
5. Assessment of the Safety Documentation.	20
6. Assessment of the Operating Records.	16
7. Assessment of the Safety equipment & Access Control.	8
8. Assessment of the Engineering Systems.	8
9. Assessment of the Engineering Work Spaces.	8

Is the system safe to continue?	Yes, under the supervision of the AE
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4. Next Audit Date

The next audit visit is planned to take place in

November 2019

Signature:

[Redacted Signature]

Date:

13-Dec-18

Name:

Jamie Minhinnick

Turner Professional Engineering Services
Team Q Maintenance Ltd
Collier House
Mead Lane
Hertford SG13 7AX

E-mail:

[Redacted E-mail]

Mobile Phone:

[Redacted Mobile Phone]

Key to Assessments:

		<u>Severity</u>				
		INSIGNIFICANT	MINOR	MODERATE	MAJOR	EXTREME
<u>Likelihood</u>	ALMOST CERTAIN	5	10	15	20	25
	LIKELY	4	8	12	16	20
	POSSIBLE	3	6	9	12	15
	UNLIKELY	2	4	6	8	10
	REMOTE	1	2	3	4	5

NHS Contract:

Ms Mary-Anne Kane	Associate Director of Estates and Facilities
Mr Alan Gallacher	General Manager (Estates)
Mr Gary Cullen	Compliance Manager
Mr Darryl Conner	Interim Site Manager Operational Estates QEUH (AP(V) Des)
Mr Paul Allen	Estates Manager AP(V)
Mr Cyril Dowson	Coordinating Supervisor AP(V)

Turner Professional Engineering Services:

Mr P Clinton	Coordinating Authorising Engineer
Mr J Minhinnick	Authorising Engineer (Ventilation)
Mrs D Halsey	AE Administrator
File	TIME

SCART Risk Grades	
	Very High
	High
	Medium
	Low

PREVIOUS ACTION PLAN

Serial	Rating	Reference	Action Required	Remarks
1	6	141208/4	CPs should be occasionally monitored when carrying out works and a record of monitoring activities retained in the Documents Register.	No progress to date. Review at next audit.
2	20	141208/6	In-house CPs should be trained, assessed and appointed. Certificates of appointment and evidence of training should be retained in the Documents Register.	CP's have now been trained but are yet to be formally appointed. Reduced risk rating applied, review at next audit.
3	20	141208/7	Letters of competency should be obtained from the employers of contractor CPs and retained in the Documents Register.	No progress to date. Reduced risk rating applied. Review at next audit.
4	12	141208/8	A CP Register should be produced listing the contractor CPs and should be retained in the Documents Register.	Now on SMART sheet. Closed.
5	20	141208/9	Plant shutdown/make-safe risk assessments should be produced to identify the hazards associated with taking critical ventilation systems out of use and for work on LEVs that present a hazard to the maintainer. The risk assessments should be retained in the Documents Register.	No progress to date. Reduced risk rating applied. Review at next audit.
6	20	141208/10	Ensure task risk assessments are held for all works on ventilation systems. This documentation should be retained or referenced in the Documents Register.	No progress to date. Review at next audit.
7	20	141208/12	Produce a schedule of ventilation systems to identify all systems as critical, non-critical or LEV in accordance with SHTM 03-01, Part B, Para 4.7. Retain the schedule in the Documents Register.	Schedule is now compiled, it should include columns for "area served" and "Critical or Non-Critical". Reduced risk rating, review at next audit.
8	8	141208/18	Display safety signs at the entrance to all plant rooms.	Works in progress, review at next audit.
9	8	141208/19	Display unique plant room identity signs at the entrance to all plant rooms.	Works in progress, review at next audit.
10	16	141208/23	Implement a planned maintenance regime for emergency lights fitted in all plant rooms. Where DALI systems are installed a formal check of the automatic test results should be carried out.	On-going, review at next audit.

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11	20	141208/37	Carry out annual inspections on all non-critical ventilation systems in accordance with SHTM 03-01, Part B, Appendix 1.	As of Nov 18 all AHU's are inspected. Reduced risk rating applied. The requirements of SHTM03/01 Pt B Appendix 1 and 2 is being developed. Review at next audit.
12	25	141208/40	Test fire dampers in accordance with SHTM 03-01, Part B, Para 4.13.	Discussed with the DP, No progress to date, review at next audit.
13	8	141208/42	Oversee the 14 monthly examinations of LEVs to ensure all the LEVs listed in the schedule of ventilation systems are examined.	On-going, review at next audit.
14	20	151209/7	Use permits to work when taking critical systems out of service and when carrying out intrusive maintenance on hazardous LEVs.	Permits have been produced and will be put into use ASAP.
15	12	151209/9	Only issue permits to work to appointed NHS CPs or contractor CPs listed in the CP Register.	Not yet in use, overtaken by events, closed.
16	20	151209/11	Populate the CAFM system (FM First) with planned maintenance tasks for all ventilation systems and retain records of all planned maintenance tasks carried out.	The FM First system is not yet in use however a spreadsheet is in use to plan maintenance and inspections at QEUH. New action raised, closed.
17	20	151209/14	Rectify the unserviceable lighting on the Old Maternity 4th floor plant room and install emergency lighting.	Lighting repaired. Closed.
18	12	151209/15	Fit identify signs or labels to the HEPA filter enclosures in the Adult and Children's Plant room 21.	Bio Hazard signs fitted. Closed.
19	8	151209/17	Fit access hatches to all AHU intake ductwork sections to allow inspections.	On-going, review at next audit.
20	4	151209/18	Fit drainage pipework to the glass drain traps on the retained estate Neurosurgery AHUs.	Unit planned for replacement. Review at next audit.
21	4	151209/21	Consider fitting inspection windows and internal lighting on all Lab Block AHU's.	Not SMART, closed.
22	12	151209/24	Rectify the collapsing pre-filters on the Old Maternity level 4 plant room intake plenum and fit a pressure differential gauge/manometer.	Completed, closed.
23	8	151209/25	Fit direction of flow labels to the isolation room extract ductwork in the Adult & Children's Plant room 21.	No progress to date, review at next audit.
24	20	151209/26	Carry out annual verifications on the Adult & Children's isolation rooms, critical care and MRI ventilation systems. Carry out annual verifications on the retained estate Neonatal and MRI/CT ventilation systems.	Works have started with isolation rooms. Discussion to be held at TUM regarding definition of critical systems for MRI/CT. New action raised. Closed.

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25	12	151209/27	Record annual the annual cleaning of AHUs in the Lab Block. Carry out and record the annual cleaning of all AHUs in the retained estate.	No records for any cleaning of AHUs was witnessed. Discussed with lead AP. New action raised, closed.
26	20	151209/29	Ensure that LEV examinations and tests are carried out on the Mortuary dissection tables every 14 months in accordance with the COSHH Regulations.	Works in the planning to incorporate with the Joiners LEV. Review at next audit.
27	5	151209/31	Survey the Clinical Research department to identify any LEVs. Subject all identified LEVs to examinations and tests every 14 months in accordance with the COSHH Regulations.	No progress to date, new action raised, closed.
28	12	151209/32	Critical ventilation systems that do not meet the performance criteria specified in SHTM 03-01 should be taken out of service. If the clinical requirement prevents this the User and infection control should be notified in writing by the AP.	This is now directed in the ventilation SOP. Closed.
29	8	161114/1	Produce a local action plan to address the actions raised in this report.	Now on SMART sheet. Closed.
30	12	161114/2	Review the time available for APs to carry out AP (V) duties taking into consideration other disciplines they are responsible for.	Completed. 4 APs to be trained and appointed.
31	12	161114/6	Populate the existing Document Register with information relating to the retained estate and Adult & Children's, or setup and populate individual document registers.	No progress to date, new action raised, closed.
32	16	161114/7	Carry out planned maintenance on the retained estate AHUs. Carry out quarterly hygiene checks on split air conditioning units. Carry out 6 monthly chilled beam cleaning.	No progress to date. New action raised, closed.
33	12	161114/8	Inspect the half masks issued to the CPs annually and retain a record of the inspections.	No progress to date.
34	25	20171113/01	An open bottle of lubricating oil and drip tray was observed on the top of Theatre No 2 AHU in the Neonatal plant room. Various wood and materials were leaning against the AHU. These must be removed.	Completed. Closed.
35	25	20171113/02	Fire dampers were not subject to annual testing. This should be actioned at a strategic level.	Overtaken by events. Closed.
36	8	20171113/03	Paul Allan should attend a AP (V) refresher course.	Overtaken by events. Closed.

37	20	20171113/ 04	The number of AP (V) should be assessed against other workloads. A further 2 APs are recommended.	Overtaken by events. Closed.
38	20	20171113/ 05	The use of authority for disconnection (permit to work) should be reintroduced to prevent unintentional loss of supplies to the theatres and critical equipment.	Overtaken by events. Closed.

AP Training and Appointments Matrix

AP Name	Paul Allan	Cyril Dowson	Darryl Conner	Mark McKaig	Melville MacMillan
Status	AP (V)	AP (V)	Lead AP(V) Des	AP(V) Des	AP(V) Des
Based at	QEUH	QEUH	QEUH	QEUH	QEUH
Appointment Certificate	GG&C V 07	GG&C V 16	N/A	N/A	N/A
Issue Date	05-Jan-15	12-Dec-16	N/A	N/A	N/A
Expiry Date	04-Jan-18	11-Dec-19	N/A	N/A	N/A
Sites covered	QEUH	QEUH	QEUH	QEUH	QEUH
Ventilation Training Date	30-Oct-14	27-Apr-15	14-Sep-18	01-Oct-18	01-Oct-18
First Aid Expiry Date	11-Dec-19	29-Jul-21	17-Apr-21	tbc	23-Dec-18
Permit-to-work	0	0	N/A	N/A	N/A
Number checked by AE	0	0	N/A	N/A	N/A

Comments

Darryl Conner, Melville MacMillan and Mark McKaig should be assessed and appointed for AP Ventilation duties.

REPORT			
Personnel			
Duty Holder	Mary-Anne Kane		1
Designated Person	Alan Gallacher		5
Authorising Engineer	Jamie Minhinnick		1
Authorised Persons	Darryl Conner		5
	Paul Allan		1
	Cyril Dowson		1
1. Management Policy			
	Y/N	Comments	
Is there a Board Ventilation Safety Policy In place?	Y	NHS GG&C Ventilation Safety Policy.	1
Is the Ventilation Safety Policy approved at Board level?	Y	The policy was approved.	1
Is the Board Ventilation Safety Policy reviewed periodically?	Y	The policy was reviewed in Nov 17 and will be reviewed bi-annually.	1
Is the Board Ventilation Safety Policy a controlled Document?	Y	The policy is a controlled document. A copy was held on SMART sheet.	1
Are the Duty Holder (V) responsibilities clearly defined in the Policy?	Y	The policy states that the Duty Holder is responsible for ensuring the ventilation systems are operated, maintained and repaired in accordance with SHTM 03-01.	1
Is the Designated Person appointed in writing?	N	No appointment made or held on SMART sheet.	5
Does the Board Ventilation Safety Policy include emergency procedures?	N	Emergency procedures were not yet included in the policy but are in development with the compliance manager.	5
Have the emergency procedures been validated or tested during the current audit period?	N/A	Not applicable.	
Has the Authorising Engineer (AE) (V) appointment been correctly made and is it in date?	Y	No issues found.	1
2. Authorised Persons (V)			
	Y/N	Comments	
Are all APs (V) currently certified?	N	Only 2 of the 5 AP's are formally appointed.	8
Are the APs (V) due for refresher training in SHTM 03-01?	N	No issues found.	1
Are the APs (V) due for training in emergency first-aid?	Y	No issues found.	1

Are the APs (V) carrying out AP (V) duties on a regular basis?	N	The APs are not using permits to control maintenance activities.	8
Are the APs (V) formally monitoring the work-in-progress and are they recording their observations?	N	CP Monitoring had not been carried out. Identified in previous audit.	12
Is the provision of APs (V) adequate?	N	5 AP's have been identified and trained but only 3 are appointed. See training summary.	16

3. Competent Persons (V)			
	Y/N	Comments	
Have the NHS CPs (V) been formally assessed and appointed by an AP (V)?	N	In house CPs have been trained but are yet to be formally appointed.	8
Is evidence of the competency of Contractor CPs (V) held in the Document Register?	Y	Evidence is held on Smart Sheet for H&V and Howarths. MAT and other ventilation contractors should be added.	8
Are the roles and responsibilities of Contractor CPs (V) defined in writing?	N/A	Not checked.	
Are records held in the Document Register of the site induction for the Contractor CPs (V)?	Y	The GG&C Contractor Control & Permit Register includes the issue of an identity card that listed the fundamental site rules and procedures.	1
Is there an up to date Register of CPs (V) appointed for the Trust included in the Document Register?	N	A register is held on SMART sheet.	1
Are the NHS CPs (V) carrying out their duties on a regular basis?	Y	In-house CPs and contractor CPs had been carrying out duties on a regular basis.	1

4. Incidents, Accidents and Dangerous Occurrences			
	Y/N	Comments	
Sine the last audit has the site been free from any accidents, incidents, dangerous occurrences or "near misses" in connection with the ventilation systems?	Y	None reported.	1
Have the details of incidents, accidents or dangerous occurrences been properly recorded and reported?	N/A	Not applicable.	

5. Safety Documentation

Job Number:

Originating AP (V):

Y/N

Comments

Was there a suitable & sufficient Risk Assessment to cover the work undertaken?	n/a	No permits issued since last audit.	
Was the permit-to-work completed by the AP (V) specifying the work to be carried out?	n/a	No permits issued since last audit.	
Was the permit-to-work signed by the User (V) to allow the work to proceed?	n/a	No permits issued since last audit.	
Was the permit-to-work issued to a CP (V)?	n/a	No permits issued since last audit.	
Was the permit-to-work cleared by a CP (V) and did they state that system was fit or unfit for use?	n/a	No permits issued since last audit.	
Was the permit-to-work cancelled by an AP (V) and did they acknowledge that the system was fit or unfit for use?	n/a	No permits issued since last audit.	
Did the User (V) acknowledge that the system should or should not be brought back into use?	n/a	No permits issued since last audit.	
Were the site records up-dated on completion of the work?	n/a	No permits issued since last audit.	

6. Operating Records

General

Y/N

Comments

Are the ventilation operating record documents kept in a secure location?	Y	The ventilation documents register is held electronically on SMART sheet.	1
Do the APs (V) have access to copies of relevant SHTMs and other reference documents?	Y	An electronic copy was held.	1
Does the Document Register index include all of the subjects required by SHTM 03-01?	Y	Held on SMART sheet.	1
Is the working Ventilation Document Register periodically reviewed and out-of-date information transferred to the archive Ventilation Document Register?	N/A	The Document Register was in the process of being populated. Not assessed.	
Is there a schedule of ventilations systems detailing which are critical, non-critical or LEVs?	Y	Modify the existing ventilation schedule to include LEV's, ACB's, Split AC's, Cassettes, FCU's etc and add columns for "area served" and "Critical or Non-Critical".	12
Are adequate technical drawings available to the APs?	Y	Technical drawings are held on Zutec. Can be difficult to navigate.	4

Are adequate O&M manuals available to the APs?	Y	O&M information was held electronically (Zutec) and on the shared drive for the Adult & Children's and the Lab Block. Original O&M information for the retained estate maternity theatres was reported to be held.	4
Are all of the ventilation systems included in the Trust's planned maintenance programme?	N	Maintenance of ventilation systems is not planned and appears to be done on a reactive basis following planned inspections when faults are identified. The planned maintenance issued to NHS competent persons should be reviewed and risk assessed. It is recommended that SFG 20 is used as a maintenance schedule for ventilation systems and implemented.	16
Are the planned maintenance records suitable, sufficient and accessible to the APs?	N	In-house maintenance was documented manually on check sheets. Service sheets were held for work carried out by contractor CPs. None of the maintenance was scheduled on FM First.	12
Are the results of the Trust's planned maintenance programme formally reviewed annually to establish trends and gaps? Are these reviews recorded?	N/A	Not checked.	

Inspection and Verification	Y/N	Comments	
Are critical ventilation systems being inspected quarterly?	Y	PPM files were held for all critical AHU. Monthly and quarterly checks were retained.	1
Are non-critical systems being inspected annually?	Y	PPM files were held for all non critical AHU. Monthly and quarterly checks were retained.	1
Are critical ventilation systems being verified annually?	Y	All theatres were subject to a rolling programme of annual verifications. Other critical systems in the Adult & Children's such as isolation wards are in the process of being verified with 50% complete. The retained estate ventilations systems for MRI/CT were not subject to annual verifications.	12

Are the inspections and verifications being recorded as per SHTM 03-01, Part B, Appendices 1 & 2 and the records retained in the Ventilation Documents Register?	Y	Verification reports produced by H&V Commissioning Services Ltd provided an executive summary, air change rates, pressure differentials and noise levels. The quarterly inspections carried out on the Adult & Children's isolation rooms, MRI/CT and critical care areas did not conform fully to Appendix 1.	8
Are the main components in AHUs serving critical and non-critical areas being cleaned annually?	Y	Annual cleaning of the AHUs is reportedly being carried out but was difficult to evidence with paperwork.	8
Are the fire dampers being tested annually?	N	Fire dampers were not subject to annual testing. A list of the fire dampers in the Lab Block had begun to be populated.	20
Are the LEV systems being examined and tested by a competent person at least every 14 months?	N	All Lab Block safety cabinets and fume cupboards have had COSHH LEV performance tests carried out in the past 14 months. Records were held by Estates. The Mortuary dissection table had not been subjected to a COSHH LEV test in the past 14 months.	8
Are critical systems that are unable to meet the required standards being taken out of service after receipt of condemnatory reports?	Y	All critical AHU's verified in the last 12 months are performing to the required standard. Immediate reports are given to estates before H&V leave site allowing problems to be rectified in the shut down period. A process is documented in an SOP held on SMART sheet.	1

7. Safety Equipment & Access Control		Y/N	Comments	
Do the APs (V) have sufficient isolation safety devices for the likely number of concurrent jobs?	Y	Adequate safety devices were held at the hospital.	1	
Do the APs (V) have sufficient safety signage for the likely number of concurrent jobs?	Y	Adequate safety signs were held at the hospital.	1	
Do the NHS CPs (V) have sufficient safety devices and signs for their routine work?	N/A	Not checked.		
Are records available of annual NHS safety and protective equipment inspections by an AP (V)?	N	The half masks issued to the CPs should be visually inspected annually by an AP and a record kept of the inspections.	8	
Do all NHS test instruments have in date calibration certificates?	N	Micro Manometer 4902159510 and Anememomter13450118 were calibrated on 24 Feb 16. Certificates could not be located during this audit.	5	
Have contractors provided in-date calibration certificates for all of their test instruments and safety equipment?	Y	Copies of calibration certificates were provided for the test instruments used by H&V Commissioning Services Ltd who carry out annual verifications.	1	
Is there an effective and auditable system for the control of plant room access in use?	Y	An access control procedure was held in the document register.	1	

8. Engineering Systems

Air Handling Units (AHUs)	Y/N	Comments	
Is each AHU clearly and uniquely labelled and does this label exactly correspond to the AHU Register?	Y	Those checked.	1
Is the general condition of each AHU satisfactory?	Y	Those checked.	1
Is the AHU constructed according to the principles in SHTM 03-01, Part A, Figure 1?	Y	Those checked.	1
Are the automatic controls fitted to critical systems capable of being overridden in the event of a software failure?	Y	Those checked.	1
Are fresh air intakes sited correctly, constructed correctly and are access hatches or hinged louvres installed?	N	AHUs in the Adult & Children's Plant rooms 21 & 22 and in the Lab Block Cat 2 and Cat 3 plant rooms did not have access hatches fitted to the intake ducts to allow for inspection.	8
Are drainage systems installed for wet components and are the drainage systems properly constructed?	N	Some of the traps fitted to the retained estate neurosurgery AHUs had no drainage pipework fitted. Some drain traps were visibly dirty. The drain traps on the Lab Block AHUs were connected directly to drain with no air gap.	8
Are belt driven fan drives situated outside of the air stream?	N	Some fan drives were internal to the AHUs. No action required.	4

Is there adequate access around the AHU and are access doors provided for all major components?	Y	The Lab Block Cat AHUs had no inspection windows fitted.	5
Are inspection windows and internal lights provided for cooling coils and filters?	Y	Those checked.	1
Are the filters the correct grade and correctly fitted to minimise bypass?	Y	No issues found.	1
Are the filters provided with a means of checking the differential pressure across them?	Y	There was no means of checking pressure differential on the pre filters fitted to the walk-in plenum in the retained estate Old Maternity Level 4 plant room.	8
Is the direction of air flow clearly marked on all main and branch ducts?	N	The extract ductwork serving the isolation rooms in Adult & Children's Plant room 21 did not have direction of flow labels fitted.	8
Are all air flow test-points properly located, clearly identified and is the size of the duct provided at each point?	Y	No issues found.	1

9. Engineering work spaces

Plant room externals	Y/N	Comments	
Is there a legible and secure safety sign displayed at the entrance to the plant room?	N	Adult & Children Plant rooms 21 & 22 and the Old Maternity 4th floor plant room did not have warning signs displayed at the entrance doors.	8
Is the name of the plant room exactly the same as the AHU Register?	N	Adult & Children Plant rooms 21 & 22 and the Old Maternity 4th floor plant room did not have unique name signs displayed at the entrance doors.	8
Is the correct contact telephone number shown?	N/A	Not applicable.	
Plant room security	Y/N	Comments	
Is the door soundly made and kept secure?	Y	No issues found.	1
Is there an emergency escape door and can it be opened from the inside?	N/A	Not checked.	
Is there a clear escape route outside the plant room?	Y	No issues found.	1
Are adequate emergency communications systems available?	Y	Staff entering plant rooms carry either a mobile telephone or PDA.	1
Is the plant room free from any unauthorised items stored within?	Y	No issues found.	1
If so, are the access arrangements to the plant room adequately controlled?	N/A	Not applicable.	

Plant room structure

Is the plant room structure and condition satisfactory?	Y	No issues found.	1
Are posters and drawings displayed as required?	N/A	Not checked.	

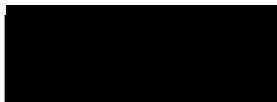
Fire Precautions

Y/N

Comments

Is the plant room free from combustion equipment?	Y	No issues found.	1
Is the plant room free from rubbish or fire hazardous materials stored inside or immediately outside the plant room?	Y	No issues found.	1
Is there at least one suitable fire extinguisher provided in the plant room and has it been inspected in the last 12 months?	Y	All fire extinguishers checked were serviced in April 2018.	1

I confirm that, where actions are required, a report has been submitted to the Designated Person



Jamie Minhinnick

(Signature of AE (V))

(Name)

SCART Risk Grades	
	Very High
	High
	Medium
	Low

UPDATED ACTION PLAN

Serial	Rating	Reference	Action Required	Responsible Person	Date due
Action points carried forward from previous audit					
1	8	141208/4	CPs should be occasionally monitored when carrying out works and a record of monitoring activities retained in the Documents Register.	All APs	31-Mar-19
2	9	141208/6	In-house CPs should be trained, assessed and appointed. Certificates of appointment and evidence of training should be retained in the Documents Register.	Lead AP	31-Mar-19
3	6	141208/8	A CP Register should be produced listing the contractor CPs and should be retained in the Documents Register.	Lead AP	31-Mar-19
4	16	141208/9	Plant shutdown/make-safe risk assessments should be produced to identify the hazards associated with taking critical ventilation systems out of use and for work on LEVs that present a hazard to the maintainer. The risk assessments should be retained in the Documents Register.	Lead AP	30-Nov-19
5	16	141208/10	Ensure task risk assessments are held for all works on ventilation systems. This documentation should be retained or referenced in the Documents Register.	Lead AP	30-Nov-19
6	12	141208/12	Produce a schedule of ventilation systems to identify all systems as critical, non-critical or LEV in accordance with SHTM 03-01, Part B, Para 4.7. Retain the schedule in the Documents Register.	Lead AP	31-Mar-19
7	8	141208/18	Display safety signs at the entrance to all plant rooms.	Lead AP	31-May-19
8	8	141208/19	Display unique plant room identity signs at the entrance to all plant rooms.	Lead AP	31-May-19
9	16	141208/23	Implement a planned maintenance regime for emergency lights fitted in plant rooms. Where DALI systems are installed a formal check of the automatic test results should be carried out.	Lead AP	31-May-19

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10	12	141208/37	Carry out annual inspections on the retained estate non-critical ventilation systems in accordance with SHTM 03-01, Part B, Appendix 1.	Lead AP	31-Mar-19
11	20	141208/40	Test fire dampers in accordance with SHTM 03-01, Part B, Para 4.13.	DP	TBC
12	8	141208/42	Oversee the 14 monthly examinations of LEVs to ensure all the LEVs listed in the schedule of ventilation systems are examined.	Lead AP	31-Mar-18
13	20	151209/7	Use permits to work when taking critical systems out of service and when carrying out intrusive maintenance on hazardous LEVs.	Lead AP	ASAP
14	8	151209/17	Fit access hatches to all AHU intake ductwork sections to allow inspections.	Lead AP	12-Dec-19
15	4	151209/18	Fit drainage pipework to the glass drain traps on the retained estate Neurosurgery AHUs.	Lead AP	12-Dec-19
16	8	151209/25	Fit direction of flow labels to the isolation room extract ductwork in the Adult & Children's Plant room 21.	Lead AP	31-Mar-19
17	16	151209/29	Ensure that LEV examinations and tests are carried out on the Mortuary dissection tables every 14 months in accordance with the COSHH Regulations.	Lead AP	31-Mar-19
18	12	161114/8	Inspect the half masks issued to the CPs annually and retain a record of the inspections.	Lead AP	31-Mar-19

Action points from this audit

19	16	20181212/01	Introduce a true planned maintenance regime for ventilation systems from an agreed maintenance schedule and add to all ventilation assets.	Lead AP	01-Jun-19
20	9	20181212/02	Modify the existing ventilation schedule to include LEV's, ACB's, Split AC's, Cassettes, FCU's etc and add columns for "area served" and "Critical or Non-Critical".	Lead AP	01-Jun-19
21	16	20181212/03	The criticality of all ventilation systems should be reviewed with user groups to positively identify all systems that should be deemed critical.	Lead AP/DP	01-Jun-19
22	9	20181212/04	Populate all relevant information into the documents register on SMART sheet.	Lead AP	01-Jun-19
23	16	20181212/05	Split AC's, Cassette Units and FCU's should be subjected to 3m inspections and cleaning.	Lead AP	01-Jun-19

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24	16	20181212/ 06	All Active Chilled Beams (ACB's) should be inspected on a 6m basis and cleaned as required.	Lead AP	01-Jun-19
25	12	20181212/ 07	Darryl Conner, Melville MacMillan and Mark McKaig should be assessed and appointed for AP Ventilation duties.	Compliance Manager / AE	31-Mar-19

DP-Designated Person : AE- Authorising Engineer : AP- Authorised Person with Line Management Support

The **Designated Person** should sign this Action Plan to acknowledge the contents. The original copy should then be filed in the Document Register.

Signature: _____

Date: _____

Name: Mary-Anne Kane

I have the following comments/feedback on this report or the service I have received from Turner Professional Engineering Services:

Appendix A**Reconciliation of Ventilation Safety Documents**

Site: Queen Elizabeth University Hospital **Board:** Greater Glasgow and Clyde
From (date): 07-Nov-17 **To (date):** 12-Dec-18

Ser	Authorised Person	<u>Ventilation / LEV</u>				Competent person	Comments
		Isolation Diagram (if needed)	Safety programme (if needed)	Permit-to-work	Permission for disconnection / Interruption		
1							



Hospital

Queen Elizabeth University Hospital (QEUH)
Campus

Satellite Hospitals

Nil

Date(s) of Audit 17-18 Dec 19

Date(s) of Previous Audit 11-12 Dec 18

Site Address

1345 Govan Road,
Glasgow
G51 4TF

Reference 20191218-250-QEUH-V-JM-003

1. Terms of Reference

1.1 This audit was conducted in accordance with the following current reference documents:

- a. Scottish Health Technical Memorandum 00: Policies and principles of healthcare engineering.
- b. Scottish Health Technical Memorandum 03-01: Specialised ventilation for healthcare premises.

2. Executive Summary

2.1 Introduction. The purpose of this audit was to assess the compliance, operation and maintenance of the Safe System of Work at the Hospital(s) in accordance with the discipline specific Health Technical Memoranda, Acts, Regulations and HSE Guidance documents. The resulting Action Plan will be reviewed periodically. The appointments of the discipline specific Authorised Persons were also assessed during the audit.

2.2 Report Summary

Another good year of progress was witnessed at QEUH Campus in terms of management of ventilation. Progress on the action plan was pleasing to see with 23/25 actions completed or in progress.

Some areas that still need to be addressed are as follows:

1. Fire damper testing has not been carried out in the adults and children's hospital. There has been good progress with a survey of the retained estates but the vast proportion are in the A&C.
2. The updated policy should be published and roles communicated accordingly following proposed structure changes. Once completed the AP's should be appointed formally.
3. Safety paperwork and 40 point checks are auditable and accountable documents. Care should be taken by both AP's and CP's to ensure they are filled out correctly and in line with guidance.
4. If the Neurology AHU's on level 2 are to be retained works should be carried out to prolong the life and improve the standards. It is the opinion of the AE that the units are capable of being refurbished in situ and have a number of years of life remaining if action is taken within the next 12m.
5. It is strongly recommended that an AP(V) is trained and appointed for each shift to assist in the delivery of the safe system of work.

Overall a good audit. Details of new actions are contained within this report.

3. Conclusion

ASSESSMENT OF SAFE SYSTEM OF WORK	CONCLUSION
1. Assessment of the Management Policy.	6
2. Assessment of the Authorised Persons.	10
3. Assessment of the Competent Persons.	6
4. Assessment of Incidents, Accidents and Dangerous Occurrences.	1
5. Assessment of the Safety Documentation.	12
6. Assessment of the Operating Records.	20
7. Assessment of the Safety equipment & Access Control.	1
8. Assessment of the Engineering Systems.	8
9. Assessment of the Engineering Work Spaces.	1

Is the system safe to continue?	Yes, under the supervision of the AE
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4. Next Audit Date

The next audit visit is planned to take place in

December 2020

Signature:

[Redacted Signature]

Date:

19-Dec-19

Name:

Jamie Minhinnick

t/a Turner Professional Engineering Services
Turner Property Services
65 Craigton Road
Glasgow
G51 3EQ

E-mail:

[Redacted E-mail]

Mobile Phone:

[Redacted Mobile Phone]

Key to Assessments:

		<u>Severity</u>				
		INSIGNIFICANT	MINOR	MODERATE	MAJOR	EXTREME
<u>Likelihood</u>	ALMOST CERTAIN	5	10	15	20	25
	LIKELY	4	8	12	16	20
	POSSIBLE	3	6	9	12	15
	UNLIKELY	2	4	6	8	10
	REMOTE	1	2	3	4	5

NHS Contract:

Mr Tom Steele	Director of Estates and Facilities
Mr Alan Gallacher	General Manager
Mr Gary Cullen	Compliance Manager
Mr Darryl Conner	Interim Site Manager Operational Estates QEUH AP(V)
Mr Paul Allen	Estates Manager AP(V)
Mr Jim Guthrie	Estates Manager AP(V)
Mr Cyril Dowson	Coordinating Supervisor AP(V)

Turner Professional Engineering Services:

Mr P Clinton	Coordinating Authorising Engineer
Mr J Minhinnick	Authorising Engineer (Ventilation)
Mrs D Halsey	AE Administrator
File	TIME

SCART Risk Grades	
	Very High
	High
	Medium
	Low

REVIEW OF 2018 ACTION PLAN

Serial	Rating	Reference	Action Required	
1	8	141208/4	CPs should be occasionally monitored when carrying out works and a record of monitoring activities retained in the Documents Register.	All available CPs have been assessed by J Guthrie and works are monitored through the use of a PTW system. Well done closed.
2	9	141208/6	In-house CPs should be trained, assessed and appointed. Certificates of appointment and evidence of training should be retained in the Documents Register.	10 in house CPs are trained assessed and appointed at QEUH with 4 potential CPs to be appointed. Closed.
3	6	141208/8	A CP Register should be produced listing the contractor CPs and should be retained in the Documents Register.	Held in the VDR on SMARTSHEET. T Ramsay and G Bennett should be added to the CP register on SMARTSHEET. Closed.
4	16	141208/9	Plant shutdown/make-safe risk assessments should be produced to identify the hazards associated with taking critical ventilation systems out of use and for work on LEVs that present a hazard to the maintainer. The risk assessments should be retained in the Documents Register.	Risk assessment V/001 "Shutting Down of AHU for Planned Maintenance Tasks" was held dated 17/12/19. Hazardous LEV's are included in the PTW system. Closed.
5	16	141208/10	Ensure task risk assessments are held for all works on ventilation systems. This documentation should be retained or referenced in the Documents Register.	Task risk assessments for maintenance of ventilation AHU are now held for the main areas. This should be developed to include all assets and LEV's. Updated action, closed.
6	12	141208/12	Produce a schedule of ventilation systems to identify all systems as critical, non-critical or LEV in accordance with SHTM 03-01, Part B, Para 4.7. Retain the schedule in the Documents Register.	A comprehensive working schedule of ventilation systems is held and maintained on the shared drive VSDR. Closed.
7	8	141208/18	Display safety signs at the entrance to all plant rooms.	Completed, closed.
8	8	141208/19	Display unique plant room identity signs at the entrance to all plant rooms.	Completed, closed.
9	16	141208/23	Implement a planned maintenance regime for emergency lights fitted in plant rooms. Where DALI systems are installed a formal check of the automatic test results should be carried out.	Planned maintenance is now scheduled on FM First. Closed.

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10	12	141208/37	Carry out annual inspections on the retained estate non-critical ventilation systems in accordance with SHTM 03-01, Part B, Appendix 1.	Completed, closed.
11	20	141208/40	Test fire dampers in accordance with SHTM 03-01, Part B, Para 4.13.	Retained estates have now been surveyed. No progress to date on A&C Hospitals.
12	8	141208/42	Oversee the 14 monthly examinations of LEVs to ensure all the LEVs listed in the schedule of ventilation systems are examined.	All captured LEVs are now listed and subjected to 14m examination and testing. Records are retained in the shared drive VSDR. Closed.
13	20	151209/7	Use permits to work when taking critical systems out of service and when carrying out intrusive maintenance on hazardous LEVs.	Now in place. New action raised. Closed.
14	8	151209/17	Fit access hatches to all AHU intake ductwork sections to allow inspections.	Works progressing as funds/time allows. Approx. 100 fitted in last 12m. Review at next audit.
15	4	151209/18	Fit drainage pipework to the glass drain traps on the retained estate Neurosurgery AHUs.	Completed, closed.
16	8	151209/25	Fit direction of flow labels to the isolation room extract ductwork in the Adult & Children's Plant room 21.	Completed, closed.
17	16	151209/29	Ensure that LEV examinations and tests are carried out on the Mortuary dissection tables every 14 months in accordance with the COSHH Regulations.	Completed, closed.
18	12	161114/8	Inspect the half masks issued to the CPs annually and retain a record of the inspections.	Disposable masks are routinely used and a PPE issued following a toolbox talk in Jan 18. Closed.
19	16	20181212/01	Introduce a true planned maintenance regime for ventilation systems from an agreed maintenance schedule and add to all ventilation assets.	Planned maintenance is now scheduled on FM First. Closed.
20	9	20181212/02	Modify the existing ventilation schedule to include LEV's, ACB's, Split AC's, Cassettes, FCU's etc and add columns for "area served" and "Critical or Non-Critical".	Completed, closed.
21	16	20181212/03	The criticality of all ventilation systems should be reviewed with user groups to positively identify all systems that should be deemed critical.	A ventilation safety group has been set up for QUEH and these topics are now being discussed. As decisions are made the schedule is updated to reflect the changes and maintenance regimes adjusted accordingly. Closed.

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22	9	20181212/ 04	Populate all relevant information into the documents register on SMART sheet.	A comprehensive working documents register is held on the shared drive. A link should be added to SMARTSHEET. Closed.
23	16	20181212/ 05	Split AC's, Cassette Units and FCU's should be subjected to 3m inspections and cleaning.	All assets have been captured and have been cleaned within the last 3m. Contract let with Correct Air Solutions. Closed.
24	16	20181212/ 06	All Active Chilled Beams (ACB's) should be inspected on a 6m basis and cleaned as required.	Chilled beams are now cleaned and inspected every 6m or less depending on location and risk. Closed.
25	12	20181212/ 07	Darryl Conner, Melville MacMillan and Mark McKaig should be assessed and appointed for AP Ventilation duties.	Overtaken by events. New action raised. Closed.

AP Training and Appointments Matrix

AP Name	Darryl Conner	James Guthrie	Mark McKaig	Cyril Dowson	Paul Allen
Status	AP(V) Des	AP(V) Des	AP(V) Des	AP(V)	AP(V) Des
Based at	QEUH	QEUH	QEUH	QEUH	QEUH
Appointment	250/QEUH/V/001	250/QEUH/V/003	250/QEUH/V/002	GG&C-V-16	250/QEUH/V/003
Issue Date				12-Dec-16	
Expiry Date				11-Dec-19	
Sites covered	QEUH Campus	QEUH Campus	QEUH Campus	QEUH Campus	QEUH Campus
Ventilation Training Date	14-Sep-18	14-Sep-18	01-Oct-18	27-Mar-15	01-Nov-14
First Aid Expiry Date	18-Apr-21	15-May-21	13-Feb-19	23-Jun-18	12-Dec-19
Permit-to-work	6	23	0	0	0
Number checked by	1	1	0	0	0

Comments

D Conner, J Guthrie, M McKaig and P Allen should be formally appointed in writing as AP(V) by the designated person.

C Dowson should be re-assessed for continued competency as AP(V).

P Allen and C Dowson should provide evidence of first aid training.

Further work should be done to populate the competences of APs in the documents register on SMARTSHEET.

Due to the size and scale of the systems a QEUH Campus it is recommended that at least 1 AP(V) is trained and appointed on each shift to cover shift work.

REPORT			
Personnel			
Duty Holder	Jane Grant		1
Designated Person	Tom Steele/Alan Gallacher tbc		5
Authorising Engineer	Jamie Minhinnick		1
Authorised Persons	Darryl Conner		5
	Jim Guthrie		5
	Cyril Dowson		5
	Paul Allan		5
	Mark McKaig		5
1. Management Policy			
	Y/N	Comments	
Is there a Board Ventilation Safety Policy In place?	Y	A copy was held on SMARTSHEET. Overdue review as at 23/11/19.	6
Is the Ventilation Safety Policy approved at Board level?	Y	The policy has been reviewed and updated. Pre-approved by the SCART group and awaiting second review for the addition of asbestos guidance.	6
Is the Board Ventilation Safety Policy reviewed periodically?	Y	Overdue review in November 2019.	6
Is the Board Ventilation Safety Policy a controlled Document?	Y	Held securely on SMARTSHEET.	1
Are the Duty Holder (V) responsibilities clearly defined in the Policy?	Y	No significant issues identified.	1
Is the Designated Person appointed in writing?	N	The DP is identified as the Director of Estates and Facilities. No written appointment was available.	6
Does the Board Ventilation Safety Policy include emergency procedures?	N	Emergency procedures are not included. They are incorporated in the re-write.	6
Have the emergency procedures been validated or tested during the current audit period?	N/A	See above.	
Has the Authorising Engineer (AE) (V) appointment been correctly made and is it in date?	Y	No significant issues identified.	1
2. Authorised Persons (V)			
	Y/N	Comments	
Are all APs (V) currently certified?	N	None of the trained and assessed APs have been formally appointed.	10
Are the APs (V) due for refresher training in SHTM 03-01?	N	No issues found.	1
Are the APs (V) due for training in emergency first-aid?	Y	P Allen and C Dowson should provide evidence of first aid training in the VDR.	6
Are the APs (V) carrying out AP (V) duties on a regular basis?	Y	J Guthrie and D Conner are actively involved in writing permits. C Dowson and M McKaig are also involved in ventilation works.	1

Are the APs (V) formally monitoring the work-in-progress and are they recording their observations?	Y	CP work is monitored by APs using the permit to work system.	1
Is the provision of APs (V) adequate?	N	Due to the size and scale of the systems at QEUH Campus it is recommended that at least 1 AP(V) is trained and appointed on each shift to cover shift work.	12
3. Competent Persons (V)			
	Y/N	Comments	
Have the NHS CPs (V) been formally assessed and appointed by an AP (V)?	Y	10 in house CPs have been assessed and appointed in writing by J Guthrie. Records are held on SMARTSHEET.	1
Is evidence of the competency of Contractor CPs (V) held in the Document Register?	N	A boardwide ventilation contractor competence register is held on SMARTSHEET. More work should be done to enhance the information on SMARTSHEET.	6
Are the roles and responsibilities of Contractor CPs (V) defined in writing?	Y	Verification reports produced by H&V and Correct Air Solutions detail the scope of works.	1
Are records held in the Document Register of the site induction for the Contractor CPs (V)?	Y	The GG&C Contractor Control & Permit Register includes the issue of an identity card that listed the fundamental site rules and procedures.	1
Is there an up to date Register of CPs (V) appointed for the Trust included in the Document Register?	Y	A register is held on SMART sheet.	1
Are the NHS CPs (V) carrying out their duties on a regular basis?	Y	In-house CPs and contractor CPs had been carrying out duties on a regular basis.	1
4. Incidents, Accidents and Dangerous Occurrences			
	Y/N	Comments	
Sine the last audit has the site been free from any accidents, incidents, dangerous occurrences or "near misses" in connection with the ventilation systems?	Y	None reported.	1
Have the details of incidents, accidents or dangerous occurrences been properly recorded and reported?	N/A	Not applicable.	
5. Safety Documentation			
Job	2270	Originating AP (V):	J Guthrie
		Y/N	Comments
Was there a suitable & sufficient Risk Assessment to cover the work undertaken?	Y	Risk assessment for the maintenance of Air Handling Equipment in plantroom 21 was held and dated 04/01/19. SOP held for occupied critical area ppm procedure 17/7/19.	1
Was the permit-to-work completed by the AP (V) specifying the work to be carried out?	N	J Guthrie is not yet formally appointed. Isolation time was not agreed.	5
Was the permit-to-work signed by the User (V) to allow the work to proceed?	Y	Signed by A Moyes.	1

Was the permit-to-work issued to a CP (V)?	Y	Issued to T Ramsay who was not appointed at the time but has been since.	4
Was the permit-to-work cleared by a CP (V) and did they state that system was fit or unfit for use?	N	Strike through box not completed.	5
Was the permit-to-work cancelled by an AP (V) and did they acknowledge that the system was fit or unfit for use?	N	Signed but strike through box not completed.	12
Did the User (V) acknowledge that the system should or should not be brought back into use?	Y	Signed by A Moyes.	1
Were the site records up-dated on completion of the work?	Y	Verification documentations were provided within 24 hours.	1
5. Safety Documentation			
Job	2253	Originating AP (V): Y/N	D Connor Comments
Was there a suitable & sufficient Risk Assessment to cover the work undertaken?	Y	Risk assessment for the maintenance of Air Handling Equipment in plantroom 22 was held and dated 04/01/19.	1
Was the permit-to-work completed by the AP (V) specifying the work to be carried out?	N	D Connor is not yet formally appointed. Isolation time was not agreed.	5
Was the permit-to-work signed by the User (V) to allow the work to proceed?	Y	Signed by A Morrison.	1
Was the permit-to-work issued to a CP (V)?	Y	Issued to G Harvey who was not appointed at the time but has been since.	4
Was the permit-to-work cleared by a CP (V) and did they state that system was fit or unfit for use?	N	Strike through box not completed.	5
Was the permit-to-work cancelled by an AP (V) and did they acknowledge that the system was fit or unfit for use?	N	Signed but with errors above not rectified.	8
Did the User (V) acknowledge that the system should or should not be brought back into use?	Y	Signed by A Morrison.	1
Were the site records up-dated on completion of the work?	Y	Verification documentations were provided within 24 hours.	1
6. Operating Records			
General	Y/N	Comments	
Are the ventilation operating record documents kept in a secure location?	Y	There is an electronic VDR held on the SGH shared S drive. Access should be restricted to APs and the compliance team. Each critical system has a hard file log book held securely in the CAP office.	6
Do the APs (V) have access to copies of relevant SHTMs and other reference documents?	Y	An electronic copy was held.	1
Does the Document Register index include all of the subjects required by SHTM 03-01?	Y	A comprehensive file structure is held in the shared drive.	1

Is the working Ventilation Document Register periodically reviewed and out-of-date information transferred to the archive Ventilation Document Register?	Y	The VDR is well maintained by the CAP.	1
Is there a schedule of ventilations systems detailing which are critical, non-critical or LEVs?	Y	Good registers are maintained for critical and non-critical AHU. Information is held for LEVs, split AC's and FCU/chilled beams. These should be collated into a master schedule.	6
Are adequate technical drawings available to the APs?	Y	Technical drawings are held on Zutec. Can be difficult to navigate.	4
Are adequate O&M manuals available to the APs?	Y	O&M information was held electronically (Zutec) and on the shared drive for the Adult & Children's and the Lab Block. Original O&M information for the retained estate maternity theatres was reported to be held.	4
Are all of the ventilation systems included in the Trust's planned maintenance programme?	Y	FM first is now in place to schedule maintenance and hard check sheets are retained in the theatre files.	1
Are the planned maintenance records suitable, sufficient and accessible to the APs?	Y	Maintenance is recorded on FM first and 40 point checks are held in hard copy in each ventilation file.	1
Are the results of the Trust's planned maintenance programme formally reviewed annually to establish trends and gaps? Are these reviews recorded?	N/A	Not checked.	
Inspection and Verification			
	Y/N	Comments	
Are critical ventilation systems being inspected quarterly?	Y	PPM files were held for all critical AHU. Monthly and quarterly checks were retained. RHC Theatre 4 (22 AHU 17) was witnessed as in date.	1
Are non-critical systems being inspected annually?	Y	PPM files were held for all non critical AHU. Monthly and quarterly checks were retained.	1
Are critical ventilation systems being verified annually?	Y	All critical ventilation systems have been verified within the last 12m with the exception of the MRI which is planned for January.	1
Are the inspections and verifications being recorded as per SHTM 03-01, Part B, Appendices 1 & 2 and the records retained in the Ventilation Documents Register?	Y	Good records are now held in the log books in the CAPs office.	1

Are the main components in AHUs serving critical and non-critical areas being cleaned annually?	Y	Records retained with the annual inspections in the log books. 121 AHU 26 was witnessed as last cleaned on 22/11/19.	1
Are the fire dampers being tested annually?	N	Fire dampers were not subject to annual testing in the A&C hospital. All retained buildings have been surveyed and tested this year. Remedial works are now required to complete this area.	20
Are the LEV systems being examined and tested by a competent person at least every 14 months?	Y	All Lab Block safety cabinets and fume cupboards and the Mortuary dissection tables have had COSHH LEV performance tests carried out in the past 14 months. Records were held by Estates. A register of all LEVs should be populated and maintained by the CAP.	6
Are critical systems that are unable to meet the required standards being taken out of service after receipt of condemnatory reports?	Y	All critical AHU's verified in the last 12 months are performing to the required standard. Immediate reports are given to estates before Correct air Solutions leave site allowing problems to be rectified in the shut down period. A process is documented in an SOP.	1
7. Safety Equipment & Access Control			
	Y/N	Comments	
Do the APs (V) have sufficient isolation safety devices for the likely number of concurrent jobs?	Y	Adequate safety devices were held at the hospital.	1
Do the APs (V) have sufficient safety signage for the likely number of concurrent jobs?	Y	Adequate safety signs were held at the hospital.	1
Do the NHS CPs (V) have sufficient safety devices and signs for their routine work?	N/A	Not checked.	
Are records available of annual NHS safety and protective equipment inspections by an AP (V)?	Y	PPE toolbox talk records are held.	1
Do all NHS test instruments have in date calibration certificates?	N	None held	1
Have contractors provided in-date calibration certificates for all of their test instruments and safety equipment?	Y	Copies of calibration certificates were provided for the test instruments used by Correct Air Solutions who carry out annual verifications.	1
Is there an effective and auditable system for the control of plant room access in use?	Y	An access control procedure was held in the document register.	1

8. Engineering Systems			
		Visited Childrens Hospital Plantroom 41A	
Air Handling Units (AHUs)	Y/N	Comments	
Is each AHU clearly and uniquely labelled and does this label exactly correspond to the AHU Register?	Y	Those checked.	1
Is the general condition of each AHU satisfactory?	Y	Those checked.	1
Is the AHU constructed according to the principles in SHTM 03-01, Part A, Figure 1?	Y	Those checked.	1
Are the automatic controls fitted to critical systems capable of being overridden in the event of a software failure?	Y	Those checked.	1
Are fresh air intakes sited correctly, constructed correctly and are access hatches or hinged louvres installed?	N	All AHU in plantroom 41A should have access hatches cut into the intake plenums to facilitate cleaning and inspection.	8
Are drainage systems installed for wet components and are the drainage systems properly constructed?	N	Suitable air breaks should be installed on each drain as they currently terminate at the floor drain in plantroom 41A.	5
Are belt driven fan drives situated outside of the air stream?	N	No issues found.	1
Is there adequate access around the AHU and are access doors provided for all major components?	Y	No issues found.	1
Are inspection windows and internal lights provided for cooling coils and filters?	Y	Those checked.	1
Are the filters the correct grade and correctly fitted to minimise bypass?	Y	No issues found.	1
Are the filters provided with a means of checking the differential pressure across them?	Y	Magnehelic type gauges fitted. These should be fitted with clean/dirty indicators.	6
Is the direction of air flow clearly marked on all main and branch ducts?	Y	Printed identification labels were fitted.	1
Are all air flow test-points properly located, clearly identified and is the size of the duct provided at each point?	N	Not found. These should be located and labelled.	6
9. Engineering work spaces Visited Plant Room 21			
Plant room externals	Y/N	Comments	
Is there a legible and secure safety sign displayed at the entrance to the plant room?	Y	No issues found.	1
Is the name of the plant room exactly the same as the AHU Register?	Y	No issues found.	1
Is the correct contact telephone number shown?	N/A	Not applicable.	

Plant room security		Y/N	Comments	
Is the door soundly made and kept secure?	Y	No issues found.		1
Is there an emergency escape door and can it be opened from the inside?	Y	2 x escapes onto the roof space.		1
Is there a clear escape route outside the plant room?	Y	No issues found.		1
Are adequate emergency communications systems available?	Y	Staff entering plant rooms carry either a mobile telephone or PDA.		1
Is the plant room free from any unauthorised items stored within?	Y	No issues found.		1
If so, are the access arrangements to the plant room adequately controlled?	N/A	Not applicable.		
Plant room structure				
Is the plant room structure and condition satisfactory?	Y	No issues found.		1
Are posters and drawings displayed as required?	Y	No issues found.		1
Fire Precautions		Y/N	Comments	
Is the plant room free from combustion equipment?	Y	No issues found.		1
Is the plant room free from rubbish or fire hazardous materials stored inside or immediately outside the plant room?	Y	No issues found.		1
Is there at least one suitable fire extinguisher provided in the plant room and has it been inspected in the last 12 months?	Y	All fire extinguishers checked were serviced in April 2019. By contract arrangement with interserve.		1

I confirm that, where actions are required, a report has been submitted to the Designated Person	
	Jamie Minhinick
(Signature of AE (V))	(Name)

SCART Risk Grades	
	Very High
	High
	Medium
	Low

UPDATED ACTION PLAN

Serial	Rating	Reference	Action Required	Responsible Person	Date due
Action points carried forward from previous audit					
1	20	141208/40	Test fire dampers in accordance with SHTM 03-01, Part B, Para 4.13.	DP	TBC
2	8	151209/17	Fit access hatches to all AHU intake ductwork sections to allow inspections.	Lead AP	12-Dec-20
Action points from this audit					
3	5	20191218/02	T Ramsay and G Bennet should be added to the CP register on SMARTSHEET.	Compliance Manager	17-Mar-20
4	12	20191218/03	A PTW should be used when taking critical systems out of use at all times. The 29 permits issued since 21/01/19 is not representative of the work carried out.	AP's	NTQ
5	12	20191218/04	Due to the size and scale of the systems a QEUH Campus it is recommended that at least 1 AP(V) is trained and appointed on each shift to cover shift work.	DP	17-Dec-20
6	6	20191218/05	The information held in the shared drive documents register should be linked to SMARTSHEET if possible.	Compliance Manager	17-Mar-20
7	6	20191218/06	The designated person should be appointed in writing by the duty holder.	DP	17-Mar-20
8	6	20191218/07	D Conner, J Guthrie, M McKaig and P Allen should be formally appointed in writing as AP(V) by the designated person.	DP	17-Mar-20
9	6	20191218/08	C Dowson should be re-assessed for continued competency as AP(V).	AE	17-Mar-20
10	6	20191218/09	Further work should be done to populate the competences of APs in the documents register on SMARTSHEET.	Compliance Manager/CAP	17-Jan-20
11	6	20191218/10	P Allen and C Dowson should provide evidence of in date first aid training.	CAP	31-Jan-20
12	6	20191218/11	The updated ventilation systems policy should be ratified and published.	DP	ASAP

13	6	20191218/ 12	Further work should be done to populate the competences of contractors in the documents register on SMARTSHEET (Correct Air Solutions, ATLAS etc).	Compliance Manager/CAP	NTQ
14	12	20191218/ 13	Care should be taken to ensure that permits to work are correctly issued and cancelled. Strike through boxes and signatures were missing in multiple permits.	AP's	NTQ
15	12	20191218/ 14	Risk assessments for maintaining/working on LEV's that present a hazard to the maintainer should be produced.	AP's	17-Mar-20
16	6	20191218/ 15	Access to the electronic VDR should be restricted to APs and the compliance team.	CAP	TBC
17	6	20191218/ 16	A register of all LEV's, split AC's, ACBs and FCU's should be collated and maintained by the CAP.	CAP	17-Jan-20
18	6	20191218/ 17	The ventilation serving the MRI suites should be subjected to annual performance verification.	CAP	28-Feb-20
19	6	20191218/ 18	All magnehelic gauges and manometers should be fitted with clean/dirty filter indication labels.	AP's	17-Dec-20
20	6	20191218/ 19	Care should be taken by CP's when completing 40 point checks. The guidance provided in the CP course notes and SHTM03/01 Pt B should be followed.	CP's	NTQ
21	12	20191218/ 20	The quality of maintenance at the Neurology level 2 roof AHU plant space should be addressed. The following issues should be rectified: 1. The AHU externals should be cleaned, primed and painted to prolong the life and prevent ingress of contamination. 2. The duct flexible connections between AHU sections should be repaired. (This should be surveyed for asbestos). 3. The roof flooring should be cleaned of algae and vegetation below the AHU and around the intakes. 4. The intakes should be cleaned and repaired to remove corrosion. 5. Small areas of internal corrosion should be removed and treated.	AP's	17-Dec-20
22	12	20191218/ 21	Where steam humidification is fitted to AHUs but not used it should be physically disconnected at the AHU and ideally stripped back to the running main.	AP's	17-Jan-20

DP-Designated Person : AE- Authorising Engineer : AP- Authorised Person with Line Management Support

The **Designated Person** should sign this Action Plan to acknowledge the contents. The original copy should then be filed in the Document Register.

Signature: _____

Date: _____

Name: _____

I have the following comments/feedback on this report or the service I have received from Turner Professional Engineering Services:



Hospital

Queen Elizabeth University Hospital (QEUH)
Campus

Satellite Hospitals

Nil

Date(s) of Audit 15-16 Dec 20

Date(s) of Previous Audit 17-18 Dec 19

Site Address

1345 Govan Road,
Glasgow
G51 4TF

Reference 20201216-250-QEUH-V-JM-004

1. Terms of Reference

1.1 This audit was conducted in accordance with the following current reference documents:

- a. Scottish Health Technical Memorandum 00: Policies and principles of healthcare engineering.
- b. Scottish Health Technical Memorandum 03-01: Specialised ventilation for healthcare premises.

2. Executive Summary

2.1 Introduction. The purpose of this audit was to assess the compliance, operation and maintenance of the Safe System of Work at the Hospital(s) in accordance with the discipline specific Health Technical Memoranda, Acts, Regulations and HSE Guidance documents. The resulting Action Plan will be reviewed periodically. The appointments of the discipline specific Authorised Persons were also assessed during the audit.

2.2 Report Summary

Another good year of progress was witnessed at QEUH Campus in terms of management of ventilation. Progress on the action plan was pleasing to see with 9/22 actions completed or in progress.

Some areas that still need to be addressed are as follows:

1. Fire damper testing has not been carried out in the adults and children's hospital. There has been good progress with a survey of the retained estates but the vast proportion are in the A&C.
2. Safety paperwork and 40 point checks are auditable and accountable documents. Care should be taken by both AP's and CP's to ensure they are filled out correctly and in line with guidance.
3. Efforts should continue to have AP(V)'s trained and appointed for each shift to assist in the delivery of the safe system of work.
4. AP's should interrogate 40 point checks for accuracy and ensure issues identified are rectified in a suitable timeframe.

Overall a good audit. Details of new actions are contained within this report.

3. Conclusion

ASSESSMENT OF SAFE SYSTEM OF WORK	CONCLUSION
1. Assessment of the Management Policy.	1
2. Assessment of the Authorised Persons.	1
3. Assessment of the Competent Persons.	1
4. Assessment of Incidents, Accidents and Dangerous Occurrences.	1
5. Assessment of the Safety Documentation.	12
6. Assessment of the Operating Records.	20
7. Assessment of the Safety equipment & Access Control.	1
8. Assessment of the Engineering Systems.	12
9. Assessment of the Engineering Work Spaces.	4

Is the system safe to continue?	Yes, under the guidance of this report.
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4. Next Audit Date

The next audit visit is planned to take place in

December 2021

Signature:

[Redacted Signature]

Date:

16-Dec-20

Name:

Jamie Minhinnick

t/a Turner Professional Engineering Services

Turner Services
65 Craigton Road
Glasgow
G51 3EQ

E-mail:

[Redacted Email Address]

Mobile Phone:

[Redacted Mobile Phone Number]

Key to Assessments:

		Severity				
		INSIGNIFICANT	MINOR	MODERATE	MAJOR	EXTREME
Likelihood	ALMOST CERTAIN	5	10	15	20	25
	LIKELY	4	8	12	16	20
	POSSIBLE	3	6	9	12	15
	UNLIKELY	2	4	6	8	10
	REMOTE	1	2	3	4	5

NHS Contract:

Mr Tom Steele	Director of Estates and Facilities
Mr Jerry Cox	Deputy Director of Estates and Facilities
Mr Alan Gallacher	Head of Corporate Estates
Mr Mark Riddell	Head of Operational Estates
Mr Euan Smith	Assistant Head of Operational Estates QEUH
Mr Dayle McGlinchey	Trainee Compliance Manager
Mr Hugh Brown	Site Manager Operational Estates (Mechanical) AP(V) Designate
Mr Darryl Conner	Site Manager Operational Estates (Electrical) AP(V)
Mr Paul Allen	Estates Manager AP(V)
Mr Jim Guthrie	Estates Manager AP(V)
Mr Mel Macmillan	Estates Manager AP(V)
Mr Mark McKaig	Estates Officer AP(V)

Turner Professional Engineering Services:

Mr P Clinton	Coordinating Authorising Engineer
Mr J Minhinick	Authorising Engineer (Ventilation)
Mrs D Halsey	AE Administrator
File	PES

SCART Risk Grades	
	Very High
	High
	Medium
	Low

REVIEW OF PREVIOUS ACTION PLAN

Serial	Rating	Reference	Action Required	Remarks
1	20	141208/40	Test fire dampers in accordance with SHTM 03-01, Part B, Para 4.13.	Works reportedly progressing but no evidence presented at audit. Review at next audit.
2	8	151209/17	Fit access hatches to all AHU intake ductwork sections to allow inspections.	Works progressing. Not all yet fitted. A plan should be put in place to identify areas still required and a time frame for completion. Review at next audit.
3	5	20191218/02	T Ramsay and G Bennet should be added to the CP register on SMARTSHEET.	Completed and held on the estates shared. Closed.
4	12	20191218/03	A PTW should be used when taking critical systems out of use at all times. The 29 permits issued since 21/01/19 is not representative of the work carried out.	Works progressing with 115 permits issued in the audit period. It is estimated for maintenance there should be circa 400 per annum. Review at next audit.
5	12	20191218/04	Due to the size and scale of the systems a QEUH Campus it is recommended that at least 1 AP(V) is trained and appointed on each shift to cover shift work.	Work in progress with David Smeaton and Grant Bennett going through the assessment process. Review at next audit.
6	6	20191218/05	The information held in the shared drive documents register should be linked to SMARTSHEET if possible.	Work in progress with Lead AP and Compliance Manager.
7	6	20191218/06	The designated person should be appointed in writing by the duty holder.	No progress to date. Review at next audit.
8	6	20191218/07	D Conner, J Guthrie, M McKaig and P Allen should be formally appointed in writing as AP(V) by the designated person.	Completed closed. 5 AP's are now appointed in writing with 1 due imminent appointment and 4 Designate AP's. Well done.
9	6	20191218/08	C Dowson should be re-assessed for continued competency as AP(V).	Overtaken by events. Closed.
10	6	20191218/09	Further work should be done to populate the competences of APs in the documents register on SMARTSHEET.	Works in progress. Review at next audit.
11	6	20191218/10	P Allen and C Dowson should provide evidence of in date first aid training.	Completed. Closed.

12	6	20191218/ 11	The updated ventilation systems policy should be ratified and published.	Completed in Feb 20. Closed.
13	6	20191218/ 12	Further work should be done to populate the competences of contractors in the documents register on SMARTSHEET (Correct Air Solutions, ATLAS etc).	Completed, Closed.
14	12	20191218/ 13	Care should be taken to ensure that permits to work are correctly issued and cancelled. Strike through boxes and signatures were missing in multiple permits.	The standards of permits has improved significantly with most AP's issuing these documents during the audit period. Closed.
15	12	20191218/ 14	Risk assessments for maintaining/working on LEV's that present a hazard to the maintainer should be produced.	A risk assessment is now held on the estates shared drive. Closed.
16	6	20191218/ 15	Access to the electronic VDR should be restricted to APs and the compliance team.	The documents register is the process of being transferred to SMARTSHEET. Review at next audit.
17	6	20191218/ 16	A register of all LEV's, split AC's, ACBs and FCU's should be collated and maintained by the CAP.	Schedules are now held on the shared drive. Closed.
18	6	20191218/ 17	The ventilation serving the MRI suites should be subjected to annual performance verification.	Completed in Jan 20. Closed.
19	6	20191218/ 18	All magnehelic gauges and manometers should be fitted with clean/dirty filter indication labels.	Works in progress. Review at next audit.
20	6	20191218/ 19	Care should be taken by CP's when completing 40 point checks. The guidance provided in the CP course notes and SHTM03/01 Pt B should be followed.	Works in progress. Review at next audit.
21	12	20191218/ 20	The quality of maintenance at the Neurology level 2 roof AHU plant space should be addressed. The following issues should be rectified: 1. The AHU externals should be cleaned, primed and painted to prolong the life and prevent ingress of contamination. 2. The duct flexible connections between AHU sections should be repaired. (This should be surveyed for asbestos). 3. The roof flooring should be cleaned of algae and vegetation below the AHU and around the intakes. 4. The intakes should be cleaned and repaired to remove corrosion. 5. Small areas of internal corrosion should be removed and treated.	The plant in this area has been subjected to upgrades in situ to rectify. Well done. Closed.

22	12	20191218/ 21	Where steam humidification is fitted to AHUs but not used it should be physically disconnected at the AHU and ideally stripped back to the running main.	A survey should be conducted to identify all areas requiring this action. Review at next audit.
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AP Training and Appointments Matrix

AP Name	Darryl Conner	James Guthrie	Mark McKaig	Paul Allen	Melville Macmillan
Status	AP(V)	AP(V)	AP(V)	AP(V)	AP(V)
Based at	QEUH	QEUH	QEUH	QEUH	QEUH
Appointment	250/QEUH/V/001	250/QEUH/V/003	250/QEUH/V/002	250/QEUH/V/004	250/QEUH/V/006
Issue Date	22-Jan-19	03-Dec-18	09-May-19	03-Jul-19	04-Dec-20
Expiry Date	21-Jan-22	02-Dec-21	08-May-22	15-Nov-23	03-Dec-23
Sites covered	QEUH Campus	QEUH Campus	QEUH Campus	QEUH Campus	QEUH Campus
Ventilation Training Date	14-Sep-18	14-Sep-18	01-Oct-18	01-Nov-14	17-Jan-20
First Aid Expiry Date	18-Apr-21	15-May-21	13-Feb-19	10-Nov-23	24-Feb-22
Permit-to-work	0	95	14	0	1
Number checked by	0	1	1	0	0

AP Name	Hugh Brown	Grant Bennett	David Smeaton	Connor Stepney	Scott Macer
Status	AP(V) Des	AP(V) Des	AP(V) Des	AP(V) Des	AP(V) Des
Based at	QEUH	QEUH	QEUH	QEUH	QEUH
Appointment	250/QEUH/V/006	250/QEUH/V/007	250/QEUH/V/008	250/QEUH/V/009	250/QEUH/V/010
Issue Date	not yet	not yet	not yet	not yet	not yet
Expiry Date	not yet	not yet	not yet	not yet	not yet
Sites covered	QEUH Campus	QEUH Campus	QEUH Campus	QEUH Campus	QEUH Campus
Ventilation Training Date	14-Sep-18	17-Jan-20	17-Jan-20	17-Jan-20	Not Yet
First Aid Expiry Date	20-Jun-21	16-Feb-23	16-Feb-23	15-Nov-23	24-Feb-22
Permit-to-work	0	0	0	0	0
Number checked by	0	0	0	0	0

Comments

Due to the size and scale of the systems a QEUH Campus it is recommended that at least 1 AP(V) is trained and appointed on each shift to cover shift work.

REPORT			
Personnel			
Duty Holder	Jane Grant		1
Designated Person	Tom Steele/Alan Gallacher tbc		5
Authorising Engineer	Jamie Minhinnick		1
Authorised Persons	Darryl Conner AP		1
	Jim Guthrie AP		1
	Paul Allan AP		1
	Mark McKaig AP		1
	Hugh Brown AP (Des)		5
	Melville Macmillan		1
	Scott Macer Lead AP (Des)		5
	Grant Bennett AP (Des)		5
	David Smeaton AP (Des)		5
	Connor Stepney AP (Des)		5
1. Management Policy			
	Y/N	Comments	
Is there a Board Ventilation Safety Policy In place?	Y	NHS GG&C Ventilation Policy dated 21/02/20 was held on SMARTSHEET policies.	1
Is the Ventilation Safety Policy approved at Board level?	Y	Approved by the SCART group.	1
Is the Board Ventilation Safety Policy reviewed periodically?	Y	Last reviewed Feb 20.	1
Is the Board Ventilation Safety Policy a controlled Document?	Y	Held securely on SMARTSHEET.	1
Are the Duty Holder (V) responsibilities clearly defined in the Policy?	Y	No significant issues identified.	1
Is the Designated Person appointed in writing?	N	No written appointment was available.	5
Does the Board Ventilation Safety Policy include emergency procedures?	N	Emergency procedures are not included.	5
Have the emergency procedures been validated or tested during the current audit period?	N/A	See above.	
Has the Authorising Engineer (AE) (V) appointment been correctly made and is it in date?	Y	No significant issues identified.	1
2. Authorised Persons (V)			
	Y/N	Comments	
Are all APs (V) currently certified?	Y	5 APs are now appointed with 1 due appointment and 4 AP's designate in training/mentoring.	1
Are the APs (V) due for refresher training in SHTM 03-01?	N	No issues found.	1

Are the APs (V) due for training in emergency first-aid?	N	All appointed AP's were in date for first aid training.	1
Are the APs (V) carrying out AP (V) duties on a regular basis?	Y	Ap's are actively involved in the day to day operational management of ventilation systems at QEUH.	1
Are the APs (V) formally monitoring the work-in-progress and are they recording their observations?	Y	CP work is monitored by APs using the permit to work system.	1
Is the provision of APs (V) adequate?	Y	Once AP's are appointed to cover shift patterns the provision of staff will be adequate.	1
3. Competent Persons (V)			
	Y/N	Comments	
Have the NHS CPs (V) been formally assessed and appointed by an AP (V)?	Y	10 in house CPs have been assessed and appointed in writing by J Guthrie. Records are held on SMARTSHEET and in the shared drive.	1
Is evidence of the competency of Contractor CPs (V) held in the Document Register?	Y	Good evidence was held for Correct Air Solutions, FREWS, H&V and Livingston Mechanical in the estates shared drive.	1
Are the roles and responsibilities of Contractor CPs (V) defined in writing?	Y	Verification reports produced by H&V and Correct Air Solutions detail the scope of works.	1
Are records held in the Document Register of the site induction for the Contractor CPs (V)?	Y	The GG&C Contractor Control & Permit Register includes the issue of an identity card that listed the fundamental site rules and procedures.	1
Is there an up to date Register of CPs (V) appointed for the Trust included in the Document Register?	Y	A register is held on SMART sheet.	1
Are the NHS CPs (V) carrying out their duties on a regular basis?	Y	In-house CPs and contractor CPs had been carrying out duties on a regular basis.	1
4. Incidents, Accidents and Dangerous Occurrences			
	Y/N	Comments	
Sine the last audit has the site been free from any accidents, incidents, dangerous occurrences or "near misses" in connection with the ventilation systems?	Y	None reported.	1
Have the details of incidents, accidents or dangerous occurrences been properly recorded and reported?	N/A	Not applicable.	
5. Safety Documentation			
Job	2112	Originating AP (V):	J Guthrie
		Y/N	Comments
Was there a suitable & sufficient Risk Assessment to cover the work undertaken?	Y	Risk assessment for the maintenance of Air Handling Equipment in plantroom 41 was held and dated 17/12/19. SOP held for occupied cortical area ppm procedure 17/7/19.	1

Was the permit-to-work completed by the AP (V) specifying the work to be carried out?	Y	J Guthrie is formally appointed.	1
Was the permit-to-work signed by the User (V) to allow the work to proceed?	Y	Signed by L Bleasdale.	1
Was the permit-to-work issued to a CP (V)?	Y	Issued to S Gilmour (NHS CP) details are in the shared drive.	1
Was the permit-to-work cleared by a CP (V) and did they state that system was fit or unfit for use?	Y	No issues found.	1
Was the permit-to-work cancelled by an AP (V) and did they acknowledge that the system was fit or unfit for use?	Y	No issues found.	1
Did the User (V) acknowledge that the system should or should not be brought back into use?	Y	Signed by L Bleasdale.	1
Were the site records up-dated on completion of the work?	Y	No issues found.	1
5. Safety Documentation			
Job	2127	Originating AP (V): Y/N	M McKaig Comments
Was there a suitable & sufficient Risk Assessment to cover the work undertaken?	N	No risk assessment by Correct Air Solutions was witnessed.	12
Was the permit-to-work completed by the AP (V) specifying the work to be carried out?	N	Mark McKaig AP is appointed.	1
Was the permit-to-work signed by the User (V) to allow the work to proceed?	Y	Signed by Ian Thomson.	1
Was the permit-to-work issued to a CP (V)?	Y	Signed by Sharon McLaughlan. Correct air solutions. Evidence of competence held in shared drive.	1
Was the permit-to-work cleared by a CP (V) and did they state that system was fit or unfit for use?	Y	No issues found.	1
Was the permit-to-work cancelled by an AP (V) and did they acknowledge that the system was fit or unfit for use?	Y	No issues found.	1
Did the User (V) acknowledge that the system should or should not be brought back into use?	Y	Signed by Ian Thomson.	1
Were the site records up-dated on completion of the work?	Y	Verification documents were provided within 24 hours.	1
6. Operating Records			
General	Y/N	Comments	
Are the ventilation operating record documents kept in a secure location?	Y	There is an electronic VDR held on the shared S drive. Access should be restricted to APs and the compliance team. Each critical system has a hard file log book held securely in the supervisors office.	6

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Do the APs (V) have access to copies of relevant SHTMs and other reference documents?	Y	An electronic copy was held.	1
Does the Document Register index include all of the subjects required by SHTM 03-01?	Y	A comprehensive file structure is held in the shared drive.	1
Is the working Ventilation Document Register periodically reviewed and out-of-date information transferred to the archive Ventilation Document Register?	Y	The VDR is well maintained by the CAP.	1
Is there a schedule of ventilations systems detailing which are critical, non-critical or LEVs?	Y	Good registers are maintained for critical and non-critical AHU. Information is held for LEVs, split AC's and FCU/chilled beams. These should be collated into a master schedule.	6
Are adequate technical drawings available to the APs?	Y	Technical drawings are held on Zutec. Can be difficult to navigate.	4
Are adequate O&M manuals available to the APs?	Y	O&M information was held electronically (Zutec) and on the shared drive for the Adult & Children's and the Lab Block. Original O&M information for the retained estate maternity theatres was reported to be held.	4
Are all of the ventilation systems included in the Trust's planned maintenance programme?	Y	FM first is now in place to schedule maintenance and hard check sheets are retained in the theatre files.	1
Are the planned maintenance records suitable, sufficient and accessible to the APs?	Y	Maintenance is recorded on FM first and 40 point checks are held in hard copy in each ventilation file.	1
Are the results of the Trust's planned maintenance programme formally reviewed annually to establish trends and gaps? Are these reviews recorded?	N/A	Not checked.	
Inspection and Verification			
	Y/N	Comments	
Are critical ventilation systems being inspected quarterly?	Y	PPM files were held for all critical AHU. Monthly and quarterly checks were retained. At the time of audit some filing needs to be completed but on the whole satisfactory.	1
Are non-critical systems being inspected annually?	Y	PPM files were held for all non critical AHU. Monthly and annual checks were retained.	1
Are critical ventilation systems being verified annually?	Y	All identified critical ventilation systems have been verified within the last 12m.	1

Are the inspections and verifications being recorded as per SHTM 03-01, Part B, Appendices 1 & 2 and the records retained in the Ventilation Documents Register?	Y	Good records are now held in the log books in the Supervisors office.	1
Are the main components in AHUs serving critical and non-critical areas being cleaned annually?	Y	Records retained with the annual inspections in the log books.	1
Are the fire dampers being tested annually?	N	Fire dampers were not subject to annual testing in the A&C hospital. All retained buildings have been surveyed and tested this year. Remedial works are now required to complete this area.	20
Are the LEV systems being examined and tested by a competent person at least every 14 months?	Y	All Lab Block safety cabinets and fume cupboards and the Mortuary dissection tables have had COSHH LEV performance tests carried out in the past 14 months. Records were held by Estates. A register of all LEVs was held on the shared drive.	1
Are critical systems that are unable to meet the required standards being taken out of service after receipt of condemnatory reports?	Y	All critical AHU's verified in the last 12 months are performing to the required standard. Immediate reports are given to estates before Correct air Solutions leave site allowing problems to be rectified in the shut down period. A process is documented in an SOP in the shared drive.	1
7. Safety Equipment & Access Control			
	Y/N	Comments	
Do the APs (V) have sufficient isolation safety devices for the likely number of concurrent jobs?	Y	Adequate safety devices were held at the hospital.	1
Do the APs (V) have sufficient safety signage for the likely number of concurrent jobs?	Y	Adequate safety signs were held at the hospital.	1
Do the NHS CPs (V) have sufficient safety devices and signs for their routine work?	N/A	Not checked.	
Are records available of annual NHS safety and protective equipment inspections by an AP (V)?	Y	PPE toolbox talk records are held.	1
Do all NHS test instruments have in date calibration certificates?	N	None held	1
Have contractors provided in-date calibration certificates for all of their test instruments and safety equipment?	Y	Copies of calibration certificates were provided for the test instruments used by Correct Air Solutions who carry out annual verifications.	1
Is there an effective and auditable system for the control of plant room access in use?	Y	An access control procedure was held in the document register.	1

8. Engineering Systems		Visited Maternity Hospital Level 3 Plant Room AHU 9 Serving Theatre 2	
Air Handling Units (AHUs)	Y/N	Comments	
Is each AHU clearly and uniquely labelled and does this label exactly correspond to the AHU Register?	Y	A clear label was affixed to the end of the AHU. Including area served.	1
Is the general condition of each AHU satisfactory?	Y	The general condition of the AHU is assessed as fair to poor.	1
Is the AHU constructed according to the principles in SHTM 03-01, Part A, Figure 1?	Y	The basic fundamentals have been followed.	1
Are the automatic controls fitted to critical systems capable of being overridden in the event of a software failure?	Y	Local control panel with ability to switch to hand. The panel light functions could not be checked.	1
Are fresh air intakes sited correctly, constructed correctly and are access hatches or hinged louvres installed?	N	A fine mesh vermin screen was fitted and completely clogged. Evidence of rain water ingress was witnessed corroding the exhaust ductwork and tracking into the AHU.	12
Are drainage systems installed for wet components and are the drainage systems properly constructed?	N	Insufficient air gaps and dirty traps were observed.	8
Are belt driven fan drives situated outside of the air stream?	N	No issues found.	1
Is there adequate access around the AHU and are access doors provided for all major components?	N	Items of waste material were stacked against the AHU obstructing access to the VSD's.	8
Are inspection windows and internal lights provided for cooling coils and filters?	Y	Those checked.	1
Are the filters the correct grade and correctly fitted to minimise bypass?	N	The pre-filters were showing evidence of failure in situ.	8
Are the filters provided with a means of checking the differential pressure across them?	N	No means provided for the pre-filter.	8
Is the direction of air flow clearly marked on all main and branch ducts?	Y	Printed identification labels were fitted.	1
Are all air flow test-points properly located, clearly identified and is the size of the duct provided at each point?	N	Not found. These should be located and labelled.	6
9. Engineering work spaces Maternity Hospital Level 3 Plant Room			
Plant room externals	Y/N	Comments	
Is there a legible and secure safety sign displayed at the entrance to the plant room?	Y	No issues found.	1

Is the name of the plant room exactly the same as the AHU Register?	Y	No issues found.	1
Is the correct contact telephone number shown?	N/A	Not applicable.	

Plant room security		Y/N	Comments	
Is the door soundly made and kept secure?	Y	No issues found.		1
Is there an emergency escape door and can it be opened from the inside?	Y	No issues found.		1
Is there a clear escape route outside the plant room?	Y	No issues found.		1
Are adequate emergency communications systems available?	Y	Staff entering plant rooms carry either a mobile telephone or PDA.		1
Is the plant room free from any unauthorised items stored within?	N	Waste materials stored within and workshop for Medical Gas repairs.		6
If so, are the access arrangements to the plant room adequately controlled?	N/A	Not applicable.		
Plant room structure				
Is the plant room structure and condition satisfactory?	N	Extract plenums were leaking rainwater.		12
Are posters and drawings displayed as required?	Y	No issues found.		1
Fire Precautions		Y/N	Comments	
Is the plant room free from combustion equipment?	Y	No issues found.		1
Is the plant room free from rubbish or fire hazardous materials stored inside or immediately outside the plant room?	N	Waste timber and scrap material though stored out of escape routes.		6
Is there at least one suitable fire extinguisher provided in the plant room and has it been inspected in the last 12 months?	Y	All fire extinguishers checked were serviced in April 2018.		8

I confirm that, where actions are required, a report has been submitted to the Designated Person	
 _____ (Signature of AE (V))	Jamie Minhinnick _____ (Name)

SCART Risk Grades	
	Very High
	High
	Medium
	Low

UPDATED ACTION PLAN

Serial	Rating	Reference	Action Required	Responsible Person	Date due
Action points carried forward from previous audit					
1	20	141208/40	Test fire dampers in accordance with SHTM 03-01, Part B, Para 4.13.	DP	TBC
2	8	151209/17	Fit access hatches to all AHU intake ductwork sections to allow inspections.	Lead AP	16-Dec-21
3	12	20191218/03	A PTW should be used when taking critical systems out of use at all times. The 110 permits issued since 18/12/19 is not representative of the work carried out.	AP's	NTQ
4	12	20191218/04	Due to the size and scale of the systems a QEUH Campus it is recommended that at least 1 AP(V) is trained and appointed on each shift to cover shift work.	DP	16-Dec-21
5	6	20191218/05	The information held in the shared drive documents register should be linked to SMARTSHEET if possible.	Compliance Manager	16-Mar-21
6	6	20191218/06	The designated person should be appointed in writing by the duty holder.	DP	16-Mar-21
7	6	20191218/09	Further work should be done to populate the competences of APs in the documents register on SMARTSHEET.	Compliance Manager/CAP	16-Mar-21
8	6	20191218/12	Further work should be done to populate the competences of contractors in the documents register on SMARTSHEET (Correct Air Solutions, ATLAS etc).	Compliance Manager/CAP	NTQ
9	12	20191218/13	Care should be taken to ensure that permits to work are correctly issued and cancelled. Strike through boxes and signatures were missing in multiple permits.	AP's	NTQ
10	6	20191218/15	Access to the electronic VDR should be restricted to APs and the compliance team.	AP	16-Mar-21
11	6	20191218/18	All magnehelic gauges and manometers should be fitted with clean/dirty filter indication labels.	AP's	16-Dec-21

12	6	20191218/ 19	Care should be taken by CP's when completing 40 point checks. The guidance provided in the CP course notes and SHTM03/01 Pt B should be followed.	CP's	NTQ
13	12	20191218/ 21	Where steam humidification is fitted to AHUs but not used it should be physically disconnected at the AHU and ideally stripped back to the running main.	AP's	16-Mar-21
Action points from this audit					
14	8	20201216/ 01	The risk assessments for working on ventilation systems should include Covid19 as a hazard and appropriate mitigation included.	AP's	ASAP
15	12	20201216/ 02	The fine mesh vermin screens in the Maternity Hospital Level 3 Plant room should be replaced with appropriate sized (6-12mm) mesh.	AP's	16-Mar-21
16	12	20201216/ 03	The rainwater leaking into AHU 9 exhaust at Maternity Hospital Level 3 Plant room should be investigate and rectified as necessary.	AP's	16-Mar-21
17	8	20201216/ 04	The AHU pre-filters in the Maternity Hospital Level 3 Plant room should be provided with a means to observe the differential pressures.	AP's	16-Jun-21
18	16	20201216/ 05	The services preventing the removal of AHU cooling coil drip trays in the Maternity Hospital Level 3 Plant room should be moved to allow inspection and cleaning of this critical area.	AP's	ASAP
19	8	20201216/ 06	Ap's should ensure contractors provide risk assessments for all works prior to issuing safety paperwork.	AP's	NTQ

DP-Designated Person : AE- Authorising Engineer : AP- Authorised Person with Line Management Support

The **Designated Person** should sign this Action Plan to acknowledge the contents. The original copy should then be filed in the Document Register.

Signature: _____

Date: _____

Name: _____

I have the following comments/feedback on this report or the service I have received from Turner Professional Engineering Services:

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SOP Objective

To ensure that patients are cared for in the appropriate area in order to minimise the risk of cross-infection, and to protect immune compromised patients from environmental infection.

This SOP applies to all staff employed by NHS Greater Glasgow & Clyde and locum staff on fixed term contracts and volunteer staff.

KEY CHANGES FROM THE PREVIOUS VERSION OF THIS GUIDANCE

- Addition 2A RHC and 4B QEUH.

Document Control Summary

Approved by and date	Board Infection Control Committee 21 st February 2024
Date of Publication	28 th February 2024
Developed by	IPCT, Estates and Facilities Management.
Related Documents	National IPC Manual http://www.nipcm.hps.scot.nhs.uk/
Distribution/ Availability	NHSGGC Infection Prevention and Control Internet www.nhsggc.scot/hospitals-services/services-a-to-z/infection-prevention-and-control
Lead Manager	Director of Infection Prevention and Control
Responsible Director	Board Nurse Director and Executive Lead for Infection Prevention and Control.

The most up-to-date version of this guidance can be viewed at the following web page:

This is based on information from clinical team and EFM Colleagues

A48946859 www.nhsggc.scot/hospitals-services/services-a-to-z/infection-prevention-and-control

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1. Responsibilities

Health Care Workers (HCW) must:

- Follow this SOP.
- Follow the advice of the Infection Prevention Control Team (IPCT)
- Escalate to line manager if they are unable to follow this SOP.

Managers must:

- Support HCWs in following this SOP.
- Cascade new policies/SOPs to clinical staff.

Infection Prevention and Control Teams must:

- Keep this SOP up-to-date.
- Provide education opportunities on this SOP.

Facilities / Estates Teams must:

- Carry out verifications on all rooms annually or following any works carried out on the room.
- Keep up-to-date verification records.

The most up-to-date version of this guidance can be viewed at the following web page:

This is based on information from clinical team and EFM Colleagues

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2. General Information on Specialist Ventilation

Across NHS Greater Glasgow and Clyde there are a number of specially ventilated rooms designed to protect patients within the healthcare environment from potentially harmful pathogens. The tables below provide a list of wards and rooms on each of the main hospital sites, indicating the type of ventilation and filtration available in each. This will direct staff to the correct placement of patients who are suspected or confirmed to have an airborne or high consequence infectious disease, as well as airborne protective isolation for immune compromised patients. Below is a description of what each type of ventilation means, while Table 1 should be used to guide staff to the type of patient that can be safely cared for in each.

What is a Positive Pressure Ventilated Lobby (PPVL) Room? (HEPA filtered air)

A PPVL room has a flow of air from the lobby which moves into the main room. The contaminated air is extracted via a vent in the en suite toilet when one is available. In all instances in QEUG and RHC there is an additional extract in variable locations in the ceiling of the patient room. The lobby itself is positively pressurised to both the patient's room and the outer corridor providing a barrier between the patient within the room and the surrounding ward. This movement of air effectively prevents infection spreading between the room and the surrounding ward. Some PPVL rooms have an air supply to the lobby via a filter (HEPA filter) providing some further protection for patients who are immunosuppressed within the room. It is important to keep the door to the main room and to the lobby closed when not in use to ensure that this flow of air is maintained. The pressure on the gauge from corridor to lobby should read +8 to +12 PA.

What is a Negatively Pressured Room?

A negative pressure room has a flow of air which moves from the corridor into the room preventing the escape of room air to the surrounding ward. The ventilation within the room is such that it dilutes any airborne pathogens which are circulating. The room provides a negative air flow / 'cascade' from ward corridor to lobby, and lobby to isolation room, whilst allowing control of room temperature. The room is validated for 10 air changes per hour within an isolation room and a pressure differential of -8Pa to -10Pa in relation to the corridor. It is important to keep the door to the main room and the lobby closed when not in use to ensure that this flow of air is maintained.

What is a Bone Marrow Transplant (BMT) Room?

BMT rooms are reserved for use by those patients who are highly susceptible to infection, for example, those undergoing bone marrow transplant. The air supply to the room is via a filter (HEPA filter) to further provide protection to the vulnerable patient within the room from external airborne pathogens such as fungi. These rooms are currently only located within Ward 2A Children Hospital and also Ward 4B in the QEUG, and are reserved for use by BMT patients.

The most up-to-date version of this guidance can be viewed at the following web page:

This is based on information from clinical team and EFM Colleagues

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3. Room Types

Type of Room	Patient allocation / suitability
PPVL with Lobby HEPA	Immunosuppressed patients, i.e. Haem-onc patients, should be prioritised for these rooms
	Immunosuppressed with chickenpox / measles
	Patients with Atypical Mycobacteria
	Patients with infections (non-airborne route)
Negative pressure	Chickenpox, Measles, Pathogens of High Consequence
	Tuberculosis (incl MDRTB and XDRTB) Prioritise airborne infection
BMT Rooms	Bone Marrow Transplant patients These are located in specialist units: QEUH 4B RHC 2A

The most up-to-date version of this guidance can be viewed at the following web page:

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4. Signage

Patient bedrooms with specialist ventilation will have a sign at the door indicating the specific ventilation afforded by that particular room. The signs will be one of the following (QEUH):

Negative Pressure Isolation Room

Pressure gauge should be between
-8Pa & -12Pa

If the positive side of the gauge is out of range please contact estates department
Help desk 5555

HEPA FILTERED PPVL Isolation Room

Pressure gauge should be between
+8Pa & +12Pa

If the positive side of the gauge is out of range please contact estates department
Help desk 5555

These templates only and should be modified for local use.

The most up-to-date version of this guidance can be viewed at the following web page:

This is based on information from clinical team and EFM Colleagues

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Table 1. Special Ventilation Rooms – Royal Hospital for Children (RHC)

Location	Room Number	Type of Room	HEPA filter (Lobby supply)	Type of Patient	Comment	En suite Y/N
CDU	17	PPVL	Yes	Prioritise immunosuppressed		Y
CDU	18	Negative Pressure	Yes	Not immunosuppressed	Varicella Zoster, TB, VHF, MERS, Respiratory illnesses	Y
1D	5	Negative Pressure	Yes	Not immunosuppressed	Varicella Zoster, TB, VHF, MERS, Respiratory illnesses	N
1D	12	PPVL	Yes	Prioritise immunosuppressed		N
1D	17	PPVL	Yes	Prioritise immunosuppressed		N
1D	18	PPVL	Yes	Prioritise immunosuppressed		N
1E	13	PPVL	Yes	Prioritise immunosuppressed		Y
1E	14	PPVL	Yes	Prioritise immunosuppressed		Y
2C	5	PPVL	Yes	Prioritise immunosuppressed		Y
2C	6	Negative Pressure	Yes	Not immunosuppressed	Varicella Zoster, TB, VHF, MERS, Respiratory illnesses	Y
3A	15	PPVL	Yes	Prioritise immunosuppressed		Y
3A	16	PPVL	Yes	Prioritise immunosuppressed		Y
3B	19	PPVL	Yes	Prioritise immunosuppressed		Y
3B	5	PPVL	Yes	Prioritise immunosuppressed		Y
3C	9	PPVL	Yes	Prioritise Immunosuppressed		Y
3C	10	PPVL	Yes	Prioritise Immunosuppressed		Y

The most up-to-date version of this guidance can be viewed at the following web page:

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Table 2. Special Ventilation Rooms – Adult Queen Elizabeth University Hospital (QEUH)

Location	Room Number	Type of Room	HEPA filter (Lobby Supply)	Type of Patient	Comment	En suite Y/N
HDU UNIT 1	3	PPVL	Yes	Prioritise Immunosuppressed		Y
HDU UNIT 1	4	Negative Pressure	Yes	Not immunosuppressed	Varicella Zoster, TB, VHF, MERS, Respiratory illnesses	Y
HDU UNIT 2	11	PPVL	Yes	Prioritise Immunosuppressed		Y
ICU UNIT 3	23	PPVL	Yes			N
ICU UNIT 3	24	Negative Pressure	Yes	Not immunosuppressed	Varicella Zoster, TB, VHF, MERS, Respiratory illnesses	N
ICU UNIT 4	31	PPVL	Yes			N
ICU UNIT 4	40	PPVL	Yes			N
ICU UNIT 5	43	Negative Pressure	Yes	Not immunosuppressed	Varicella Zoster, TB, VHF, MERS, Respiratory illnesses	Y
ICU UNIT 5	44	Negative Pressure	Yes	Not immunosuppressed	Varicella Zoster, TB, VHF, MERS, Respiratory illnesses	Y
HDU UNIT 6	50	PPVL	Yes	Prioritise Immunosuppressed		Y

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Table 3. Special Ventilation Rooms – Royal Alexandra Hospital (RAH)

Location	Room Number	Type of Room	HEPA Filter (Lobby Supply)	Type of Patient	Comment	En suite Y/N
ICU	2	Negative Pressure	No	Not immunosuppressed	Varicella Zoster, TB, VHF, MERS, Respiratory illnesses	N
ICU	5	Negative Pressure	No	Not immunosuppressed	Varicella Zoster, TB, VHF, MERS, Respiratory illnesses	N

Please note there are no negative pressure isolation rooms in either Vale of Leven Hospital or Inverclyde Royal Hospital.

Table 4. Special Ventilation Rooms – Glasgow Royal Infirmary (GRI)

Location (Wards)	Room Number	Type of Room	HEPA Filter (Lobby Supply)	Type of Patient	Comment	En suite Y/N
6	3/25	Negative Pressure	No	Not immunosuppressed	Varicella Zoster, TB, VHF, MERS, Respiratory illnesses	Y
6	3/39	Negative Pressure	No	Not immunosuppressed	Varicella Zoster, TB, VHF, MERS, Respiratory illnesses	Y
7	3/52	Negative Pressure	No	Not immunosuppressed	Varicella Zoster, TB, VHF, MERS, Respiratory illnesses	Y
16	3/31	Negative Pressure	No	Not immunosuppressed	Varicella Zoster, TB, VHF, MERS, Respiratory illnesses	Y

NB - In ITU due to the variability of different types of isolation facilities any patients who require source or protective isolation will be discussed with IPCT to ascertain isolation priority and placement.

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This is based on information from clinical team and EFM Colleagues

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Table 5. Bone Marrow Transplant (BMT) Rooms – Royal Hospital for Children (RHC)

Location	Room Number	Type of Room	HEPA filter (Lobby supply)	Type of Patient	En suite Y/N
2A	2	HEPA Filtered PPIR	N	Immunosuppressed	Y
2A	3	HEPA Filtered PPIR	SHARED	Immunosuppressed	Y
2A	4	HEPA Filtered PPIR	SHARED	Immunosuppressed	Y
2A	5	HEPA Filtered PPIR	SHARED	Immunosuppressed	Y
2A	6	HEPA Filtered PPIR	SHARED	Immunosuppressed	Y
2A	7	HEPA Filtered PPIR	N	Immunosuppressed	Y
2A	8	HEPA Filtered PPIR	N	Immunosuppressed	Y
2A	9	HEPA Filtered PPIR	N	Immunosuppressed	Y
2A	10	HEPA Filtered PPIR	N	Immunosuppressed	Y
2A	11	HEPA Filtered PPIR	N	Immunosuppressed	Y
2A	12	HEPA Filtered PPIR	N	Immunosuppressed	Y

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Location	Room Number	Type of Room	HEPA filter (Lobby supply)	Type of Patient	En suite Y/N
2A	14	HEPA Filtered PPIR	N	Immunosuppressed	Y
2A	15	HEPA Filtered PPIR	N	Immunosuppressed	Y
2A	16	HEPA Filtered PPIR	N	Immunosuppressed	Y
2A	17	HEPA Filtered PPIR	Y	BMT	Y
2A	18	HEPA Filtered PPIR	Y	BMT	Y
2A	19	HEPA Filtered PPIR	Y	BMT	Y
2A	20	HEPA Filtered PPIR	Y	BMT	Y
2A	21	HEPA Filtered MIBG	-	-	Y
2A	22	HEPA Filtered PPVL	Y	Immunosuppressed	Y
2A	23	HEPA Filtered NPVL	Y	Immunosuppressed	Y
2A	24	HEPA Filtered PPVL	Y	Immunosuppressed	Y
2A	25	HEPA Filtered PPVL	Y	Immunosuppressed	Y

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Table 6. Bone Marrow Transplant (BMT) Rooms – Adult Queen Elizabeth University Hospital (QEUH)

Location	Room Number	Type of Room	HEPA filter	Type of Patient	En suite Y/N
4B	All Rooms	Positive Pressure	Y	Immunosuppressed	Y

The most up-to-date version of this guidance can be viewed at the following web page:
This is based on information from clinical team and EFM Colleagues
www.nhsggc.scot/hospitals-services/services-a-to-z/infection-prevention-and-control

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5. Definition of immunosuppressed/Immunocompromised

NIPCM definition is “Any person whose immune response is reduced or deficient, usually because they have a disease or are undergoing treatment. People who are immunocompromised are more vulnerable to infection”.

6. Evidence Base

<http://www.nipcm.hps.scot.nhs.uk/>

The most up-to-date version of this guidance can be viewed at the following web page:

This is based on information from clinical team and EFM Colleagues

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The most up-to-date version of this guidance can be viewed at the following web page: www.nhsggc.scot/hospitals-services/services-a-to-z/infection-prevention-and-control			

Guidance Objective

To ensure that patients suspected of or confirmed to have tuberculosis are diagnosed and treated promptly and their contacts followed-up to minimise the risk of cross-infection and identify further cases.

This guidance applies to all staff employed by NHS Greater Glasgow & Clyde and locum staff on fixed term contracts and volunteer staff.

KEY CHANGES FROM THE PREVIOUS VERSION OF THIS GUIDANCE

- Updated definition of XDR-TB
- Minor wording changes
- Updated references and links

Approved by and date	Board Infection Control Committee 22 nd June 2021
Date of Publication	25 th June 2021
Developed by	Infection Prevention and Control Policy Sub-Group
Related Documents	National Infection Control Manual NHSGGC Hand Hygiene Guidance
Distribution/ Availability	NHSGGC Infection Prevention and Control web page: www.nhsggc.scot/hospitals-services/services-a-to-z/infection-prevention-and-control
Lead Manager	Director Infection Prevention and Control
Responsible Director	Executive Director of Nursing

The most up-to-date version of this guidance can be viewed at the following web page:
www.nhsggc.scot/hospitals-services/services-a-to-z/infection-prevention-and-control

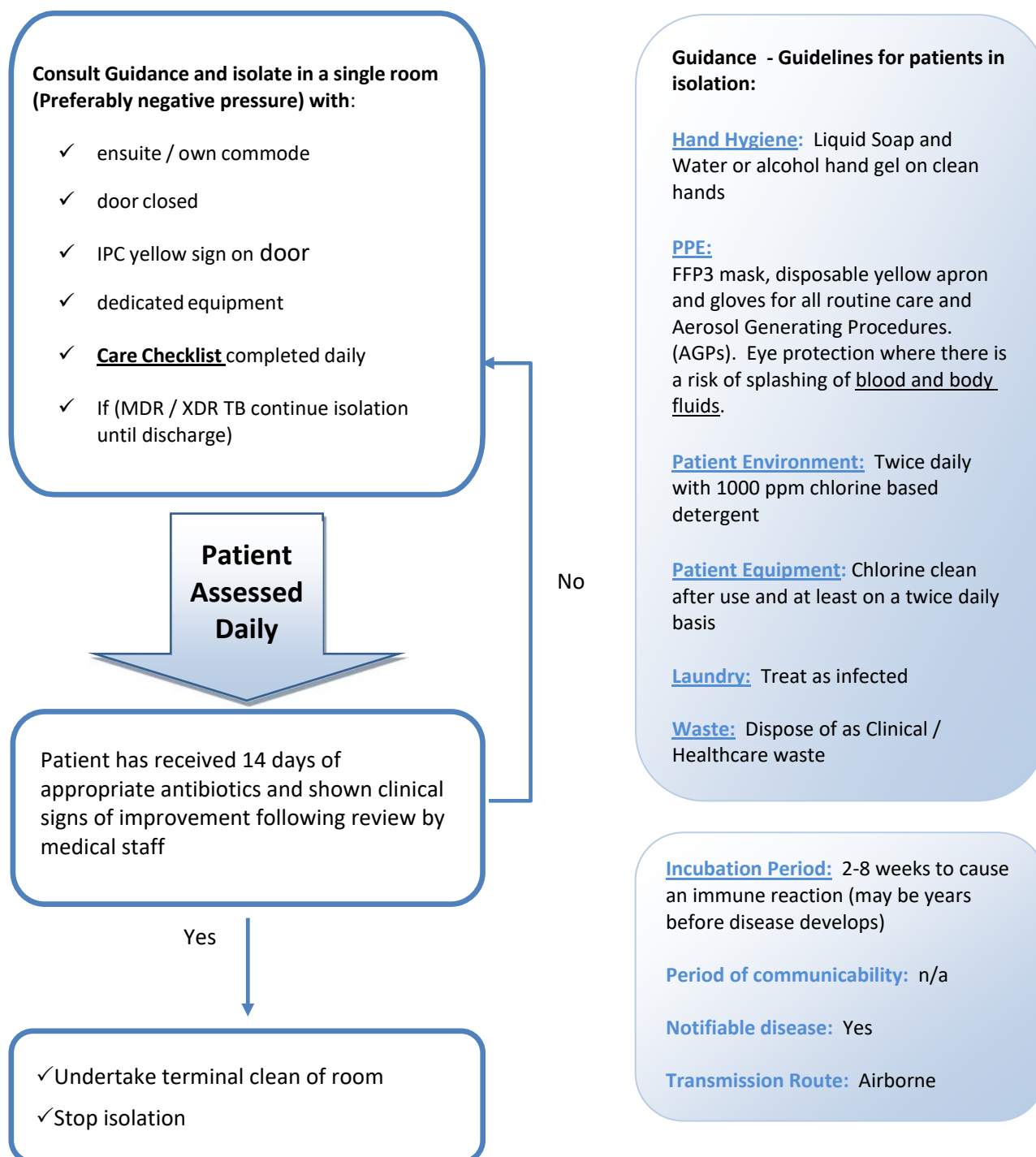
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Pulmonary TB Aide Memoire



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1. Responsibilities

Healthcare Workers (HCWs) must:

- Follow this guidance.
- Wear Personal Protective Equipment (PPE) and respiratory protection if advised to do so.
- Inform a member of the Infection Prevention Control Team (IPCT) if this policy cannot be followed.

Managers must:

- Ensure HCWs have access to this guidance.
- Support HCWs and IPCTs in following this guidance.
- Ensure HCWs are aware how to use respiratory protection and have access to effective equipment and are fit tested.

Infection Prevention and Control Teams (IPCTs) must:

- Keep this guidance up-to-date.
- Provide education opportunities on this policy.
- Take the lead role in conjunction with the ward manager, consultant in charge and microbiologist to identify In-patients who have had sufficient exposure to the index case to merit screening.
- If HCW unable to follow this guidance, IPCT will support staff to carry out a risk assessment

Clinicians must:

- Notify Public Health of any newly diagnosed patient.
- Notify the TB Liaison Nurse of any newly diagnosed patients.
- Assess inpatient contacts of smear positive patients and liaise with GP and TB liaison

TB Liaison Nurse:

- Liaise with Clinicians, Infection Prevention and Control and CPHM.
- Identify community contacts promptly and arrange appropriate screening.
- Take a leading role in advising and informing the patient and the patient's contacts in the community for the duration of therapy.
- Liaise with Occupational Health regarding the provision of information and advice to staff exposed to a patient with smear/ sputum positive TB.

Occupational Health:

- Take the lead role in identifying, advising and informing staff exposed to a patient with smear positive pulmonary TB and arrange appropriate screening as required.

The most up-to-date version of this guidance can be viewed at the following web page:

www.nhsggc.scot/hospitals-services/services-a-to-z/infection-prevention-and-control

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2. General Information on Tuberculosis

Communicable Disease/ Alert Organism	Tuberculosis is a disease caused by infection with the <i>Mycobacterium tuberculosis</i> complex of organisms (<i>M. tuberculosis</i> , <i>M. Bovis</i> , <i>M. Africanum</i> and <i>M. Micoti</i>) which may cause pulmonary and/ or non- pulmonary tuberculosis.
Clinical Condition(s)	Pulmonary and laryngeal TB both require the respiratory precautions set out in this guidance. From this point both these forms of TB will be referred to as pulmonary TB For respiratory granuloma without cavity standard infection control precautions are recommended.
Definitions	<u>TB Infection</u> : defined as the bacteria having caused an immune reaction with no evidence of disease. <u>TB Disease</u> : the patient has symptoms or clinical evidence of disease. Sputum smear positive = infectious Sputum smear negative = low infectivity risk
Mode of Spread	Airborne: The infectious particles are very small droplets (1-5µ) containing tubercle bacilli expelled during talking, singing but especially coughing, and inhaled by susceptible individuals.
Incubation period	2-8 weeks to cause an immune reaction. May be many years before disease develops.
Notifiable disease	Yes. It is the clinician's responsibility to notify the Public Health Protection Unit (PHPU), Gartnavel Royal Hospital (West House, 1055 Great Western Road, Glasgow G12 0XH. Notification may also be by the Pathologist. NB notification (not confirmed) is on suspicion – usually considered to be equivalent to initiation of therapy. Telephone PHPU - 0141 201 4917 (64917)
Persons most at Risk	- Individuals whose cumulative exposure time is more than 8 hours to a sputum smear positive patient. - Those who have immunodeficiency for any reason.

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3. Transmission Based Precautions

Accommodation	• Suspected TB: single-room is required for all patients thought to have pulmonary tuberculosis until the patient has 3 smear negative sputum/bronchial alveolar lavage specimens or in the case of a child, negative gastric washings. • Sputum smear positive TB: if possible, place patient in a negative pressure single room (where available) until 14 days of appropriate tolerated drug treatment and there is definite clinical improvement on treatment; for example, absence of cough, remaining afebrile for a week The patient may be discharged before the 14 days. • Confirmed Multi-Drug Resistant TB: negative pressure in a single room with an en suite is mandatory for those patients with, or suspected of having pulmonary multi-drug resistant (MDR-TB, XDR-TB) until discharge from hospital. Patients who have had sputum smear positive TB and have had 14 days adequate therapy and are improved must not on release from isolation be placed next to HIV positive or other immunocompromised patients, if remaining in hospital. Where possible they should be on a separate ward from such patients. If the patient is clinically unsuitable to be placed in a single room or door cannot remain closed, a risk assessment must be undertaken by the clinical team. The risk assessment should be documented and reviewed daily. • If XDR TB/MDR TB, isolations should continue until discharge.
Care Checklist available	Yes.
Clinical / Healthcare Waste	Waste should be designated as clinical/ healthcare waste and placed In an orange bag. Please refer to the NHSGCC Waste Management Policy .

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Contact tracing	The TB Liaison Nurse will assess all community contacts of the patient. Working with the TB Liaison Nurse, the IPCT, microbiologist and senior ward staff will assess if any other patients have had sufficient exposure during the patient stay (>8hours close contact with a sputum smear positive patient). In paediatrics resident parents/guardians must be assessed. For hospital patient contacts, the clinician in charge of the patient must ensure follow up with the patients either via their GP or with the assistance of the HPN/TB liaison. Any hospital patient contacts will also be informed of any relevant subsequent action. The Immediate Discharge Letter must be completed at the time of discharge and include details of planned screening and follow up after discussion with the TB liaison nurse.(8 weeks after exposure)
Discharge Planning	A treatment plan and follow up must be arranged prior to discharge and discussed with TB liaison and any relevant carers. Arrangements must be in place for accommodation, necessary support, and supervision of therapy. It is important to communicate the infectious status of the patient to clinical teams and precautions required when arranging follow up clinic or community visits. If the patient self-discharges or absconds from the ward and is still considered to be an infection risk contact the CPHM via 0141 201 4917 (64917). The TB Liaison nurse should also be informed
Drug Resistance	All patients with, or suspected of having TB must be assessed for risk of drug resistance by a respiratory /ID consultant. This is done by identifying on admission if the patient has had: • previous treatment for tuberculosis, • previous history of poor compliance with TB treatment • contact with a person with known drug resistant disease • History of travel to a country with high risk of MDR TB http://www.who.int/tb/publications/global_report/en/ Discuss with microbiology about rapid molecular testing and fast track of samples to the TB reference lab and during therapy monitoring for: • Failure of clinical response, e.g. temperature remains elevated after 4 months. If the patient is suspected of having MDRTB then until confirmed otherwise the procedures for multi-drug resistance will be followed.

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	MDR TB - TB that is resistant to at least isoniazid and rifampicin XDR TB - TB caused by M. tuberculosis strains that fulfil the definition of MDR/Rifampicin Resistant-TB and which are also resistant to any fluoroquinolone and at least one additional group A drug. Group A drugs are the most potent group of drugs in the ranking of second-line medicines for the treatment of drug-resistant forms of TB, using longer treatment regimens and comprise levofloxacin, moxifloxacin, bedaquiline and linezolid.
Equipment	No special requirements provided equipment is decontaminated as per NHSGGC Decontamination Guidance .
Exposures	The primary measure to reduce exposure in healthcare settings are; early diagnosis, early isolation, appropriate application of TBPs and early commencement of appropriate therapy. All HCWs who have been involved in the care of a sputum smear positive patient with pulmonary Tuberculosis prior to infection control precautions being instigated who have had 8 or more hours close contact with the index case, or who are immunocompromised will be referred to the Occupational Health Service (OHS).
Hand Hygiene	See NHSGGC Hand Hygiene Guidance
Last Offices	Special precautions are required for Last Offices. See National Guidance for Last Offices .
Moving between wards, hospitals and departments (including theatres)	If possible avoid unnecessary movement of patient until therapy has been established. If movement is necessary, for smear positive adult patients within the first 14 days of therapy, ask the patient to wear a fluid repellent surgical mask. Notify the receiving department.
Notice for Door	Yes, if patient is isolated a yellow IPC sign should be placed on door. NB Keep door closed until restrictions are lifted.
Outbreak	Unlikely in hospital settings provided infection control precautions are followed.
Patient Clothing	No special requirements. Advise relatives that there is no risk from washing the patient's clothes at home. See NHSGGC Washing Clothes at Home Leaflet

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Personal Protective Equipment (PPE)	HCWs caring for patients with suspected of or confirmed (sputum smear positive) tuberculosis, a yellow disposable apron, disposable gloves and a face fit tested FFP3 mask must be worn for both routine care and when undertaking aerosol generating procedures (AGP's) Where there is an identified risk of splashing of blood and or body fluids into the mucous membranes of the eyes, suitable eye protection must also be worn. All PPE should be kept on for up to 2 hours after an AGP if remaining in the patient's room, and the FFP3 mask should be removed outside the room. Once the patient has had 14 days of treatment and shown signs of clinical improvement following review by medical staff and a risk assessment carried out, PPE can be discontinued. For full list of AGPs see Appendix 11 NIPCM Footnote 3 https://hpspubsrepo.blob.core.windows.net/hps-website/nss/3032/documents/1_nipcm-appendix-11.pdf For PPE information: https://hpspubsrepo.blob.core.windows.net/hps-website/nss/3037/documents/1_nipcm-appendix-16.pdf For suspected and confirmed MDR TB/ XDRTB: PPE should be worn as above. https://www.nhsggc.org.uk/working-with-us/hr-connect/health-safety/policies-guidance-documents-forms/personal-protective-equipment/respiratory-protection-equipment-ffp3-masks/
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Precautions Required Until	Sputum Smear positive not MDR TB / XDR TB: • had a minimum of 14 days appropriate therapy, which has been tolerated e.g. no diarrhoea or vomiting and patient has been fully compliant • Definite clinical improvement as a response to therapy, e.g. cessation of cough Seek the advice of a member of the IPCT before removing a patient from isolation. Once removed from isolation keep the patient under review. Return to isolation if they deteriorate clinically. Pulmonary MDR TB: For duration of stay Pulmonary XDR TB: For duration of stay Discuss all cases of MDR or XDR TB with infection specialist / ICD. Smear negative / Suspected TB: Three separately taken microscopy sputum smears /gastric washings. (ideally early morning and taken on consecutive days). Samples should be sent for both <u>smear</u> and <u>culture</u> Extra-pulmonary TB: Pulmonary disease must be excluded before transmission based precautions are stopped. Unless TB lesions draining, in which case SICPs should be followed.
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Procedure Restrictions	- Sputum and cough inducing procedures should be undertaken by HCWs wearing full PPE as above in a single / negatively-pressurised room with the door closed. HCW should continue to wear their PPE for up to 2 hours following an AGP. Each area will differ depending on air exchanges. Discuss with ICD if not known. - Patient procedures to reduce aerosolisation of droplet nuclei: patients should be taught to cover both the nose and mouth with a tissue whenever they cough or sneeze; - In-patients should be asked to wear fluid repellent surgical masks if they are required to leave their room, until they have had 14 days of appropriate tolerated drug treatment and shown clinical improvement. - Bronchoscopy's in those suspected of Pulmonary TB should be done last with adequate ventilation as above. Bronchoscopy suites managers should be aware of the number of air exchanges and the duration of time required before staff and other patients can re-enter the area.
Referral	All patients suspected of having TB should be referred to a Respiratory Physician or Infectious Diseases Physician before commencing TB treatment. Microbiologist to inform the clinician by telephone of positive smear results.
Risk assessment	- For patients with extra-pulmonary disease the transmission based precautions in this guidance must be followed until pulmonary involvement can be ruled out. - Young children are broadly considered to be paucibacillary and unlikely to be of high infectivity risk. TBP in paediatric inpatients will require a case by case risk assessment.
Screening on Admission	Pulmonary tuberculosis should be considered in any patient with an unexplained cough lasting more than three weeks, with or without weight loss, anorexia, fever, night sweats or haemoptysis. They should usually have three separate sputum samples sent to the laboratory and a chest X-Ray. These specimens should be marked 'URGENT' and AAFB requested in addition to culture. Patients whose history is indicative of pulmonary tuberculosis on admission should be isolated as stated in the <i>Accommodation</i> section.
Terminal Cleaning of Room	Follow NHSGGC SOP Terminal Clean of Ward/Isolation Room

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Visitors	Restrict visitors to contacts who have visited the patient prior to hospitalisation until 14 days after therapy has commenced and tolerated. Children should not be allowed to visit unless exceptional circumstances. Visitors who do not fit the criteria of household contacts should not visit unless under exceptional circumstances when consideration of fit testing should be undertaken. Paediatric patients: It is important to make sure that parents/carers are not themselves infectious with Tb before allowing them to visit/stay in hospital with the child. In the case of suspected or proven pulmonary MDR or XDR TB a plan for visiting should be discussed with the local IPCT in the first instance. If visitors are unwell or have symptoms of TB, they should not visit until assessed by the TB liaison nurse. Those who are immunocompromised should not visit. Visitors should only visit the patient with TB and not other patients.
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4. Evidence Base

Immunisation against infectious disease 'Green Book' Department of Health.
<https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book>

HPS (2020) Transmission Based Precautions Literature Review: Respiratory Protective Equipment (RPE)

https://hpspubsrepo.blob.core.windows.net/hps-website/nss/1722/documents/1_tbp-lr-rpe-v4.0.pdf

NICE Guidance (NG 33) 2016 Updated September 2019

<https://www.nice.org.uk/guidance/ng33>

WHO 2021 Updated definition of XDR-TB
<https://www.who.int/news/item/27-01-2021-who-announces-updated-definitions-of-extensively-drug-resistant-tuberculosis>

Appendix 11 National Infection Prevention and Control Manual
[National Infection Prevention and Control Manual: Appendix 11 - Best Practice - Aide Memoire for Optimal Patient Placement and Respiratory Protective Equipment \(RPE\) for Infectious agents whilst a patient is in hospital](#)

The most up-to-date version of this guidance can be viewed at the following web page:
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5. List of AGPs

Aerosol Generating Procedures	During certain healthcare procedures, small particle aerosols may be generated which could increase the risks to HCWs in the immediate vicinity. These aerosol generating procedures include: • Intubation, extubation and related procedures, e.g. manual ventilation and open suctioning. • Cardiopulmonary resuscitation. • Induction of sputum • Bronchoscopy. • Positive pressure ventilation via face mask, e.g. BiPAP, CPAP • High frequency oscillating ventilation • Some Dental procedures (e.g. drilling) • Surgery and post mortem procedures in which high speed devices are used • High flow nasal oxygen
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SOP Objective

To provide Healthcare Workers (HCW) with details of the care required to prevent cross-infection in adult patients with known/suspected *Clostridioides difficile* Infection (CDI).

This SOP applies to all staff employed by NHS Greater Glasgow & Clyde and locum staff on fixed term contracts and volunteer staff.

KEY CHANGES FROM THE PREVIOUS VERSION OF THIS SOP

- Updates to wording Section 3. Daily assessment of Severity by Clinical Team

Document Control Summary

Approved by and date	Board Infection Control Committee 17 th February 2022
Date of Publication	28 th February 2022
Developed by	Infection Prevention and Control Policy Sub-Group
Related Documents	National Infection Prevention and Control Manual: Home NHSGGC CDI Paediatrics SOP NHSGGC Cleaning of Near Patient Equipment SOP NHSGGC Terminal Clean of Ward/Isolation Rooms SOP NHSGGC Twice daily Clean of Isolation Rooms SOP Antimicrobial Prescribing Policies
Distribution/ Availability	NHSGGC Infection Prevention and Control Web Page: www.nhsggc.scot/hospitals-services/services-a-to-z/infection-prevention-and-control
Lead Manager	Director Infection Prevention and Control
Responsible Director	Executive Director of Nursing

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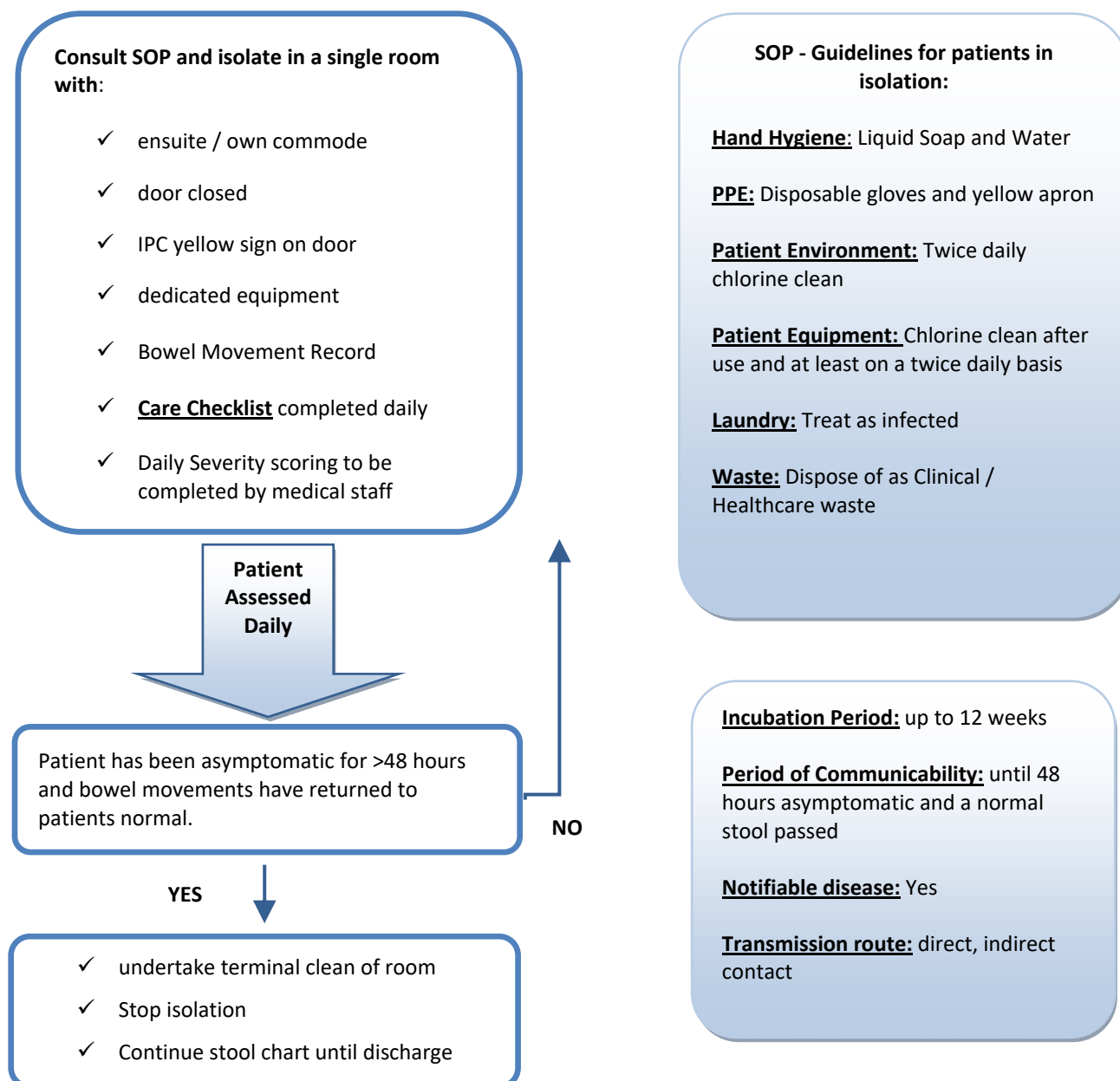
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CDI Aide Memoire



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1. Responsibilities

Healthcare Workers (HCWs) must:

- Follow this SOP.
Commence a CDI Care Checklist while patient is symptomatic, update daily and complete the risk assessment for any aspect of transmission based precautions (TBP) for CDI that cannot be implemented

[Clostridioides Difficile – IPC Care checklist](#)

- Inform their line manager and a member of the Infection Prevention and Control Team if this SOP cannot be followed.
- Provide written and verbal information on CDI for patients and their relatives as appropriate

[Clostridioides Difficile Fact Sheet](#)

Senior Charge Nurse (SCN) must:

- Ensure that the IPC Care checklist is in place while patient is deemed infectious.
- Ensure that written information is provided / available for patients and relatives.
- Ensure a failure to isolate risk assessment is in place if any aspect of TBPs for CDI cannot be implemented

Managers must:

- Support HCWs and IPCTs in following this SOP.
- Cascade new SOPs to clinical staff after approval by the Board Infection Control Committee (BICC).

Infection Prevention and Control Teams (IPCTs) must:

- Keep this SOP up-to-date.
- Provide education opportunities on this SOP.

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- Monitor epidemiology of *Clostridioides difficile* Infection (CDI) within healthcare facility(ies) and advise on infection prevention and control precautions as necessary.
- Advise and support HCWs to undertake a Risk Assessment if unable to follow this SOP.

Occupational Health Service (OHS) must:

- Advise HCW regarding possible infection exposure and return to work issues as necessary

2. General Information on *Clostridioides difficile* Infection (CDI)

Communicable Disease/ Alert Organism	<i>C. difficile</i> is a Gram positive, anaerobic, spore-forming organism implicated in CDI and pseudomembranous colitis (PMC). The overgrowth of the organism within the large intestine and toxin production causes cellular damage and increased fluid accumulation in the gut. <i>C. difficile</i> is part of the normal flora of up to 3% of the adult population and up to 90% of children less than 2 years. Asymptomatic carriage in healthcare patients is relatively common.
Case definition	<i>Clostridioides difficile</i> Infection (CDI) is defined as any patient in whose stool <i>C. difficile</i> toxin has been identified at the same time they have experienced diarrhoea not attributable to any other cause; or from patients whose stool <i>C. difficile</i> has been cultured at the same time as they have been diagnosed with pseudomembranous colitis (PMC). Health Protection Scotland (2017). Mild CDI: associated with mild diarrhoea (3 liquid/loose stools or more frequently than normal) Moderate CDI: associated with a raised WBC count above normal but $<15 \times 10^9$ /L cells , (typically 3 or more loose/liquid stools per day) Severe CDI: when a patient has at least one severity marker including temperature $>38.5^\circ\text{C}$, WBC 15×10^9/L cells, or acute rising serum creatinine ($>1.5 \times$ baseline), or evidence of severe colitis in CT scan/ abdominal X-ray examination, suspicion of PMC, toxic megacolon or ileus.

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	Life-threatening CDI is when a patient has any of the following attributable to CDI: admission to ICU, hypotension with or without need for vasopressors, ileus or significant abdominal distension, mental status changes, WBC $\geq 35 \times 10^9$/L cells or $< 2 \times 10^9$/L cells, serum lactate > 2.2 mmol/l, end organ failure (mechanical ventilation, renal failure). <u>Recurrence</u> is defined as CDI which re-occurs within 2-8 weeks of previous episode, provided symptoms from previous episode resolved after completion of initial treatment.
Clinical Condition	Clinical onset of CDI often occurs when patients are on antibiotics, or within 4 weeks and up to 12 weeks of finishing a course of antibiotics. Patients may be colonised with <i>C. difficile</i> without symptoms. <u>CDI</u> may present with malaise, abdominal pain, nausea, anorexia, watery diarrhoea, low-grade fever, and a peripheral leukocytosis. Colonoscopy reveals a non-specific diffuse or patchy erythematous colitis without pseudomembranes. <u>Pseudomembranous colitis (PMC)</u> Sigmoidoscopy reveals raised yellow/ orange plaques from 2-10mm in size scattered over the colorectal mucosa. Patients with PMC have a more serious illness than CDI. Diarrhoea may also contain blood and mucous. NB: Life-threatening symptoms develop in 1.2-3.2% of patients with CDI. This disease is a very important co-morbidity in frail, elderly patients and can have high in-patient mortality.
Mode of Spread	There is evidence of both direct and indirect spread through the hands of HCWs and patients; and environmental contamination via equipment and instruments, e.g. commodes, bedpans and washbowls. <i>C. difficile</i> produces

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	spores which can survive for long periods in the environment. Environmental cleaning is paramount.
<i>Incubation period</i>	Up to 12 weeks.
<i>Notifiable disease</i>	Notifiable under Public Health (Scotland) Act 2008 : Yes
<i>Persons most at risk</i>	Certain persons are at increased risk of acquiring CDI. CDI should be considered in persons with diarrhoea who also have : • Current or recent (within last 3 months) use of antimicrobial agents, in particular cephalosporins, broad-spectrum penicillins, fluoroquinolones and clindamycin • Increased age (over 65 years). • Prolonged stay in healthcare settings. • Serious underlying disease • Surgical procedures (in particular bowel procedures). • Immunosuppression (incl. HIV and transplant) • Use of proton pump inhibitors or H2 antagonists, e.g. omeprazole, lansoprazole, which reduce production of stomach acid.

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3. Transmission Based Precautions for CDI

Accommodation (patient placement)	The patient should be placed in a single room, with ensuite or own commode. The door to the room must be closed and a yellow IPCT sign placed on the door. If a single room is unavailable the IPCT will help the clinical team to undertake a risk assessment and advise where to nurse the patient. This must be documented on the CDI Care Checklist. Precautions should continue until the patient has been asymptomatic for 48 hours and bowel movements have returned to normal or, on the advice of a member of the IPCT. Transmission based precautions are not recommended for asymptomatic carriers.
Antibiotics	Antibiotic prescribing should be in accordance with the NHSGGC Infection Management Guidelines. Prescribing should be regularly monitored and feedback should be returned to prescribers as appropriate. • NHSGGC Antimicrobial Prescribing Policies • The Management of Suspected <i>Clostridioides difficile</i> Infection (CDI) in Adults
IPC Care Checklist available	Yes. Clostridioides difficile IPC Care Checklist
Healthcare/Clinical Waste	All non-sharps waste should be designated as Healthcare/Clinical Waste (HCW) and placed in an orange clinical waste bag within the room. Please refer to the NHSGCC Waste Management Policy.
Contacts	Specimens should not be sent from patients deemed to be contacts unless they develop loose stools, where there is no other cause for this.
Domestic Services/Facilities	Domestic staff must follow the NHSGGC Twice Daily Clean of Isolation Rooms SOP. Cleans should be undertaken at least four hours apart
Equipment	

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	Patient equipment, e.g. commode, BP cuff, washbowl should be allocated to the patient until no longer considered infectious. Consider single-use or single patient use equipment. Commodes should be decontaminated after each use with chlorine based detergent.
Hand Hygiene	Alcohol based hand rub is <u>not</u> effective against CDI: Soap and water must be used for all patients with loose stools. Hand hygiene is the single most important measure to prevent cross infection with CDI. Hands must be decontaminated before and after each direct patient contact, after contact with the environment, after exposure to body fluids and before any aseptic tasks. Patients should be encouraged to carry out thorough hand hygiene.
Health Protection Scotland (HPS) Trigger Tool	The Health Protection Scotland (HPS) Trigger Tool must be completed by the IPCT and Clinical Staff if there are two HAI CDI cases in the same ward in a two week period. IPCNs and ward staff will complete the tool daily until there is no longer a trigger i.e. one or both patients are no longer symptomatic or have been discharged. The following actions will be taken by the IPCT when a trigger is met: - request a terminal clean of the ward at the start of the trigger - advise on enhanced IPC precautions to be in place. - undertake SICPs audit with SCN - hand hygiene audit - ask the antimicrobial pharmacist to review prescribing Findings will be reported to the SCN and ward staff who will liaise with IPC and pharmacy colleagues on any actions required as a result. Following this, should another case of HAI CDI emerge, the IPCT will complete a PAG to determine the requirement for an IMT and ward closure.
Linen	Treat used linen as soiled/infected, i.e. place in a water soluble bag then a clear bag, tied and then into a laundry

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	bag. (Brown bag used in Mental Health areas) Please refer to National Guidance on the safe management of linen.
<i>Moving between wards, hospitals and departments (including theatres)</i>	Except in clinical emergencies, transfer of patients who remain in isolation is not advisable. However, acute receiving units have a high patient turnover and transfer of patients is necessary for effective patient flow and to ensure that patients receive the appropriate care within their specialty. Therefore, receiving areas MUST be informed of the patient's condition and requirement for a single room BEFORE the patient is transferred. Please follow NHSGGC Terminal Clean of Ward/Isolation Rooms SOP
<i>Notice for Door</i>	The yellow IPC isolation sign must be placed on the door to the patient's room. In Mental Health Services (MHS), on advice of IPCT.
<i>Patient Clothing</i>	Whilst patients are symptomatic they should be advised to wear hospital gowns if suitable. If relatives or carers take personal clothing home, staff must place clothing into a domestic water soluble bag then into a patient clothing bag and staff must ensure that a Washing Clothes at Home Leaflet is issued. NB: It should be recorded in the nursing notes that both the advice and information leaflet have been issued.
<i>Patient Information</i>	Inform the patient and / or if relevant, the patient's relative/ carer of their condition and the necessary precautions if required. Answer any questions and concerns they may have. A CDI Fact sheet for patients and their relatives is available to download from the IPCT web page. NB: Record in the IPC Care checklist / clinical notes that the fact sheet has been issued. IPCTs are available to speak to patients and / or relatives / carers if required.
<i>Personal Protective Equipment (PPE)</i>	To prevent spread through direct contact PPE (disposable gloves and yellow apron) must be worn for all direct contact

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	with the patient or the patient's environment/equipment. If there is a risk of splashing of blood/body fluids, then facial protection i.e. mask/visor should also be considered. Hand hygiene must be performed using liquid soap and water before donning and after doffing PPE. Alcohol based hand rub is not effective against CDI.
<i>Precautions required until</i>	Precautions should continue until the patient has been asymptomatic for 48 hours and bowel movements have returned to normal or, on advice of a member of the IPCT. If symptoms recur, reinstate precautions immediately, send further specimens and inform a member of the IPCT.
<i>Daily and weekly check by IPCT</i>	IPCNs will check daily (Monday -Friday) on the condition of patients with CDI until TBPs are no longer required and thereafter weekly for 4 weeks.

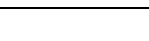
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<i>Daily assessment of severity by clinical team</i>	A patient diagnosed with CDI must be reviewed daily by the medical staff regarding fluid balance, electrolyte replacement, nutrition review, and monitoring for signs of increasing severity. Severity assessment (See below) must be scored and documented in the patient notes. Patients must have severity assessment carried out daily by medical staff until patient is asymptomatic for 48 hours and bowel movements have returned to normal. Severity markers include: • Temperature of >38.5°C • Suspicion of PMC, toxic megacolon, ileus • Colonic dilatation in CT scan/ abdominal x-ray >6cm • WBC > 15 x 10⁹ /L cells • Creatinine > 1.5 x baseline National guidance on CDI provides a list of severity markers for severe disease based on consensus and therefore is not exhaustive. A template for severity assessment is available from the IPCT. Please see The Management of Suspected <i>Clostridioides difficile</i> Infection (CDI) in Adults to determine antimicrobial therapy. Clinical cases of CDI In some circumstances the clinical team will treat a patient for CDI because either they have an equivocal result (GDH positive, toxin negative, the patient has <i>C. difficile</i> in their bowel that has the potential to produce <i>C. difficile</i> toxin, however the toxin has not been detected at this time but may cause disease) or without any positive microbiology following assessment of their presentation and symptoms. In these cases severity scores still need to be completed. Referral of severe cases onto Datix is the principle responsibility of IPCTs however if a clinician suspects a severe case of CDI they can also log this onto Datix for review.
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	If for clinical reasons the severity assessment is not deemed necessary, e.g. patient requires end of life care; this should be documented in the patient's notes by the clinical team.
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<i>Clinical review assessment (CRA) and Reporting of Severe Cases of CDI</i>	A Clinical Review is required if the patient: • has severe or life threatening CDI • was admitted to ITU for treatment of CDI or its complications • had endoscopic diagnosis of pseudomembranous colitis with or without toxin confirmation • had surgery for the complications of CDI (toxic megacolon, perforation or refractory colitis) • died within 30 days following a diagnosis of CDI where it is recorded as either the primary or a major contributory factor on the death certificate • had persisting CDI where the patient has remained symptomatic and toxin positive despite two courses of appropriate therapy
<i>Deaths due to CDI (Underlying or Contributing)</i>	Patients who have died will have their cause of death reviewed as soon as possible via the ward death certificate records. If death certificate records are not available, the lead IPCN will contact the General Manager (GM) for the service, and advise them that the records are not available. The Lead Infection Prevention and Control Doctor (LIPCD), Infection Prevention and Control Manager (IPCM), Associate Nurse Director, Infection Prevention and Control (ANDIPC), Clinical Services Manager (CSM) and Lead Nurse for the area must be informed of all patients who died in hospital who are or who have been positive for CDI during their current admission, and the cause of death if available. Medical staff completing a death certificate in which CDI is noted (part 1 or 2) should discuss this with the consultant in charge of the patient's clinical care and refer case to the Procurator Fiscals Office. If CDI is placed on part 1, medical staff should inform the CSM and GM for the area. Medical staff should familiarise themselves with NHSGGC Guidance on the Completion of Medical Certificates of Cause of Death.
<i>Specimens required</i>	Faecal specimens from any patient who has loose stools must

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	be sent if no other cause of diarrhoea is known (Norovirus is not a reason to exclude CDI as a diagnosis as co-infection is possible). If negative and loose stools persist, another two samples should be sent at 24-hour intervals. Relevant clinical information must be supplied with the specimen. Stool specimens should be obtained as soon as possible after onset of diarrhoea. Toxin testing should only be requested on stool specimens that conform to the shape of the container. See Appendix 1. • Send faecal specimens from patients who develop loose stools for culture and sensitivity– mark the form for <i>C. diff</i> toxin testing if CDI is suspected. • There is no requirement to send clearance specimens from patients who become asymptomatic. • Only when a relapse of CDI is suspected should you repeat the toxin testing and exclude other potential causes of diarrhoea, and 48 hours after completion of treatment. • Specimens should not be sent whilst patient is on treatment.
Stool Charts	It is the responsibility of staff looking after the patient within the area to record signs and symptoms of infection as appropriate, e.g. Bowel Movement Record, Appendix 1. The date, time, size and nature of the stool should be recorded while symptomatic and continued until discharge in order to reduce the risk of cross infection.
Surveillance	Surveillance of CDI is mandatory in Scotland and is reported to HPS by the Diagnostic Laboratory. Local surveillance in NHSGGC is returned to wards with a prevalence of CDI monthly using Statistical Process Control Charts (SPCs). The trigger for action is when the numbers in a ward reach the upper control limit in the SPC. SPCs are not a substitute for local referral by clinical staff and IPCTs but should be used to monitor trends and promote quality improvement.

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<i>Terminal Cleaning of Room</i>	Follow NHSGGC Terminal Clean of Ward/Isolation Rooms SOP If isolation is discontinued and the patient remains in hospital, undertake a terminal clean of the patient's room, including bed, bed locker, chair and table. Consider moving the patient to a new bed-space for ease of access. NB: relapse and re-infection from the environment can be as high as 20% in patients with CDI.
<i>Visitors</i>	Visitors are not required to wear aprons and gloves unless performing personal care. Visitors should be advised to decontaminate their hands with liquid soap and water on leaving the room/ patient. Visitors should be advised not to sit on the patient's bed at any time during visiting.

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4. Evidence Base

<http://www.nipcm.hps.scot.nhs.uk/>

<https://www.hps.scot.nhs.uk/a-to-z-of-topics/clostridioides-difficile-infection/>

Accurate Recording of Deaths from Healthcare Associated Infection and Action.
Scottish Government Health Directorates. CMO (2011) 13.

Vale of Leven Hospital Inquiry Report (2014)

The most up-to-date version of this SOP can be viewed at the following web page:
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Appendix 1 – Bowel Movement Record (adapted from the Bristol Stool Scale)

BOWEL MOVEMENT RECORD

Month: _____ Year: _____

Name: _____

Date	Time	Size S-small M-medium L-large S M L	Type 1 Separate hard lumps like nuts (hard to pass) 	Type 2 Sausage shaped but lumpy 	Type 3 Like a sausage but with cracks on surface 	Type 4 Like a sausage or snake, smooth and soft 	Type 5 Soft blobs with clear-cut edges (passed easily) 	Type 6 Fluffy pieces with ragged edges, a mushy stool 	Type 7 Watery, no solid pieces (entirely liquid) 	Staff Initials
	am									
	pm									
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Adapted from the Bristol Stool Scale developed by KW Heaton and SJ Lewis at the University of Bristol, 1997

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Guidance Objective

To ensure all relevant clinical staff are aware of the risks associated with
Respiratory Tract Infections

This guidance applies to all staff employed by NHS Greater Glasgow & Clyde and locum staff on fixed term contracts.

KEY CHANGES FROM THE PREVIOUS VERSION OF THIS GUIDANCE

Document Control Summary

Approved by and date	Board Infection Control Committee 23 rd June 2022
Date of Publication	27 th June 2022
Developed by	Infection Prevention Control Policy Sub-Group
Related Documents	National Infection Prevention and Control Manual NHSGGC Hand Hygiene Guidance NHSGGC SOP Cleaning of Near Patient Equipment NHSGGC SOP Twice Daily Clean of Isolation Rooms NHSGGC SOP Terminal Clean of Ward/Isolation Rooms
Distribution / Availability	NHSGGC Infection Prevention and Control web page www.nhsggc.scot/hospitals-services/services-a-to-z/infection-prevention-and-control
Lead Manager	Director Infection Prevention and Control
Responsible Director	Executive Director of Nursing

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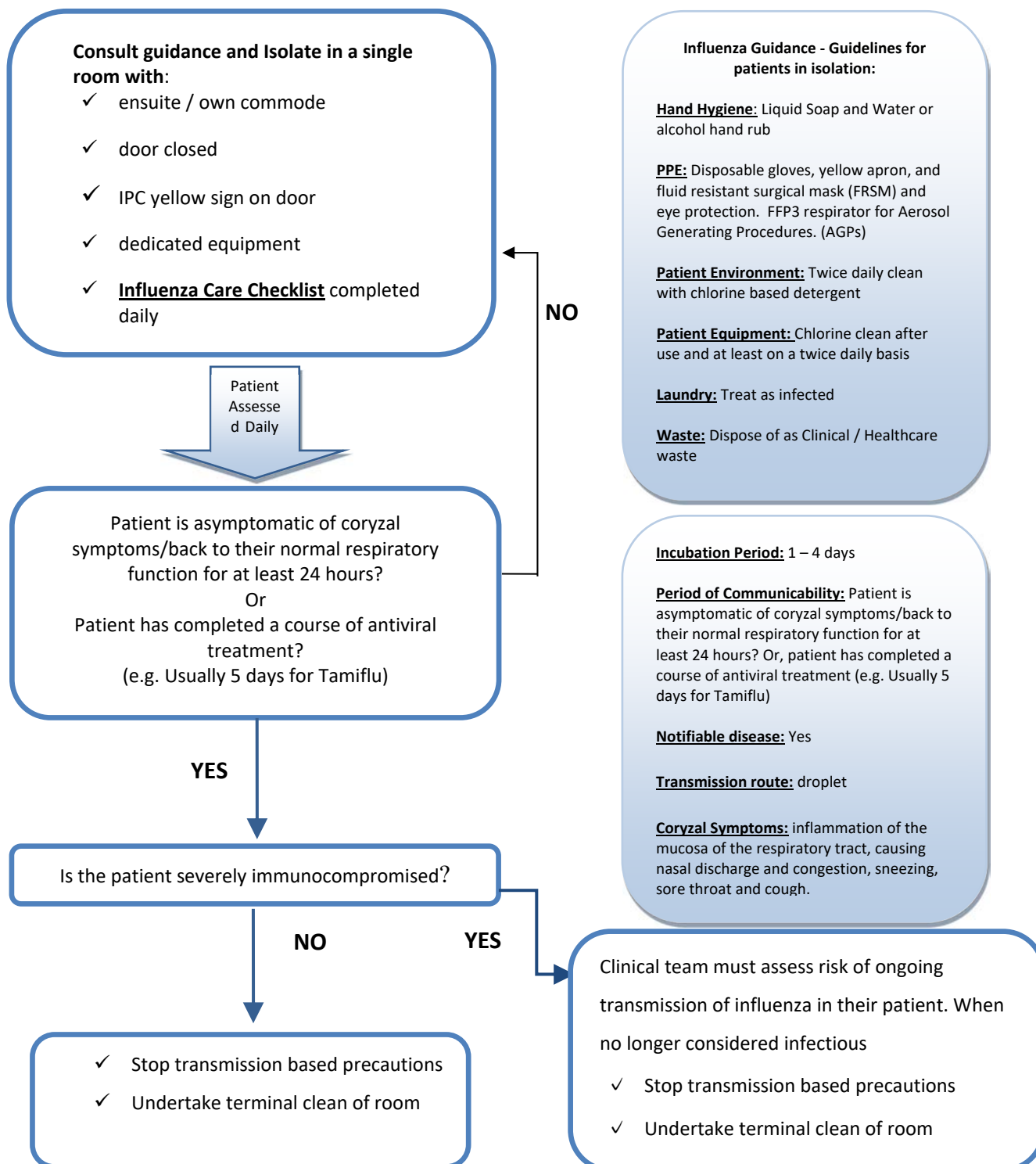
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Influenza Aide Memoire

Follow this algorithm if you have a patient with suspected or confirmed **Influenza**



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1. Responsibilities

Healthcare Workers (HCWs) must:

- Follow this guidance.
- Inform a member of the Infection Prevention and Control Team (IPCT) if this guidance cannot be followed.
- Must ensure care checklists are implemented and up to date.

Senior Charge Nurses (SCNs) / Managers must:

- Support HCWs in following this guidance.
- Cascade new policies/SOPs/guidance to clinical staff after approval by the Board Infection Control Committee (BICC).
- Ensure HCW are aware how to use respiratory protection and have access to appropriate PPE including fit testing for FFP3 masks.
- Provide staff the opportunity to receive the staff flu vaccination each year

Infection Prevention and Control Teams (IPCTs) must:

- Keep this guidance up-to-date.
- Support the clinical team to undertake a risk assessment where this guidance cannot be followed.
- Provide education opportunities on this guidance.

Occupational Health Service (OHS) must:

- Public Health and OHS will plan and promote the uptake of staff seasonal flu vaccination
- OHS will provide opportunity for staff to receive their flu vaccination during working hours

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Influenza

Infections with a particular strain of influenza (type A or B) occur every year and are referred to as seasonal influenza. Pandemic influenza occurs when a new influenza sub-type appears that is different to previous sub-types and can:

- infect humans
- spread effectively from human to human
- causes significant clinical illness in a high proportion of those who acquire the virus

Primary strategies for preventing influenza are:

- **VACCINATION - the most effective way of preventing the spread of influenza**
- early detection and treatment
- standard infection control precautions and transmission based precautions must be followed, to prevent transmission during patient care

2. Symptoms of Influenza

Influenza is a respiratory illness characterised by coryzal symptoms including fever, cough, headache, sore throat and aching muscles and joints. There is a wide spectrum of illness ranging from minor symptoms through to pneumonia and death. The most common complications of influenza are bronchitis and secondary bacterial pneumonia.

The typical incubation period for non-pandemic influenza is one to four days, with an average of two to three days. Adults can be infectious from the day before symptoms begin to approximately five days after illness onset. Children can be infectious for seven or more days, and young children can shed virus for several days before their illness onset. Severely immunocompromised persons can shed virus for weeks or months.

Routes of Transmission

There are three main routes of transmissions:

i. Droplet Transmission

Large droplets (greater than 5 microns in size) may be generated from a person with clinical disease during coughing or sneezing and may land directly on the conjunctiva, or mucous membranes of the nose and mouth of a susceptible person. Large droplets are heavy and do not remain suspended in the air for long periods of time and only travel for up to 1 metre, so close contact is required for transmission.

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ii. Direct / Indirect Contact Transmission

Direct contact transmission is when the virus is spread person to person either by contact with the infectious person skin or droplet transmission, e.g. symptomatic patient to a HCW, from a sneeze or cough directly onto the nose or mouth.

Indirect contact transmission is the transfer of an infectious agent through a contaminated intermediate object or person, e.g. from a contaminated surface, bed table, to the hands of another person who then transfers the virus to their nose, mouth or eyes. Influenza virus is known to survive well in the environment; up to 24 hours.

iii. By the Airborne Route during and after Aerosol Generating Procedures (AGPs)

Transmission may occur at short distances through inhalation of small particle aerosols which are produced during Aerosol Generating Procedures (AGPs).
(See section 5 below)

Smaller droplets or aerosol produced during these types of procedures can be inhaled and cause infection. They may also remain in the air for a prolonged period and travel over distances.

3. Aerosol Generating Procedures (AGPs)

Healthcare staff that perform AGPs on patients with confirmed or suspected influenza should don additional protective clothing (see **Section 5E** Personal Protective Equipment).

Where possible, AGPs should be avoided or alternative methods considered. Only essential staff should be present.

Aerosol Generating Procedures (AGPs) are defined as:

Tracheal intubation and extubation

- Manual ventilation
- Tracheotomy or tracheostomy procedures (insertion or removal)
- Bronchoscopy
- Dental procedures (using high-speed devices, for example, ultrasonic scalers/high-speed drills)

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- Non-invasive ventilation (NIV): Bi-level Positive Airway Pressure Ventilation (BiPAP) and Continuous Positive Airway Pressure Ventilation (CPAP)
- High flow nasal oxygen (HFNO)
- High frequency oscillatory ventilation (HFOV)
- Induction of sputum using nebulised saline
- Respiratory tract suctioning
- Upper ENT airway procedures that involve respiratory suctioning
- Upper gastrointestinal endoscopy where open suction beyond the oro-pharynx occurs
- High speed cutting in surgery/post-mortem procedures

4. Testing for Influenza

- Patients who present to hospital with flu-like illness should be tested **if** clinically relevant.
- Repeat testing to confirm clearance of influenza is **not** required.

Anti-viral Prescribing for patients with flu-like illness

Treatment and prophylaxis

Please contact infectious disease consultant or virologist to obtain advice regarding treatment of suspected or known cases of influenza and / or prophylaxis of specific vulnerable groups. The most up-to-date information on treatment issued by the Scottish Government Health Directorates (SGHD) can be viewed at <https://www.hps.scot.nhs.uk/a-to-z-of-topics/influenza/>

5. Limiting the Spread of Influenza

A. Patient Placement

- All patients with confirmed or suspected influenza should be nursed in a single room with en suite facilities. If a single room is not available staff must contact a member of the local IPCT for further advice.
- A yellow IPC isolation sign should be clearly visible on the door.
- Patients should be considered infectious until patient is asymptomatic / back to their normal respiratory function for at least 24 hours OR patient has completed a course of antiviral treatment.
- Patients who are diagnosed as having influenza but are asymptomatic are unlikely to spread the virus and can be regarded as non-infectious.
- Patients who are immunocompromised or with prolonged illness or complications should be assessed by clinical staff and the IPCT, and isolation

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precautions discontinued if deemed appropriate. Patients who fall into this category must be assessed individually.

- PCR tests can remain positive for considerable periods and should not be used to determine infectivity.
- Patients with underlying medical conditions or patients who have gone on to develop a secondary complication as a result of infection should be considered infectious until they return to their previous health state.
- If patient is in ICU please discuss with IPCT.
- Patients who are immunocompromised or with prolonged illness or complications should be assessed by clinical staff and the IPCT, and isolation precautions discontinued if deemed appropriate. Patients who fall into this category must be assessed individually.
- In the event of increase in the number of patients with influenza requiring admittance to hospital, in conjunction with the IPCT, an influenza cohort bay or ward can be considered. Please see [Appendix 2](#) for IPC guidance.

B. Patient Movement / Inter-Hospital Transfers

Influenza patients who are still infectious must not leave the area unless there is an urgent clinical need. If patient has to leave the single room while symptomatic, they should wear a fluid-resistant surgical mask (FRSM) if possible to minimise the dispersal of respiratory secretions and prevent environmental contamination. The FRSM should be worn until the patient is returned to the single room / cohort area. On removal of the FRSM, the patient should be offered the opportunity to undertake hand hygiene.

If a patient requires transfer to another department the following procedures must be followed:

- The department must be informed in advance.
- HCWs transporting the patient **do not need** to wear PPE if the patient is wearing an FRSM but must undertake hand hygiene.
- If the patient cannot wear/tolerate a FRSM then any HCW transporting the patient must wear a FRSM
- The patient must be taken straight to and returned from the department and must not wait in a communal area.
- If possible patients should be placed at the end of a list, to allow appropriate decontamination after any procedure.
- If the patient requires oxygen via a mask, then the patient need not wear the FRSM however, if nasal prongs are used to deliver oxygen then the patient should also wear an FRSM over the prongs.

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Hospital Transfers and Discharges

Patients must not be transferred from one hospital to another for routine care however some patients may require specialist care, e.g. renal dialysis. If a patient has to be transferred this **MUST** be discussed with the local IPCT who will alert the IPCT at the receiving hospital. It will be the responsibility of the clinical area that the patient is being discharged from to alert the Scottish Ambulance Service.

Discharge to residential care:

If a patient remains symptomatic or has not completed 5 days of appropriate antiviral treatment, this must be communicated to those receiving the patient, and appropriate IPC measures put in place prior to the transfer of the patient.

C. Visitor Restrictions

- Visiting in hospital should be restricted to 1-2 visitors only in order to reduce the risk of influenza transmission to visitors.
- All visitors must be free of flu-like symptoms, however in exceptional circumstances, e.g. when a patient is critically ill, then advice should be sought from the IPCT and a risk assessment will be undertaken.
- Visitors must speak to a member of staff and be instructed on hand hygiene practice and the wearing of protective clothing as appropriate prior to visiting the patient, such as a surgical mask, apron and gloves.
- Visitors to patients ventilated with NIV or HFOV may be exposed to potentially infectious aerosols. The number of such visitors should be limited to two unless there are exceptional circumstances. Visitors should be made aware of the risks and be offered PPE as recommended for staff.
- There may be further visiting restrictions if a ward is closed due to influenza.

D. Hand Hygiene

Hand hygiene remains the single most important measure to take against the spread of influenza. Effective hand hygiene with plain liquid soap and running water or alcohol based hand rub on visibly clean hands is effective, for a minimum of 20 seconds.

E. Personal Protective Equipment (PPE)

PPE is worn to protect staff from body fluids to reduce the risk of transmission of influenza between patients and staff and from one patient to another. The level of PPE used will vary based on the procedures being carried out and not all items of PPE

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will always be required. Appropriate PPE for care of patients who are suspected or confirmed to have influenza is summarised **below**.

PPE to be worn when providing direct care for service users on the respiratory pathway. [National Infection Prevention and Control Manual: Winter \(21/22\), Respiratory Infections in Health and Care Settings Infection Prevention and Control \(IPC\) Addendum \(scot.nhs.uk\)](#)

Fluid resistant surgical mask (FRSM)

Fluid resistant surgical masks (FRSM) should be worn by HCWs for contact with patients suspected or known to have influenza. The mask provides a physical barrier which becomes ineffective once wet. As masks themselves may become a reservoir for the virus great care should be taken during their removal and disposal.

When to remove the FRSM

When visiting a number of patients within an influenza cohort or A&E department, it is acceptable to wear the same mask and change it at the end of the session and if it gets wet. Great care must be taken not to contaminate the hands during this time by touching the mask. HCW/ Visitors must removal all PPE before leaving a patient care area (single room/ cohort area), FRSM or FFP3 respirators should be removed last.

Hand hygiene must be performed after removal of all PPE.

When to wear an FFP3 respirator

FFP3 respirators should be worn only by those staff carrying out AGPs. To be effective, individual users must be trained to fit the respirator properly to their face.

When to remove the FFP3

The FFP3 mask must be worn for up to 2 hours following an AGP, until fallow times have been completed during which time the aerosols will have either been removed through the ventilation system or allowed to settle. If staff wish to leave the patient room within the fallow time, gloves and aprons should be removed in the room and hand hygiene performed. The FFP3 mask should be removed on leaving the room, placed in the nearest clinical waste receptacle and hand hygiene performed.

[National Infection Prevention and Control Manual: Appendix 17 - Aerosol Generating Procedures \(AGPs\) and post AGP Fallow time \(PAGPFT\) \(scot.nhs.uk\)](#)

Domestic staff where possible should wait for the fallow time to be over before entering the room.

F. Decontamination of Patient Equipment

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Where practicable, the patient should be designated their own equipment.

See NHSGGC [Cleaning of Near Patient Equipment SOP](#)

G. Decontamination of the Environment

Domestic staff must follow the SOP for Twice Daily Clean of Isolation Rooms. Cleans should be undertaken at least four hours apart.

See NHSGGC [Twice Daily Clean of Isolation Rooms SOP](#)

All frequently touched surfaces should be decontaminated after any AGP using chlorine based detergent. Limit the amount of equipment in the room as far as possible.

H. Clinical/ Healthcare Waste

Waste should be designated as clinical / healthcare waste and placed in an orange bag.

Please refer to the NHSGGC [Waste Management Policy](#)

I. Laundry

Discard linen as soiled/ infected, i.e. in a water soluble bag then a clear plastic bag, tied and then placed into a laundry bag.

Please refer to [National guidance of the safe management of linen](#)

Sending Laundry Home

If relatives or carers wish to take personal clothing home, staff must place clothing into a domestic water soluble bag then into a patient clothing bag and ensure that a

[Washing Clothes at Home Information Leaflet](#) is issued.

NB Nursing staff in the ward should record in the nursing notes that both the advice and information leaflet has been issued.

J. Respiratory Hygiene / Cough Etiquette (Catch it, Bin it, Kill it)

Patients, staff and visitors should be encouraged to minimise potential influenza transmission by:

- Covering the nose and mouth with disposable single-use tissues when sneezing, coughing, wiping and blowing noses.
- Disposing of used tissues in nearest clinical/ healthcare waste bin, washing hands after coughing, and sneezing using tissues.
- Avoid touching eyes, mouth and nose.

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Some patients may need assistance with containment of respiratory secretions, e.g. older people and children. Those who are immobile may need a personal waste bag readily at hand for immediate disposal of tissues. They should also have a supply of hand wipes and tissues.

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6. Evidence Base

Health Protection Scotland. Guidance on use of antiviral agents for the treatment and prophylaxis of influenza

[HPS Website - Influenza](#)

Health Protection Scotland Infection Prevention and Control Guidance;

[National Infection Prevention and Control Manual: A-Z Pathogens](#)

[Winter \(21/22\), Respiratory Infections in Health and Care Settings Infection Prevention and Control \(IPC\) Addendum](#)

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Appendix 1: Influenza Cohort Nursing Aide Memoire

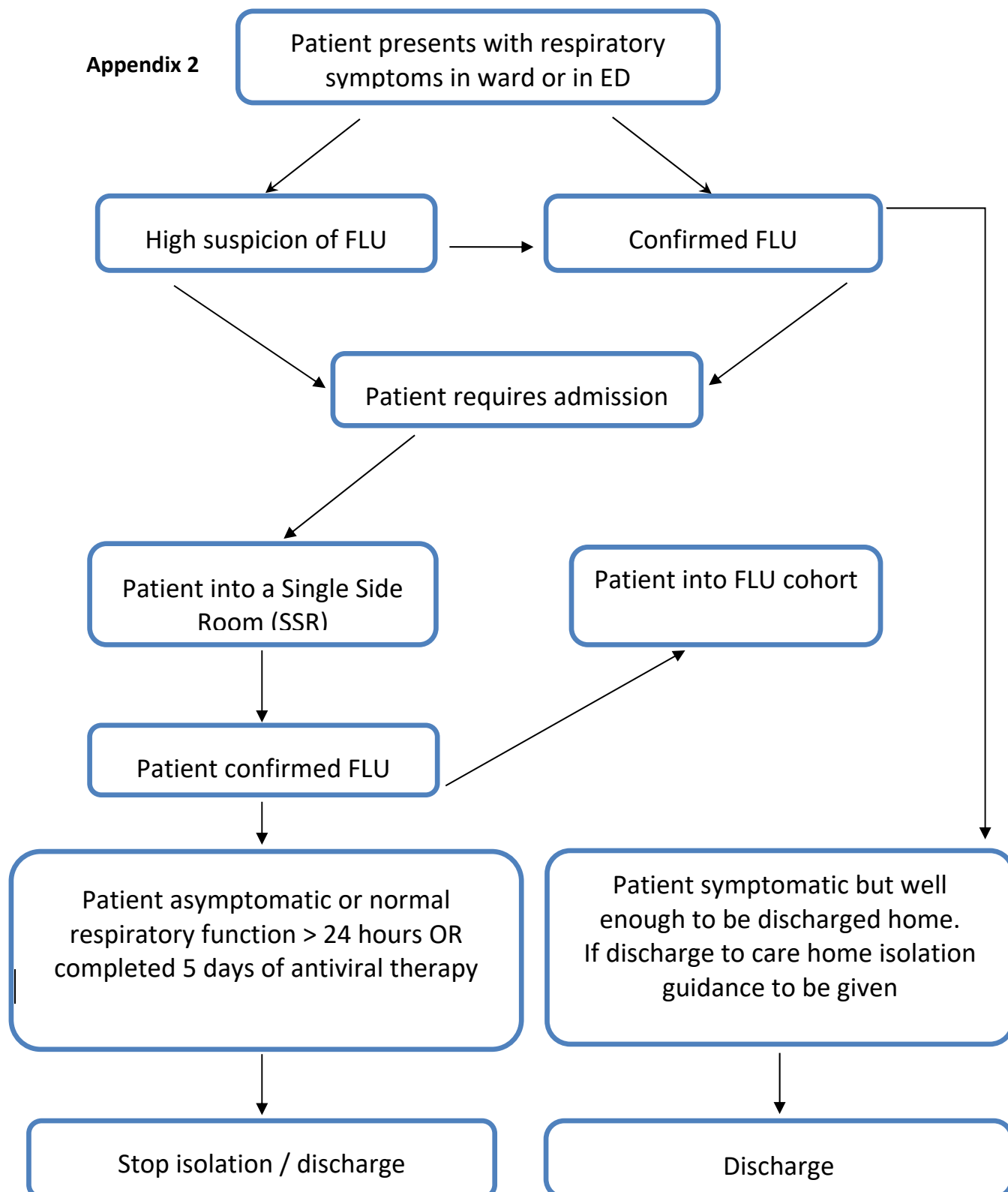
Planning and communications	On each hospital site, wards and wards with suitable bed bays will be identified and a respiratory pathway agreed from ED to discharge. This will be communicated to the appropriate staff at huddles/briefs to support patient/bed management. Daily updates on bed spaces on cohort wards/bays should be available to support patient transfers from ED and acute receiving. Wards with cohort bays will not be closed to other admissions.
Definition of a cohort ward or bay	A cohort area is a bay/ward in which a group of patients (cohort) with the same infection are placed together. Patient cohorting may be appropriate when single rooms are not available and there is more than one patient with the same confirmed infection.
Decision to create a Flu cohort	If a ward has bed bays and a number of confirmed FLU patients, those patients should be nursed in a single bay as a cohort. If there are empty beds in that cohort, they can be used for FLU patients from other areas. The decision to set up a cohort should be discussed with local IPCT/on call Microbiologist prior to being implemented.
Setting up the cohort	The cohort bay should have dedicated equipment as far as possible such as blood pressure, oxygen saturation and temperature recording devices within the cohort bay.
Staffing (cohort nursing)	Cohort nursing (dedicated teams) should be implemented to minimise the risk of contamination between groups of symptomatic and non-symptomatic patients <u>if</u> staff resource allows. If not, contact the local IPCT who will help to undertake a risk assessment
Bed spacing	Patients should be separated by at least 2.7 metres from each other in a cohort area, and bed curtains can be drawn as an additional physical barrier if required.
Cohort patients	Patients who have <u>confirmed Influenza</u> can be nursed in an influenza cohort until they have been asymptomatic / returned to normal respiratory function for at least 24 hours OR received 5 days of antiviral therapy. However, It should be noted that patients being nursed together in a cohort should all have the same type of FLU. e.g. Influenza A. Patients who remain symptomatic but are well enough to be discharged can be sent home. Patients who have FLU and another infection e.g. diarrhoea or MRSA, should be nursed in a single room.
Testing for influenza	Either laboratory or POCT testing is sufficient to identify patients with influenza. It is not necessary to test prior to discharge. Patients who are asymptomatic should not be tested.
PPE	For entering the cohort ward / bay, it is not necessary to wear PPE unless about to undertake patient care. For all direct care or contact with the patients environment staff should don a disposable plastic yellow apron, disposable gloves, a fluid resistant face mask and eye protection. For AGP, an FFP3 mask should be worn. If patients require routine AGPs, consider placing this patient in a single room.
Equipment	As far as possible, dedicated equipment should remain in the cohort bay for use on cohort patients only. For equipment that cannot be dedicated, items should be cleaned with a chlorine based solution containing 1,000 ppm active chlorine.
Ward rounds	Ward rounds within a cohort will consist of 1 member of medical team entering the cohort in appropriate PPE to examine the patient only. Once exam completed, removal of PPE and hand hygiene should be performed. Any equipment used will either stay in the cohort or be decontaminated before removal
Linen	Bed linen should be managed as infected linen
Waste	Waste should be managed as healthcare waste

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Cleaning of Environment	Domestic services should clean the cohort bed bay/ ward a minimum of daily with a solution containing 1,000 ppm active chlorine. (Consideration should be given to a dedicated cleaning team on each site). If an AGP has been carried out the domestic staff should wait until the fallow time is complete before entering the room to clean.
Visitors	Visitors are allowed but no more than two per bed space. It may be necessary to stop visiting temporarily if the situation warrants this.

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Appendix 2



High-Efficiency Particulate Air Filters in the Era of COVID-19: Function and Efficacy

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Abstract

Aerosol-generating procedures in the office represent a major concern for health care–associated infection of patients and health care providers by SARS-CoV-2, the causative agent for coronavirus disease 2019 (COVID-19). Although the Centers for Disease Control and Prevention has not yet provided any recommendations for the use of portable air purifiers, air purifiers with high-efficiency particulate air (HEPA) filters have been discussed as an adjunctive means for decontamination of SARS-CoV-2 aerosols in health care settings. This commentary discusses HEPA filter mechanisms of action, decontamination time based on efficiency and flow rate, theoretical application to SARS-CoV-2, and limitations. HEPA filter functionality and prior guidance from the Centers for Disease Control and Prevention for SARS-CoV-1 suggest theoretical efficacy for HEPA filters to decontaminate airborne SARS-CoV-2, although direct studies for SARS-CoV-2 have not been performed. Any portable HEPA purifier utilization for SARS-CoV-2 should be considered an adjunctive infection control measure and undertaken with knowledge of HEPA filter functionality and limitations in mind.

Keywords

high-efficiency particulate air filter, HEPA, air purifier, coronavirus, COVID-19, SARS-CoV-2

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Airborne transmission of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the causative agent of the coronavirus disease 2019 (COVID-19), occurs through respiratory droplets (generally $>5\ \mu\text{m}$) and aerosol droplets (generally $<5\ \mu\text{m}$) that are expectorated from the respiratory tracts of infected individuals.¹ Aerosol-generating procedures (AGPs) represent a major concern for health care–associated infection of patients and health care providers. As compared with large droplets, which are rapidly pulled downward by gravity, aerosols may remain suspended in the air for an hour or more.² Otolaryngology is one medical specialty at particularly high risk of health care–associated infection with SARS-CoV-2 due to

commonplace performance of AGPs in the office. Current guidance by the Centers for Disease Control and Prevention (CDC) is that AGPs be performed in airborne infection isolation rooms (ie, negative-pressure rooms) when possible; otherwise, procedure rooms should remain unoccupied until SARS-CoV-2-laden aerosols may be cleared through other means, such as room air exchanges from indwelling ventilation.³ The CDC has not provided any recommendations for the use of portable air purifiers. Nevertheless, air purifiers with high-efficiency particulate air (HEPA) filters have been discussed as an adjunctive means for decontamination of SARS-CoV-2 aerosols in health care settings. Consideration of portable air purifiers with HEPA filters (HEPA purifiers) during the SARS-CoV-2 pandemic should be with extensive knowledge about the functionality, efficacy, and limitations of HEPA purifiers.

Discussion

Mechanisms of Action

HEPA filters are usually manufactured by pleating microfiber glass or other fibrous media made with multiple layers of randomly arranged fibers, with diameters ranging from 2 to 500 nm.⁴ As air flows through the filter and in between the fibers, airborne particles—such as respiratory and aerosol droplets—will be trapped by 1 of 3 mechanisms: impaction, interception, and diffusion (**Figure 1**).⁵ Adhesion to filter fibers may occur through Van der Waals forces, electrostatic attraction, and capillary action. For particle sizes $>1\ \mu\text{m}$, impaction and interception are the most significant

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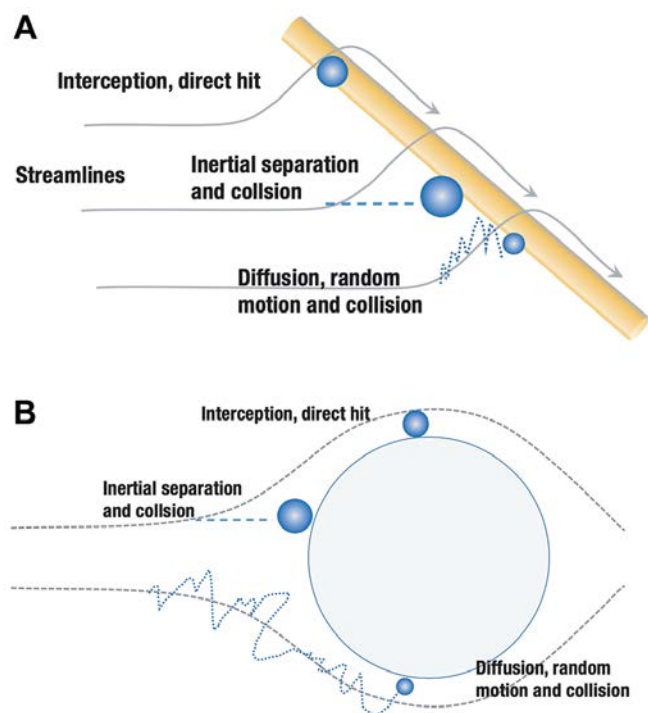


Figure 1. Schematic of filtration mechanisms of impaction, interception, and diffusion. © R. Vijayakumar, reproduced with permission.

mechanisms of filtration, whereas diffusion is the dominant mechanism for trapping particles $<0.1 \mu\text{m}$.⁴ Particles between 0.1 and $1 \mu\text{m}$ are influenced by all 3 methods of capture to a lesser degree than those larger or smaller, which leads to a lower efficiency of filtration.⁴

Efficacy

To qualify as HEPA grade, filters must remove at least 99.97% of all particles that are 0.15 to $0.2 \mu\text{m}$, for which HEPA filters are least effective. Thus, HEPA filters have at least 99.97% efficiency for removing all particles, with even higher efficiencies for particles both larger and smaller than $0.15 \mu\text{m}$ (**Figure 2**). The interesting U-shaped efficiency curve of all HEPA filters, which has a minimum at $0.15 \mu\text{m}$, is due to the relative effectiveness of the 3 mechanisms of particle capture at various sizes. Filters with efficiencies $>99.99\%$ are also termed ultralow penetration air filters.

Clean Air Delivery Rate

HEPA purifiers of various sizes and power will remove particles at different rates. The clean air delivery rate (CADR) is an important performance parameter created by the Association of Home Appliance Manufacturers to quantify the cubic feet per minute of air completely filtered of a particle by the air purifier. The CADR is calculated as flow of air through the filtration system multiplied by the efficiency of filtration of the particular particle. CADR score is specific to particle sizes and typically reported for 3 categories of particle sizes: pollen (2.5 – $80 \mu\text{m}$), dust (1 – $30 \mu\text{m}$), and tobacco

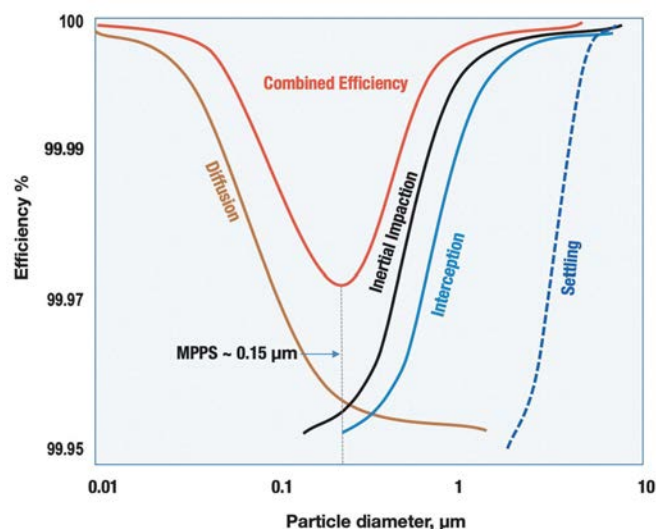


Figure 2. High-efficiency particulate air filter efficiency as a function of particle size and filtration mechanism. MPPS, most penetrating particle size. © R. Vijayakumar, reproduced with permission.

smoke (0.1 – $1 \mu\text{m}$).⁶ The CADR for dust and tobacco smoke may be most useful for determining filtration rate of aerosols and viruses, respectively, which are generally in the corresponding size range.

A previously reported study by the Environmental Protection Agency illustrates practical considerations for airborne particle decontamination by HEPA purifiers.² Based on the assumption of complete mixing of the air during filtration, which was found to be a realistic approximation, the amount of time needed to filter a certain fraction of particles out of a volume of air was derived using the CADR:

$$C(t) = C_0 e^{-\left(\frac{\text{CADR}}{V}\right)t},$$

where $C(t)$ is the concentration of the particle as a function of time, C_0 is the initial particle concentration, V is the volume of the air being filtered, and t is time.² Therefore, a HEPA purifier that has a CADR score of 300 for tobacco smoke—indicating that the device removes all tobacco smoke particles from 300 cubic feet of air every minute—would be expected to clear 99% of all tobacco smoke particles in a 1000 cubic-foot room (eg, $10 \times 10 \times 10$ ft) in 15 minutes. Location of HEPA purifier placement within the room and presence of basic furniture, such as a desk and chair, did not substantially affect efficacy, although pointing the purifier's air intake toward the particle source improved decontamination.²

HEPA Filters Applied to SARS-CoV-2

The majority of aerosols that may be produced by human cough are $<1 \mu\text{m}$,⁷ and the SARS-CoV-2 virion is reported to be 60 to 140 nm (0.06 – $0.14 \mu\text{m}$).¹ Although the CDC has recommended the use of HEPA filters in powered air-purifying respirators for effective filtration of SARS-CoV-

2,⁸ at present the CDC has not provided any recommendations for the use of portable HEPA purifiers for decontamination of SARS-CoV-2 in clinical areas or procedure rooms. The US Food and Drug Administration recommends that manufacturers of air purifiers intended for use related to SARS-CoV-2 evaluate effectiveness against a representative virus.⁹ Coincidentally, the CDC previously suggested the use of portable HEPA purifiers as an adjunctive infection control strategy for SARS-CoV-1, the causative agent of the 2003 SARS outbreak.¹⁰

Considerations for Commercial Acquisition of HEPA Purifiers

Consumers are cautioned that commercially available air purifiers make claims with labels such as true HEPA, HEPA like, and HEPA type. However, to be labeled HEPA, a filter is required to be tested and individually certified according to standards by the US Institute of Environmental Sciences and Technology (IEST-RP-CC001.6) or the International Organization for Standardization (ISO 29463). Very few air purifiers meet this requirement. By comparison, CADR rating is a more reliable performance parameter. Medical HEPA air purifiers may additionally claim to have an ultraviolet light or other decontaminating agent to kill microbes that deposit on the filter itself. In most cases, their microbicidal effectiveness has not been independently verified. Manufacturer guidelines should be followed for when to change filters, as saturation of filters affects efficiency. Finally, proper personal protective equipment should be worn to exchange air purifier filters, as these filters may contain trapped SARS-CoV-2. Proper disposal procedures should be followed to avoid contamination.

Conclusion

At present, there are no formal recommendations by the CDC for use of portable HEPA purifiers for decontamination of airborne SARS-CoV-2. Knowledge of HEPA filter functionality and prior CDC guidance for SARS-CoV-1 suggests theoretical efficacy for HEPA filters to remove airborne SARS-CoV-2, although it is important to emphasize that direct studies for SARS-CoV-2 have not been performed. Any utilization of portable HEPA purifiers for SARS-CoV-2 should be considered an adjunctive infection control measure and be undertaken with knowledge of HEPA filter functionality and limitations in mind.

Author Contributions

David A. Christopherson, manuscript design/organization, drafting and revisions, final approval; **William C. Yao**, manuscript drafting/revisions, final approval; **Mingming Lu**, manuscript drafting/revisions, final approval; **R. Vijayakumar**, manuscript drafting/revisions, final approval; **Ahmad R. Sedaghat**, manuscript conception/design/organization, drafting and revisions, final approval.

Disclosures

Competing interests: R. Vijayakumar is consultant in chief at the consulting firm Aerfil, LLC, and he has served on and chaired committees on HEPA standards at the US Institute of Environmental Sciences and Technology as well as the International Organization for Standardization. William C. Yao serves as a consultant for Stryker and is part of the speakers' bureau for OptiNose US, Inc.

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References

1. Tang D, Comish P, Kang R. The hallmarks of COVID-19 disease. *PLoS Pathog*. 2020;16:e1008536.
2. Kogan V, Harto C, Hesse DJ, Hofacre KC. Final report on evaluation of in-room particulate matter air filtration devices. Environmental Protection Agency. Published 2008. https://cfpub.epa.gov/si_public_record_report.cfm?Lab=NHSRC&subject=Homeland%2520Security%2520Research&dirEntryId=188372
3. Centers for Disease Control and Prevention. Appendix B. Air: guidance for environmental infection control in health-care facilities. Published July 22, 2019. Accessed May 22, 2020. <https://www.cdc.gov/infectioncontrol/guidelines/environmental/appendix/air.html>
4. Perry JL, Agui JH, Vijaykumar R. *Submicron and Nanoparticulate Matter Removal by HEPA-Rated Media Filters and Packed Beds of Granular Materials*. Marshall Space Flight Center; 2016.
5. First MW. HEPA filters. *J Am Biol Safety Assoc*. 1998;3:33-42.
6. Sahu SK, Tiwari M, Bhangare RC, Pandit GG. Particle size distribution of mainstream and exhaled cigarette smoke and predictive deposition in human respiratory tract. *Aerosol Air Qual Res*. 2013;13:324-332.
7. Lindsley WG, Pearce TA, Hudnall JB, et al. Quantity and size distribution of cough-generated aerosol particles produced by influenza patients during and after illness. *J Occup Environ Hyg*. 2012;9:443-449.
8. Centers for Disease Control and Prevention. Considerations for optimizing the supply of powered air-purifying respirators (PAPRs): for healthcare practitioners (HCP). Published April 19, 2020. Accessed May 22, 2020. <https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/powerd-air-purifying-respirators-strategy.html>
9. US Food and Drug Administration. Enforcement policy for sterilizers, disinfectant devices, and air purifiers during the coronavirus disease 2019 (COVID-19) public health emergency: guidance for industry and Food and Drug Administration staff. Published March 2020. <https://www.fda.gov/media/136533/download>
10. Centers for Disease Control and Prevention. III. Infection control in healthcare facilities: public health guidance for community-level preparedness and response to severe acute respiratory syndrome (SARS). Published May 3, 2005. Accessed May 22, 2020. <https://www.cdc.gov/sars/guidance/infection/healthcare.html>

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Short Report

Are positive-pressure ventilation lobby rooms effective for protective and source isolation?

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AIIR

Airborne infection isolation room

Source isolation

Protective isolation



SUMMARY

High-efficiency particulate air supplied to a positive-pressure ventilation lobby (PPVL) in isolation rooms offers the dual advantage of protective and source isolation. This study demonstrates the in-use validity of PPVL rooms for protective isolation of patients. Of the 48 PPVL air samples investigated, *Aspergillus fumigatus* was detected from only one (2%) sample. Local and remote monitoring of the PPVL rooms is essential for the safety of patients and healthcare workers. Remote and point-of-use engineering controls are essential for ongoing ventilation monitoring, but this should be complemented by visual inspection of the isolation suite. Periodic microbiological monitoring should also be considered with other control measures.

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Introduction

Positive-pressure ventilation lobby (PPVL) rooms were introduced with the arrival of UK Health Building Notes (HBN) 04–01, Supplement 1 (2005), and were hypothesized to provide a protective environment for patients. The PPVL room was

shown *in vitro* to be effective in providing the desired protection, but the literature supporting its clinical validity is sparse [1]. The HBN 04-01 Supplement 1 (2013) recommends a neutral-pressure ventilation (NPV) room with a PPVL for the prevention of transmission of infection by airborne pathogens [2]. Many newer healthcare facilities have provided PPVL-NPV rooms, and some are fitted with high-efficiency particulate air (HEPA) filters, but there are few data on their in-use effectiveness.

The at-risk patient groups for invasive aspergillosis (IA) have recently been expanded to include chronic lung disease,

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patients in critical care, and liver cirrhosis. [3] Additionally, emerging multi-triazole resistance in *Aspergillus fumigatus* limits therapeutic and prophylactic options [3]. The Irish National Guidelines recommend the use of HEPA-filtered positive-pressure facilities for patients' at increased risk of IA [4].

The aim of the study was to evaluate the in-use efficacy of the HEPA-supplied PPVL-NPV rooms for protection of patients at risk of IA, using three parameters, i.e. visualizing the direction of air flow, pressure differentials, and the microbiological monitoring for the presence of moulds, including *Aspergillus* spp.

Methods

Setting

Beaumont Hospital is an 800-bed tertiary acute adult national referral healthcare facility in Dublin, Ireland, incorporating national services in neurosurgery and kidney transplantation with a substantial cohort of haematology, oncology, and cystic fibrosis patients. The hospital has several PPVL-NPV rooms fitted with HEPA supply (hereafter referred to as 'NPV rooms') for protective isolation of immunocompromised patients to prevent IA. For bed access to any room, an appropriately sized door is required. Our NPV rooms are fitted with double-leaf sealed doors, from the corridor to the room, for bed access only and are access-controlled. Subsequent to their installation and commissioning, no demolition, construction, or renovation works have been performed to 'the envelope' in these purpose-built PPVL-NPV rooms, other than routine preventive maintenance [2].

Positive-pressure ventilation lobby room

The physical layout and airflow direction of a PPVL room is shown in Figure 1. The ante-room is supplied with HEPA-filtered air with ≥ 12 air changes per hour (ACH). The patient room and en-suite facility should have ≥ 10 ACH. While in operation, the en-suite facility should be at negative pressure with respect to

the patient room. The airflow direction should be from the ante-room to the patient room to the en-suite facility. The doors leading into and out of the ante-room and patient room must be closed to facilitate the correct airflow. Engineering controls include a pressure differential display (magnahelic pressure gauge) and alarm lights. Air pressure displays of ≥ 10 Pa in a PPVL are a measure of adequate air supply. Visual display alarms are used for local monitoring and the safe functioning of these rooms. Pressure differential data are continuously recorded by estates and facilities.

Air flow test

The air flow was assessed by visualizing the direction of smoke into and out of the PPV lobby, patient room, and en-suite facility by using a smoke test (Smoke pen, Björnax, Nora, Sweden), on three non-consecutive time-points. The expected direction of the airflow is from the PPVL to the patient room through the pressure stabilizer, and through the diffuser grill to the extract in the en-suite facility. The smoke pen was directed to the door seals as well as to the door–floor–wall fittings, to observe any smoke penetration/leakage.

Pressure differential test

The doors leading into the ante-room from the corridor were held open for 30 s; the pressure reading should fall to '0' Pa. Thereafter, the door leading to the ante-room was closed; a reading of ≥ 10 Pa was deemed adequate. These tests were repeated weekly for eight weeks.

Microbiological monitoring

Environmental air sampling was done by active air sampling, ~ 1 m above the floor, where 1 m^3 of air per sample was collected to determine the fungal spore burden, most specifically *A. fumigatus* [4]. Air samples were collected from the NPV rooms at three locations: the ante-room (lobby), patient room,

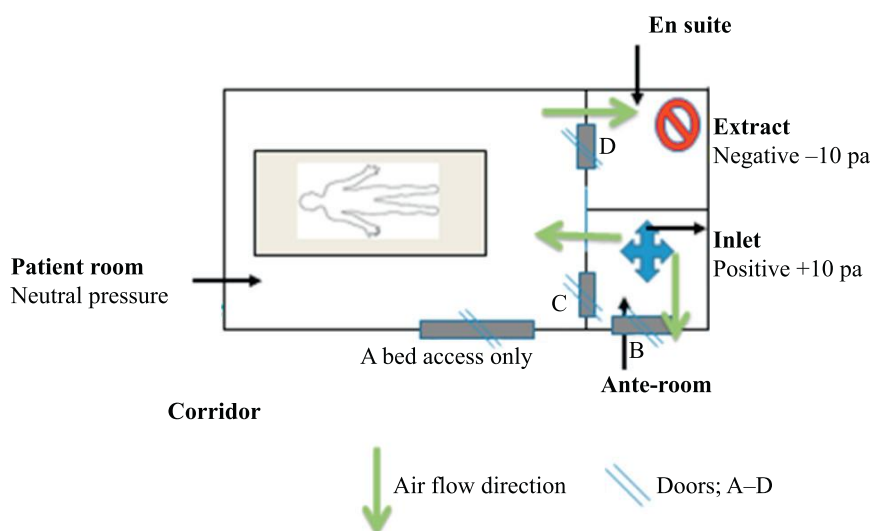


Figure 1. Layout and airflow direction of a positive-pressure ventilation lobby and neutral pressure isolation room.

Table 1

Air-sampling locations and sites where *Aspergillus fumigatus* was identified (colony-forming units)

Week	Ward A							External	
	NPV-5			NPV-6			HEPA: General	NV	
	PPVL	PR	EX	PPVL	PR	EX		NV-4	NV-1
1	—	—	—	—	—	—	—	5	—
2	—	—	—	—	—	—	1	—	—
3	—	—	—	—	—	—	—	—	—
4	—	—	—	—	—	—	—	3	—
5	—	—	3	—	—	—	1	20	3
6	—	—	—	—	—	—	—	—	—
7	—	—	—	—	—	—	—	1	1
8	—	—	—	—	—	—	—	6	—

NPV, neutral-pressure ventilation infection isolation room; HEPA, high-efficiency particulate air ventilation; PPVL, positive-pressure ventilated lobby/ante-room; PR, patient room; EX, extract *en suite*; NV, natural ventilation.

and the en-suite facility. Two air samples were collected from atmospheric air outside the built-in areas which served as the environmental control.

Sabouraud Dextrose Agar (SDA) plates (Fannin Ltd, Dublin, Ireland) were used for air sampling using a Surface Air Sampler (SAS) PBI, Milan Italy, one day per week for eight consecutive weeks. Plates were incubated at 37°C for 48 h and suspect colonies for aspergillus were identified as described [5]. Ten air samples were collected each week for eight consecutive weeks; three each from two NPV rooms, two from the positive-pressure HEPA-ventilated 24-bed ward while occupied by patients, and two external atmospheric air samples).

Results

Air flow

In the lobby, smoke flow was observed diffusing into the patient room through the pressure stabilizers. From the patient room, the flow of smoke moved into the en-suite facility through the integrated grills while the door was closed. In the en-suite facility, smoke flow was towards the ceiling-mounted extractor. No smoke penetration was observed through the bed-access-only door seals or via the flush door–floor–wall fixtures.

Pressure differential

The pressure gauge differential reading was ≥ 10 Pa in both positive-pressure lobby rooms when the doors were closed, and fell to '0' Pa upon opening the lobby door, but returned to ≥ 10 Pa when the doors were closed. The observed pressure differential readings during the eight weeks in both PPVL rooms were consistently ≥ 10 Pa.

Microbiological monitoring

Eighty air samples were collected over eight weeks. No moulds, including *A. fumigatus*, were isolated in the PPV lobby

or in the patient rooms. Three colony-forming units (cfu) of *A. fumigatus* were isolated on one occasion from the en-suite facility of one of the NPV rooms. From the two open ward locations, mould was isolated on two separate sampling points, 1 cfu each, and identified as *A. fumigatus*. Of the eight sampling points, *A. fumigatus* was isolated on five occasions from atmospheric air, i.e. the environmental control. The air-sampling results are summarized in Table 1.

Discussion

Controlled ventilation is used in healthcare facilities for the protection of patients, healthcare workers and other users. It often does not deliver the recommended ventilation, it may fail to maintain negative pressure, and it may even be under positive pressure [5]. Other problems with mechanical ventilation include the loss of negative-pressure differentials in airborne isolation rooms due to the opening of the doors and clogged filters. The undesirable airflow in and out of the negative-pressure isolation room, i.e. permeability, shows how leaky it is, as any leak presents a route of airborne transmission. In the absence of works carried out in the isolation facility that affect the envelope of the isolation suite, or any physical defects in a PPVL-NPV room, an air leak may occur from broken door seals or faulty doors [2].

Historically, isolation rooms that are switchable from positive to negative air pressure were used, but investigators found that these units were not delivering air according to the set parameters. An evaluation of 115 negative-pressure ventilation isolation rooms in the USA found that 52 (40%) of these rooms had positive airflow to the corridor with the doors closed [5]. In the absence of well-sustained negative pressure, contamination of adjacent rooms is likely, therefore posing a significant clinical risk to patients and to others such as staff [6].

Investigators in Hong Kong assessed rooms used for severe acute respiratory syndrome isolation rooms for negative pressure, airflow path, air-change rate, and local ventilation effectiveness. They found that, of the 38 rooms tested, 97% met the recommended negative-pressure difference of 2.5 Pa between the corridor and the ante-room, and 89% met the same requirement between the ante-room and the patient room. Although no leakage to the corridor was found, 60% of the en-suite facilities were operating under positive pressure. More than 90% of the corridor–ante-room or ante-room–patient room doors had a bi-directional flow when the door was open [7]. This casts doubt on the efficacy of negative-pressure ventilated rooms for source isolation.

The latest UK guidelines no longer recommend isolation rooms that are switchable from positive to negative air pressure, because of the risk of an incorrect setting [2]. The HEPA-fitted PPVL rooms therefore offer the dual advantage of 'protective' clean air supply to prevent IA, and airborne isolation with negative-pressure ventilation. The design of the PPVL room stipulates unidirectional airflow from the lobby to the patient room and this air is extracted in the en-suite facility. The design of the NPV suite limits the risk of inadvertent exposure to airborne pathogens, in the event of a failure in the air supply or extractor, which are inter-locked. However, this is dependent on robust engineering and regular safety checks.

Air permeability tests should be done as part of commissioning, at regular intervals, following physical alterations to

the room structure or if breaches to the supply and air-handling units occur, as specified in HBN (2013), Appendix 2. The UK Building Services Research and Information Association (BSRIA) standards on air permeability testing (BTS 3/2018) recommend testing at intervals not exceeding 14-month intervals. If further work is carried out in the isolation facility that affects the envelope of the isolation suite, the test must be repeated [8]. In the absence of alterations in the regular air flow, smoke tests to observe the direction of air flow could be employed as these provide reassurance of a functioning ventilation system when the intentional air flow direction is observed. Local monitoring of the pressure differential readings should be incorporated into daily visual checks to confirm the adequate functioning of the ventilation system.

We recorded pressure differential readings of the PPV lobby with the doors (B, C) closed and opened which provided visible evidence on the functioning of the HEPA-ventilated lobby. Automated remote continuous-pressure differential monitoring should be incorporated into healthcare building management systems for safety and governance. However, the poor reliability of continuous monitoring devices has been reported elsewhere, emphasizing the benefits of frequent visible smoke tests [9]. We observed the appropriate direction of smoke flow from the PPV lobby to the patient room to the en-suite facility extract, while all the doors were closed. No leakage of smoke was observed through the door-lips or seals.

The effective functioning of a PPV lobby room is dependent on the doors leading into and out of the rooms (A–D), being closed at all times. This requires a coordinated effort from clinical, engineering, hygiene services staff, patients, and visiting public. Staff must be educated on the correct functioning of these rooms in addition to noting and acting on warning alarm lights. Local monitoring and troubleshooting must be part of staff training. Patients in such rooms and their visitors must be provided with appropriate information, including the necessity of keeping the doors closed. In our experience, where patients were not given appropriate information the lobby/ante-room doors were sometimes sealed with tape, pressure dampers were blocked, doors were wedged open, and window seals broken. Sealed bed-access-only doors must be access controlled to prevent accidental and inadvertent use of these doors and thus prevent the ingress of contaminated air.

Irish guidelines recommend environmental air sampling before construction and at intervals [4]. As clean-air-supplied PPVL rooms are also intended for protective isolation, microbiological monitoring of HEPA-ventilated rooms by air sampling is prudent [3,4]. Determining baseline fungal spore burden before building works will facilitate future comparison. In the HEPA-supplied PPVL rooms, the recovery of *A. fumigatus* is unexpected, and, if present, it must be investigated. A two-year study to assess whether the PPVL room provides a similar environment to positive-pressure rooms found that mould concentrations were similar in the positive- and neutral-pressure room [1].

In our study, *A. fumigatus* was cultured once from the NPV en-suite facility. The NPV room was occupied by a patient during sampling. No environmental deficits could be detected other than dust on the extract fan grills. A comparable study has reported similar contamination from en-suite facilities in controlled ventilation rooms [10]. In the absence of a numeric

threshold for *Aspergillus* counts to indicate when action needs to be taken, a threshold of <1 cfu/m³ HEPA-filtered rooms with $>99.95\%$ efficiency is suggested [3]. The absence of fungal growth from PPVLs and NPV patient room air samples confirms the capacity for protective isolation.

Following the isolation of aspergillus in environmental air samples in another HEPA ventilation room (not the two NPV rooms studied), we noted dampness on the ceiling and walls arising from water leaks as the most likely cause. Therefore, regular environmental checks of ceilings and walls for dampness and water leaks are essential. Our findings contribute to growing evidence on the efficacy of PPVL-NPV isolation rooms for protecting at-risk patients from airborne pathogens as well as source isolation of patients with airborne-transmissible infections.

Limitations to our study include assessing only two HEPA-supplied PPVL-NPV isolation rooms and only over a period of eight weeks, in one centre yielding a small sample size. Larger studies involving multiple NPV rooms for longer duration should be performed to validate clinically the safety and efficacy of these expensive specialized rooms.

Conflict of interest statement

None declared.

Funding sources

None.

References

- [1] Ryan L, O'Mara N, Tansey S, Slattery T, Hanahoe B, Vellinga A, et al. A 2-year comparative study of mold and bacterial counts in air samples from neutral and positive pressure rooms in 2 tertiary care hospitals. *Am J Infect Cont* 2018;46:590–3.
- [2] Department of Health. Health Building Notes. Isolation facilities for infectious patients in acute settings. London: DoH; 2013.
- [3] Talento AF, Fitzgerald M, Redington B, O'Sullivan N, Fenelon L, Rogers TR. Prevention of healthcare-associated invasive aspergillosis during hospital construction/renovation works. *J Hosp Infect* 2019.
- [4] Health Protection Surveillance Centre. National guidelines for the prevention of nosocomial aspergillosis. Dublin: Health Service Executive; 2018.
- [5] Fraser VJ, Johnson K, Primack J, Jones M, Medoff G, Dunagan WC. Evaluation of rooms with negative pressure ventilation used for respiratory isolation in seven Midwestern hospitals. *Infect Cont Hosp Epidemiol* 1993;14:623–8.
- [6] World Health Organization. Natural ventilation for infection control in health care settings. Geneva: WHO; 2009.
- [7] Li Y, Ching W, Qian H, Yuen P, Seto W, Kwan J, et al. An evaluation of the ventilation performance of new SARS isolation wards in nine hospitals in Hong Kong. *Indoor Built Environ* 2007;16:400–10.
- [8] Building Services Research and Information Association. Air permeability testing of isolation facilities. London: BSRIA; 2018. p. 36.
- [9] Pavelchak N, Cummings K, Stricof R, Marshall E, Oxtoby M, London M. Negative-pressure monitoring of tuberculosis isolation rooms within New York state hospitals. *Infect Control Hosp Epidemiol* 2001;22:518–9.
- [10] Picot-Gueraud R, Khouri C, Brenier-Pinchart MP, Saviuc P, Fares A, Sellon T, et al. En-suite bathrooms in protected haematology wards: a source of filamentous fungal contamination? *J Hosp Infect* 2015;91:244–9.



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Two metres or one: what is the evidence for physical distancing in covid-19?

Rigid safe distancing rules are an oversimplification based on outdated science and experiences of past viruses, argue **Nicholas R Jones and colleagues**

Nicholas R Jones, Zeshan U Qureshi, ² Robert J Temple, ³ Jessica P J Larwood, ⁴ Trisha Greenhalgh, ¹ Lydia Bourouiba⁵

Physical distancing is an important part of measures to control covid-19, but exactly how far away and for how long contact is safe in different contexts is unclear. Rules that stipulate a single specific physical distance (1 or 2 metres) between individuals to reduce transmission of SARS-CoV-2, the virus causing covid-19, are based on an outdated, dichotomous notion of respiratory droplet size. This overlooks the physics of respiratory emissions, where droplets of all sizes are trapped and moved by the exhaled moist and hot turbulent gas cloud that keeps them concentrated as it carries them over metres in a few seconds.^{1,2} After the cloud slows sufficiently, ventilation, specific patterns of airflow, and type of activity become important. Viral load of the emitter, duration of exposure, and susceptibility of an individual to infection are also important.

Instead of single, fixed physical distance rules, we propose graded recommendations that better reflect the multiple factors that combine to determine risk. This would provide greater protection in the highest risk settings but also greater freedom in lower risk settings, potentially enabling a return towards

normality in some aspects of social and economic life.

Origins of 2 metre rule

The study of how droplets are emitted during speech or more forcefully when coughing or sneezing began in the 19th century, with scientists typically collecting samples on glass or agar plates.³ In 1897, for example, Flugge proposed a 1-2 m safe distance based on the distance over which sampled visible droplets contained pathogens.⁴ In the 1940s, visual documentation of these emissions became possible with close-up still imaging of sneezing, coughing, or talking (fig 1).⁵ A study in 1948 of haemolytic streptococci spread found 65% of the 48 participants produced large droplets only, fewer than 10% of which travelled as far as 5½ feet (1.7 m).⁶ However, in 10% of participants, haemolytic streptococci were collected 9½ feet (2.9 m) away. Despite limitations in the accuracy of these early study designs, especially for longer ranges, the observation of large droplets falling close to a host reinforced and further entrenched the assumed scientific basis of the 1-2 m distancing rule.²



Fig 1 | Short range still imaging of stages of sneezing, revealing the liquid droplets from the 1942 Jennison experiment.⁵ Reproduced with permission

Yet eight of the 10 studies in a recent systematic review showed horizontal projection of respiratory droplets beyond 2 m for particles up to 60 μm .⁷ In one study, droplet spread was detected over 6-8 m (fig 2).²⁸ These results suggest that SARS-CoV-2 could spread beyond

1-2 m in a concentrated packet through coughs or sneezes.² In recent related viral outbreaks, such as SARS-CoV-1, MERS-CoV, and Avian flu, multiple studies reported suspected spread beyond 2 m.^{9 10}

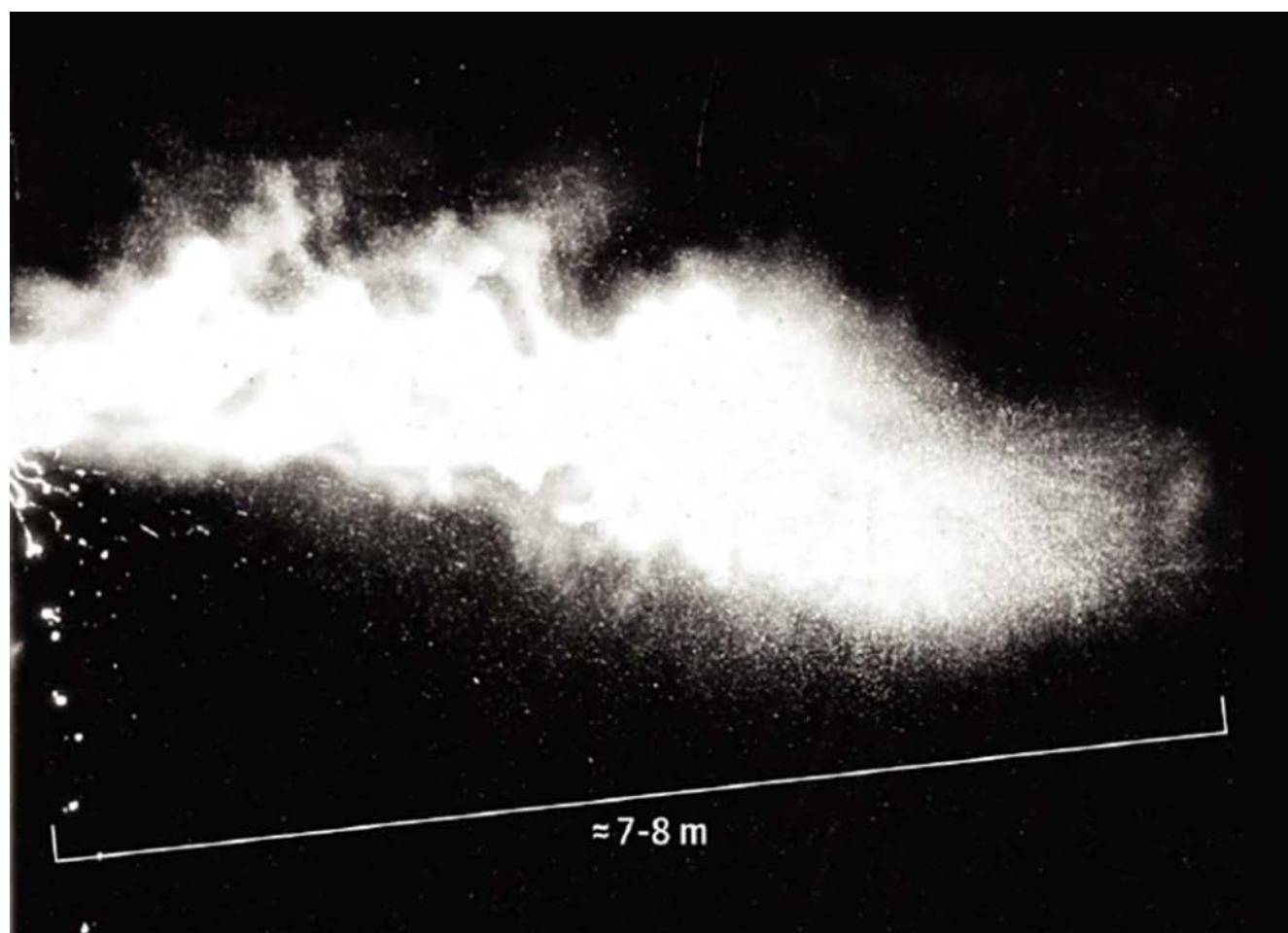


Fig 2 | Long range video imaging over 8 m of the multiphase turbulent cloud (gas cloud containing liquid droplets of all sizes) from natural human violent emission such as a sneeze, revealing a range of the cloud, and its droplet concentrated payload, of up to 7-8 m. Reproduced with permission from Bourouiba²

Droplet size, droplet spread

The 1-2 m rule is based on a longstanding framework which dichotomises respiratory droplets into two sizes, large and small. The size of a droplet is thought to determine how far it will travel from the infected person. According to studies by Wells, emitted large droplets fall through the air more quickly than they evaporate and land within a 1-2 metre range.¹¹ Small droplets (later called aerosols or airborne droplets), typically invisible to the naked eye, evaporate more quickly than they fall. Without airflow, they cannot move far, remaining in the exhaler's vicinity. With airflow they can spread along greater distances.

While conceptually useful up to a point, this dichotomy framework overlooks contemporary science about respiratory exhalations.¹² Droplets exist across a continuum of sizes. Contextual factors such as exhaled air and ambient airflow are extremely important in determining how far droplets of all sizes travel. Without exhaled airflow, the largest droplets would travel furthest (1-2 m), while the small ones would encounter high resistance (drag) and stay close to the source. When accounting for the exhaled airflow, clouds of small droplets can travel beyond 2 m in the air, and even large droplets have enhanced range.^{1,2}

Airborne particle spread of SARS-CoV-2

Diseases that can be transmitted by airborne particles, such as measles and varicella, can travel much further, and in concentrated clouds, than those transmitted by large droplets, which drop from clouds more quickly. They can therefore expose others rapidly and at greater distance^{2,13} and may need different public health measures, including extended physical distancing. Laboratory studies also suggest SARS-CoV-1, SARS-CoV-2, and MERS-CoV viral particles are stable in airborne samples, with SARS-CoV-2 persistent for longest (up to 16 hours).^{14,15}

In a literature search for studies using air sampling techniques to detect viral particles surrounding covid-19 patients, we found nine studies in hospital and two in community settings. Seven of the hospital studies reported at least one airborne sample tested positive for SARS-CoV-2, though the proportion of positive samples across studies ranged between 2% and 64%.¹⁶⁻²² Only two reported positive results in relation to distance from an infected patient (one at 2 m¹⁸ and another at ≥ 4 m in the corridor¹⁷). Of the two hospital studies that did not find SARS-CoV-2 particles in air samples,^{23,24} one collected positive swab samples from ventilation units in the patient's room, which is consistent with airborne droplet spread.²³

Neither community study reported positive air samples, although one collected specimens up to 17 days after covid-19 carriers had left the room²⁵ and the other did not report time of sampling since

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cleaning or sampling distance from the infected person.²⁶ These negative studies thus fall substantially short of proving that airborne spread does not occur.

Only two of the airborne sampling studies directly measured whether SARS-CoV-2 in the samples remained infectious, rather than just analysing for the presence of viral RNA.^{18,21} No viable virus was found in either, though one found signs of viral ability to replicate.¹⁸ Of note, no study found viable virus on surface swabs.

These studies were small, observational, and heterogeneous in terms of setting, participants, sample collection, and handling methods. They were prone to recall bias (few people can accurately recall how close they came to others when asked to remember some time later). Overall, these studies seem to support the possibility of airborne spread of SARS-CoV-2, but they do not confirm that there is a risk of disease transmission.

Force of emission, ventilation, exposure time

Breathing out, singing, coughing, and sneezing generate warm, moist, high momentum gas clouds of exhaled air containing respiratory droplets. This moves the droplets faster than typical background air ventilation flows, keeps them concentrated, and can extend their range up to 7–8 m within a few seconds.^{1,2,8}

These findings from fluid dynamic studies help explain why at one choir practice in the US, a symptomatic person infected at least 32 other singers, with 20 further probable cases, despite physical distancing.²⁷ Other indoor case clusters have been reported within fitness gyms, boxing matches, call centres, and churches, where people might sing, pant, or talk loudly.^{28–30} Interestingly, there have been few reports of outbreaks on aeroplanes,³¹ which may reflect current low volume of passengers, lack of contact tracing, or relatively low risk because speaking is limited. Although publication bias is likely (events linked to outbreaks are more likely to be reported than events where no outbreak occurred), well documented stories of outbreaks demand a scientific explanation.

The heavy panting from jogging and other sports produces violent exhalations with higher momentum than tidal breathing, closer to coughs in some instances. This increases the distance reached by the droplets trapped within the exhaled cloud and supports additional distancing during vigorous exercise.² However, respiratory droplets tend to be more quickly diluted in well aerated outdoor settings, reducing transmission risk (a preprint from Japan reports an 18.7-fold higher risk of transmission in indoor environments than outdoors).²⁸

Specific airflow patterns, and not just average ventilation and air changes, within buildings are also important in determining risk of exposure and transmission. A case report from an outbreak at a restaurant in China described 10 people within three families infected over one hour, at distances of up to 4.6 m and without direct physical contact. The pattern of transmission was consistent with the transient indoor localised ventilation airflow pattern.³²

Few studies have examined how airflow patterns influence viral transmission; most studies report (if anything) only average indoor ventilation rates. Neglecting variation in localised air flow within a space oversimplifies and underestimates risk modelling. In homogeneous flow, patterns are known to emerge in occupied indoor spaces that depend on air conditioning, ventilation system or location, occupancy of the space, air recirculation, and filtration.

Though it is widely assumed that duration of exposure to a person with covid-19 influences transmission risk (studies of contact tracing, for example, consider thresholds of 5–15 minutes beyond which risk increases^{33,34}), we are not aware of studies that quantified this variable.

Distance and transmission risk

The UK's Scientific Advisory Group for Emergencies (SAGE) estimates that the risk of SARS-CoV-2 transmission at 1 m could be 2–10 times higher than at 2 m.³⁵ A systematic review commissioned by the World Health Organization attempted to analyse physical distancing measures in relation to coronavirus transmission.³⁶ Physical distancing of <1 m was reported to result in a transmission risk of 12.8%, compared with 2.6% at distances ≥1 m, supporting physical distancing rules of 1 m or more. The review's limitations should be noted. Not all distances were explicit in the original studies; some were estimated by the review authors. Different distances were used to categorise social contact in different studies (1.8 m was considered close in one study but distant in another, for example), yet these were pooled within the same analysis. The summary relied heavily on data from the SARS-CoV-1 and MERS outbreaks and only partially accounted for environmental confounders.

More nuanced model

Environmental influences are complex and are likely to be mutually reinforcing. This is shown, for example, in meat packing plants, where outbreaks have been attributed to the combination of high levels of worker contagion, poor ventilation, cramped working conditions, background noise (which leads to shouting), and low compliance with mask wearing.³⁷ Similar compound risk situations might occur in other crowded, noisy, indoor environments, such as pubs or live music venues.

Physical distancing rules would be most effective if they reflected graded levels of risk. Figure 3 presents a guide to how transmission risk may vary with setting, occupancy level, contact time, and whether face coverings are worn. These estimates apply when everyone is asymptomatic. In the highest risk situations (indoor environments with poor ventilation, high levels of occupancy, prolonged contact time, and no face coverings, such as a crowded bar or night club) physical distancing beyond 2 m and minimising occupancy time should be considered. Less stringent distancing is likely to be adequate in low risk scenarios. People with symptoms (who should in any case be self-isolating) tend to have high viral load and more frequent violent respiratory exhalations.

Type and level of group activity	Low occupancy			High occupancy		
	Outdoors and well ventilated	Indoors and well ventilated	Poorly ventilated	Outdoors and well ventilated	Indoors and well ventilated	Poorly ventilated
Wearing face coverings, contact for short time						
Silent	Low	Low	Low	Low	Low	Medium
Speaking	Low	Low	Low	Low	Low	Medium
Shouting, singing	Low	Low	Medium	Medium	Medium	High
Wearing face coverings, contact for prolonged time						
Silent	Low	Low	Medium	Low	Medium	High
Speaking	Low	* Low	Medium	* Medium	Medium	High
Shouting, singing	Low	Medium	High	Medium	High	High
No face coverings, contact for short time						
Silent	Low	Low	Medium	Medium	Medium	High
Speaking	Low	Medium	Medium	Medium	High	High
Shouting, singing	Medium	Medium	High	High	High	High
No face coverings, contact for prolonged time						
Silent	Low	Medium	High	Medium	High	High
Speaking	Medium	Medium	High	High	High	High
Shouting, singing	Medium	High	High	High	High	High

Risk of transmission
 Low ■ Medium ■ High ■

* Borderline case that is highly dependent on quantitative definitions of distancing, number of individuals, and time of exposure

Fig 3 | Risk of SARS-CoV-2 transmission from asymptomatic people in different settings and for different occupation times, venting, and crowding levels (ignoring variation in susceptibility and viral shedding rates). Face covering refers to those for the general population and not high grade respirators. The grades are indicative of qualitative relative risk and do not represent a quantitative measure. Other factors not presented in these tables may also need to be taken into account when considering transmission risk, including viral load of an infected person and people's susceptibility to infection. Coughing or sneezing, even if these are due to irritation or allergies while asymptomatic, would exacerbate risk of exposure across an indoor space, regardless of ventilation

The levels of risk in [fig 3](#) are relative not absolute, especially in relation to thresholds of time and occupancy, and they do not include additional factors such as individuals' susceptibility to infection, shedding level from an infected person, indoor airflow patterns, and where someone is placed in relation to the infected person. Humidity may also be important, but this is yet to be rigorously established.

Further work is needed to extend our guide to develop specific solutions to classes of indoor environments occupied at various usage levels. Urgent research is needed to examine three areas of uncertainty: the cut-off duration of exposures in relation to the indoor condition, occupancy, and level of viral shedding (5-15 minute current ad-hoc rules), which does not seem to be supported by evidence; the detailed study of airflow patterns with respect to the infected source and its competition with average venting; and the patterns and properties of respiratory emissions and droplet infectivity within them during various physical activities.

Physical distancing should be seen as only one part of a wider public health approach to containing the covid-19 pandemic. It needs to be implemented alongside combined strategies of people-air-surface-space management, including hand hygiene, cleaning, occupancy and indoor space and air managements, and appropriate protective equipment, such as masks, for the setting.

Key messages

- Current rules on safe physical distancing are based on outdated science
- Distribution of viral particles is affected by numerous factors, including air flow
- Evidence suggests SARS-CoV-2 may travel more than 2 m through activities such as coughing and shouting
- Rules on distancing should reflect the multiple factors that affect risk, including ventilation, occupancy, and exposure time

Contributors and sources: This article was adapted from a rapid review undertaken as part of the Oxford COVID-19 Evidence Service (<https://www.cebm.net/covid-19/what-is-the-evidence-to-support-the-2-metre-social-distancing-rule-to-reduce-covid-19-transmission/>); all authors contributed to its development and approved the final manuscript.

ANALYSIS

Patient and public involvement: Three members of the public provided feedback on the article. They strongly supported the need for an in-depth analysis of physical distancing and thought our summary figure was helpful in presenting factors that influence categories of risk. Specific feedback led to additional discussion points addressing transmission risk in complex settings such as the meat packing industry and with exercise.

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- 1 Bourouiba L, Dehandschoewercker E, Bush John WM. Violent expiratory events: on coughing and sneezing. *J Fluid Mech* 2014;745:537-63. doi: 10.1017/jfm.2014.88.
- 2 Bourouiba L. Turbulent gas clouds and respiratory pathogen emissions: potential implications for reducing transmission of COVID-19. *JAMA* 2020. [Epub ahead of print.] doi: 10.1001/jama.2020.4756. pmid: 32215590
- 3 Papineni RS, Rosenthal FS. The size distribution of droplets in the exhaled breath of healthy human subjects. *J Aerosol Med* 1997;10:105-16. doi: 10.1089/jam.1997.10.105. pmid: 10168531
- 4 Flugge C. Über luftinfection. *Z Hyg Infektionskr* 1897;25:179-224.
- 5 Turner CE, Jennison MW, Edgerton HE. Public health applications of high-speed photography. *Am J Pub Health* 1941 Apr;319-24.
- 6 Hamburger M, JrRobertson OH. Expulsion of group A hemolytic streptococci in droplets and droplet nuclei by sneezing, coughing and talking. *Am J Med* 1948;4:690-701. doi: 10.1016/S0002-9343(48)90392-1. pmid: 18856764
- 7 Bahl P, Doolan C, de Silva C, Chughtai AA, Bourouiba L, MacIntyre CR. Airborne or droplet precautions for health workers treating COVID-19? *J Infect Dis* 2020. doi: 10.1093/infdis/jiaa189. pmid: 32301491
- 8 Bourouiba L. Images in clinical medicine. A sneeze. *N Engl J Med* 2016;375. doi: 10.1056/NEJMicm1501197. pmid: 27557321
- 9 Yu ITS, Li Y, Wong TW, et al. Evidence of airborne transmission of the severe acute respiratory syndrome virus. *N Engl J Med* 2004;350:1731-9. doi: 10.1056/NEJMoa032867. pmid: 15102999
- 10 Tang JW, Li Y, Eames I, Chan PK, Ridgway GL. Factors involved in the aerosol transmission of infection and control of ventilation in healthcare premises. *J Hosp Infect* 2006;64:100-14. doi: 10.1016/j.jhin.2006.05.022. pmid: 16916564
- 11 Wells WF. Airborne contagion and air hygiene: an ecological study of droplet infections. *JAMA* 1955;159:90.
- 12 Borak J. Airborne transmission of covid-19. *Occup Med (Lond)* 2020;70:297-9. doi: 10.1093/occmed/kqaa080. pmid: 32476011
- 13 Shiu EYC, Leung NHL, Cowling BJ. Controversy around airborne versus droplet transmission of respiratory viruses: implication for infection prevention. *Curr Opin Infect Dis* 2019;32:372-9. doi: 10.1097/QCO.0000000000000563. pmid: 31259864
- 14 Fears AC, Klimstra WB, Duprex P, et al. Persistence of severe acute respiratory syndrome coronavirus 2 in aerosol suspensions. *Emerg Infect Dis* 2020;26. doi: 10.3201/eid2609.201806. pmid: 32568661
- 15 van Doremalen N, Bushmaker T, Morris DH, et al. Aerosol and surface stability of SARS-CoV-2 as compared with SARS-CoV-1. *N Engl J Med* 2020;382:1564-7. doi: 10.1056/NEJMc2004973. pmid: 32182409
- 16 Liu Y, Ning Z, Chen Y, et al. Aerodynamic analysis of SARS-CoV-2 in two Wuhan hospitals. *Nature* 2020;582:557-60. doi: 10.1038/s41586-020-2271-3. pmid: 32340022
- 17 Guo Z-D, Wang Z-Y, Zhang S-F, et al. Aerosol and surface distribution of severe acute respiratory syndrome coronavirus 2 in hospital wards, Wuhan, China, 2020. *Emerg Infect Dis* 2020;26:1583-91. doi: 10.3201/eid2607.200885. pmid: 32275497
- 18 Santarpia JL, Rivera DN, Herrena V. Transmission potential of SARS-CoV-2 in viral shedding observed at the University of Nebraska Medical Center. *medRxiv* 2020.2003.2023.20039446. [Preprint.] doi: 10.1101/2020.03.23.20039446
- 19 Ding Z, Qian H, Xu B, et al. Toilets dominate environmental detection of SARS-CoV-2 virus in a hospital. *medRxiv* 2020.04.03.20052175. [Preprint.] doi: 10.1101/2020.04.03.20052175
- 20 Chia PY, Coleman KK, Tan YK, et al. Detection of air and surface contamination by severe acute respiratory syndrome 2 coronavirus 2 (SARS-CoV-2) in hospital rooms of infected patients. *medRxiv* 2020.03.29.20046557. [Preprint.] doi: 10.1101/2020.03.29.20046557.
- 21 Zhou J, Otter J, Price J, et al. Investigating SARS-CoV-2 surface and air contamination in an acute healthcare setting during the peak of the COVID-19 pandemic in London. *medRxiv* 2020.05.24.20110346 [Preprint.] doi: 10.1101/2020.05.24.20110346
- 22 Ma J, Qi X, Chen H, et al. Exhaled breath is a significant source of SARS-CoV-2 emission. *medRxiv* 2020.05.31.20115154. [Preprint.] doi: 10.1101/2020.05.31.20115154
- 23 Ong SWX, Tan YK, Chia PY, et al. Air, surface environmental, and personal protective equipment contamination by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) from a symptomatic patient. *JAMA* 2020. [Epub ahead of print.] doi: 10.1001/jama.2020.3227. pmid: 32129805
- 24 Wu S, Wang Y, Jin X, Tian J, Liu J, Mao Y. Environmental contamination by SARS-CoV-2 in a designated hospital for coronavirus disease 2019. *Am J Infect Control* 2020;48:910-4. doi: 10.1016/j.ajic.2020.05.003. pmid: 32407826
- 25 Yamagishi T. Environmental sampling for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) during a coronavirus disease (COVID-19) outbreak aboard a commercial cruise ship. *medRxiv* 2020.05.02.20088567. [Preprint.] doi: 10.1101/2020.05.02.20088567
- 26 Döhla M, Wilbring G, Schulte B, et al. SARS-CoV-2 in environmental samples of quarantined households. *medRxiv* 2020.05.28.20114041. [Preprint.] doi: 10.1101/2020.05.28.20114041
- 27 Hamner L, Dubbel P, Capron I, et al. High SARS-CoV-2 attack rate following exposure at a choir practice—Skagit County, Washington, March 2020. *MMWR Morb Mortal Wkly Rep* 2020;69:606-10. doi: 10.15585/mmwr.mm6919e6. pmid: 32407303
- 28 Nishiura H, Oshitani H, Kobayashi T, et al. Closed environments facilitate secondary transmission of coronavirus disease 2019 (COVID-19). *medRxiv* 2020.02.28.20029272. doi: 10.1101/2020.02.28.20029272
- 29 Leclerc QJ, Fuller NM, Knight LE, Funk S, Knight GMCMMID COVID-19 Working Group. What settings have been linked to SARS-CoV-2 transmission clusters? *Wellcome Open Res* 2020;5:83. doi: 10.12688/wellcomeopenres.15889.2. pmid: 32656368
- 30 Park SY, Kim YM, Yi S, et al. Coronavirus disease outbreak in call center, South Korea. *Emerg Infect Dis* 2020;26:1666-70. doi: 10.3201/eid2608.201274. pmid: 32324530
- 31 Yang N, Shen Y, Shi C, et al. In-flight transmission cluster of covid-19: a retrospective case series. *medRxiv* 2020.03.28.20040097 [Preprint.] doi: 10.1101/2020.03.28.20040097
- 32 Li Y, Qian H, Hang J, et al. Evidence for probable aerosol transmission of SARS-CoV-2 in a poorly ventilated restaurant. *medRxiv* 2020.04.16.20067728. [Preprint.] doi: 10.1101/2020.04.16.20067728
- 33 Cheng H-Y, Jian S-W, Liu D-P, et al. High transmissibility of covid-19 near symptom onset. *medRxiv* 2020.03.18.20034561. [Preprint.] doi: 10.1101/2020.03.18.20034561
- 34 Doung-ngern P, Suphanchaimat R, Panjagampattthana A, et al. Associations between wearing masks, washing hands, and social distancing practices, and risk of COVID-19 infection in public: a cohort-based case-control study in Thailand. *medRxiv* 2020.06.11.20128900. [Preprint.] doi: 10.1101/2020.06.11.20128900.
- 35 Scientific Advisory Group on Emergencies. Transmission of SARS-CoV-2 and mitigating measures. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/892043/S0484_Transmission_of_SARS-CoV-2_and_Mitigating_Measures.pdf
- 36 Chu DK, Akl EA, Duda S, Solo K, Yaacoub S, Schünemann HJCOVID-19 Systematic Urgent Review Group Effort (SURGE). Physical distancing, face masks, and eye protection to prevent person-to-person transmission of SARS-CoV-2 and COVID-19: a systematic review and meta-analysis. *Lancet* 2020;395:1973-87. doi: 10.1016/S0140-6736(20)31142-9. pmid: 32497510
- 37 Dyal JW, Grant MP, Broadwater K, et al. COVID-19 among workers in meat and poultry processing facilities - 19 States, April 2020. *MMWR Morb Mortal Wkly Rep* 2020;69. doi: 10.15585/mmwr.mm6918e3. pmid: 32379731

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Long distance airborne transmission of SARS-CoV-2: rapid systematic review

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Abstract

OBJECTIVES

To evaluate the potential for long distance airborne transmission of SARS-CoV-2 in indoor community settings and to investigate factors that might influence transmission.

DESIGN

Rapid systematic review and narrative synthesis.

DATA SOURCES

Medline, Embase, medRxiv, Arxiv, and WHO COVID-19 Research Database for studies published from 27 July 2020 to 19 January 2022; existing relevant rapid systematic review for studies published from 1 January 2020 to 27 July 2020; and citation analysis in Web of Science and Cocites.

ELIGIBILITY CRITERIA FOR STUDY SELECTION

Observational studies reporting on transmission events in indoor community (non-healthcare) settings in which long distance airborne transmission of SARS-CoV-2 was the most likely route. Studies such as those of household transmission where the main transmission route was likely to be close contact or fomite transmission were excluded.

DATA EXTRACTION AND SYNTHESIS

Data extraction was done by one reviewer and independently checked by a second reviewer. Primary outcomes were SARS-CoV-2 infections through long distance airborne transmission (>2 m) and any modifying factors. Methodological quality of included

studies was rated using the quality criteria checklist, and certainty of primary outcomes was determined using the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) framework. Narrative synthesis was themed by setting.

RESULTS

22 reports relating to 18 studies were identified (methodological quality was high in three, medium in five, and low in 10); all the studies were outbreak investigations. Long distance airborne transmission was likely to have occurred for some or all transmission events in 16 studies and was unclear in two studies (GRADE: very low certainty). In the 16 studies, one or more factors plausibly increased the likelihood of long distance airborne transmission, particularly insufficient air replacement (very low certainty), directional air flow (very low certainty), and activities associated with increased emission of aerosols, such as singing or speaking loudly (very low certainty). In 13 studies, the primary cases were reported as being asymptomatic, presymptomatic, or around symptom onset at the time of transmission. Although some of the included studies were well conducted outbreak investigations, they remain at risk of bias owing to study design and do not always provide the level of detail needed to fully assess transmission routes.

CONCLUSION

This rapid systematic review found evidence suggesting that long distance airborne transmission of SARS-CoV-2 might occur in indoor settings such as restaurants, workplaces, and venues for choirs, and identified factors such as insufficient air replacement that probably contributed to transmission. These results strengthen the need for mitigation measures in indoor settings, particularly the use of adequate ventilation.

SYSTEMATIC REVIEW REGISTRATION

PROSPERO CRD42021236762.

Introduction

Since the early stages of the covid-19 pandemic and the first reports of superspreader events,^{1 2} the body of evidence suggesting airborne transmission of SARS-CoV-2 in the absence of aerosol generating procedures has grown. However, despite the publication of numerous opinion pieces and narrative reviews in support of airborne transmission of SARS-CoV-2,³⁻⁹ scientific consensus on the relative importance of this route of transmission is lacking. Part of the controversy arises from differences in terminology, definitions, and size thresholds for respiratory particles.¹⁰

Traditionally, close contact transmission was assumed to occur through droplets with ballistic trajectory that directly deposit on mucous membranes,

WHAT IS ALREADY KNOWN ON THIS TOPIC

The risk of SARS-CoV-2 transmission is likely to be greatest when in close proximity (<2 m) to someone who is infected

The potential for long distance airborne transmission (>2 m) is unclear, although widespread reporting of superspreader events suggests it may occur

Emission rates of respiratory particles released vary considerably between individuals but are generally higher for singing and speaking compared with breathing and tend to increase with loudness of vocalisation

WHAT THIS STUDY ADDS

The findings from this rapid systematic review suggest that long distance airborne transmission of SARS-CoV-2 might happen in indoor settings such as restaurants, public transport, workplaces, or choir venues

These results show that factors such as insufficient air replacement, directional air flow, and activities associated with increased emissions of respiratory particles (eg, singing or speaking loudly) might contribute to long distance airborne transmission

Well conducted epidemiological investigations can provide critical insight into transmission routes, especially when other types of studies are not feasible; the question of what level of public health evidence is sufficient to support decision making for a novel infection warrants further consideration

whereas airborne transmission was assumed to occur over longer distances via smaller particles (aerosols) that remained suspended in the air and were subsequently inhaled.^{10 11} Limitations of this dichotomy are well illustrated by the challenge in defining a size range to characterise particles that are droplets or aerosols.^{6 7 10 12} For example, the World Health Organization threshold is set at 5-10 microns¹³ whereas in the UK the threshold is based on the work by Milton¹⁴ and set to 100 microns.¹⁵ This is also complicated by the role of evaporation, as a particle will get smaller as it moves from human sources.

Regardless of terminology and definitions, it is now understood that short range transmission can occur through both droplets and aerosols and that the concentration of respiratory particles is higher at short range than over longer distances.^{7 11 16 17} Consensus is, however, still lacking on the risk for long distance airborne transmission in indoor settings in the community such as hospitality venues, leisure facilities, workplaces, or apartment blocks. This lack of consensus also reflects the challenging nature of the evidence base, and high quality review level evidence is still needed; some systematic reviews have relied on environmental sampling studies, which only provide indirect evidence of the potential risk of airborne transmission,¹⁸⁻²⁰ whereas systematic reviews that have included a wider range of study designs (epidemiological, environmental, and modelling) and settings (healthcare and community) remain inconclusive.²¹⁻²⁴

This gap needs to be addressed from a public health perspective, focusing on long distance transmission (>2 m) in indoor community settings. As evidence on the biological plausibility of long distance airborne transmission is available from environmental and experimental studies,^{18 21 22} we focused on epidemiological observational studies to assess where and when human-to-human transmission are likely to occur. In this rapid review we systematically identified and examined such studies to evaluate the potential for long distance airborne transmission of SARS-CoV-2 in indoor community settings and to assess the impact of potential modifying factors.

Methods

We used a rapid systematic review approach, following streamlined systematic methodologies to accelerate the review process,²⁵ and reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020 guidelines.²⁶ The protocol for this review was registered on PROSPERO before screening took place.²⁷

Data sources and searches

We identified primary studies through two sources. Firstly, we screened studies included in the rapid systematic review by Comber et al for those published from 1 January 2020 to 27 July 2020.²¹ This systematic review, assessed to be of moderate quality using the AMSTAR 2 (A MeaSurement Tool to Assess systematic

Reviews, revised) critical appraisal tool,²⁸ contains a comprehensive search strategy and wider inclusion criteria than the current rapid review (studies related to all airborne transmission of SARS-CoV-2) and was the only relevant review available at the time we wrote our protocol.

Secondly, we conducted electronic searches in Ovid Medline, Ovid Embase, medRxiv, Arxiv, and WHO COVID-19 Research Database for studies published from 27 July 2020 to 19 January 2022. The initial search was conducted on 8 February 2021 and last updated on 19 January 2022. The search strategy was drafted by an information scientist and peer reviewed by a second information scientist. Supplementary material 1 (section 1) shows the full search strategy.

Using the studies that met our inclusion criteria, we performed a citation analysis on 1 February 2022 on Web of Science and Cocites (co-citation analysis, forward and backwards snowballing). Although this was not part of the search strategy outlined in the protocol, it was agreed a posteriori by the review team to increase the chance of additional relevant studies being retrieved.

Eligibility criteria for study selection

Our eligibility criteria for study selection were published articles, accepted manuscripts, and preprints reporting on the potential for airborne transmission of SARS-CoV-2 in indoor community (non-healthcare) settings at a distance >2 m (the 2 m threshold is based on UK regulations; we also considered for inclusion non-UK studies that used thresholds based on their respective national recommendations, such as 1.5 m or 6 feet/1.8 m). The aim was to include all observational studies (outbreak investigations and epidemiological case series, cohort, case-control, and cross sectional studies) of any human population in non-healthcare settings. We excluded systematic or narrative reviews, guidelines, opinion pieces, intervention studies, modelling studies, environmental sampling studies without epidemiological investigation, laboratory or virology studies, and animal studies. We also excluded observational studies in which close contact or fomite were the most likely transmission routes (eg, studies reporting on transmission in households).

Screening was performed using Rayyan Systems, a freely available online screening tool.²⁹ Two reviewers independently screened the first 10% of records retrieved from the initial search on title and abstract, with substantial agreement (97.7%; Cohen's $\kappa=0.61$). A single reviewer screened the remainder, and two reviewers independently screened a further 10% (of the total number of records), with almost perfect agreement (99.6%; Cohen's $\kappa=0.92$). All records selected were screened at full text by one reviewer and checked by a second reviewer, with any discrepancies resolved by discussion with a third reviewer.

Outcomes

The primary outcomes were SARS-CoV-2 infections through long distance airborne transmission (at

a distance >2 m), and any factors that might have modified the risk of transmission under these conditions. Included measures for SARS-CoV-2 infections were number of covid-19 cases; secondary attack rates; risk, rate, or odds of transmission over the stipulated distances; or any other reported measure related to transmission rate. For the modifying factors, we considered narrative on the type of effect and any potentially relevant information to be acceptable.

Additional outcomes extracted, when available, were time spent in the setting and distance over which airborne transmission was thought to have occurred.

Data extraction and synthesis

We developed a data extraction table to gather information on methods, participants, settings, outcomes, key findings, and any additional relevant information (eg, whether participants wore face coverings). Data extraction was completed for each included study by one reviewer and independently checked by a second reviewer, with discrepancies resolved by discussion. Only evidence directly relevant to the review question was extracted. For example, if studies reported on different outbreaks or on onward transmission that might have happened in different settings, we only extracted the results of outbreaks or settings when distance and transmission routes could be assessed.

A narrative summary of results according to indoor setting was produced.

Quality assessment and certainty of evidence

We used a quality criteria checklist for primary research to assess the methodological quality of each included study.³⁰ This checklist tool is composed of 10 questions, four of which are considered critical (questions on selection bias, group comparability, description of exposure/assessment of transmission routes, and validity of outcome measurements). Strict criteria were used to assess the two critical questions related to exposure and outcome assessment. In particular, a cluster of covid-19 cases in the setting of interest had to be confirmed with viral genomic sequencing to be considered as low risk of bias for validity of outcome measurements. Supplementary material 1 (section 2) lists the 10 questions of the quality criteria checklist.

A study was rated as high methodological quality if the answers were yes to the four critical questions plus at least one of the remaining questions. A study was rated as low methodological quality if answers were no to ≥50% of the critical questions. Otherwise, the study was rated as medium methodological quality. Each study was assessed independently in duplicate, with disagreements resolved by consensus.

Certainty of the evidence was assessed using a variation of the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) framework for systematic reviews without meta-analysis.³¹ We assessed each of the five GRADE domains (methodological limitations of the studies,

indirectness, imprecision, inconsistency, and likelihood of publication bias) and classified them as no limitation or not serious (not important enough to warrant downgrading), serious (downgrading the certainty rating by one level), or very serious (downgrading the certainty rating by two levels). We then classified the body of evidence for a specific outcome as high certainty, moderate certainty, low certainty, or very low certainty.

Patient and public involvement

Patients and members of the public were not involved in this rapid systematic review mainly because of time restrictions. The review question was, however, developed with the input of several public health experts and stakeholders.

Results

Study selection

After removal of duplicates, 7439 records were screened for relevance on title and abstract, with 90 reports assessed for eligibility (fig 1). Fifty six additional reports identified from the Comber et al rapid review²¹ and by citation analysis were also assessed. From these 146 reports, 124 were excluded (see supplementary material 1 (section 3) for list of reasons for exclusion), and 22 reports^{1 32-52} relating to 18 studies were included. When two or more reports related to the same study, we considered the most comprehensive report as the main publication.

All the studies investigated outbreaks of clusters of SARS-CoV-2 infections, and one study had an analytical component.³⁶ Eight studies were conducted in Asia,^{34-40 45} five in Europe,^{41 43 44 47 48} three in Oceania,^{32 33 46} and two in the United States.^{1 42} Three studies reported on transmission between flats in apartment blocks,³⁸⁻⁴⁰ two in quarantine hotels,^{32 33} two in restaurants,^{34 35} two in buses,^{36 37} one in a food processing factory,⁴¹ one in a courtroom,⁴³ one in an office,⁴⁴ one in a fitness facility,⁴² one in a department store,⁴⁵ and four during singing events.^{1 46-48} All the outbreaks occurred in 2020, except for one in January 2021 in South Korea⁴⁰ (before vaccine rollout started in this country) and one in July 2021 in a quarantine hotel in New Zealand.³³

Table 1 and table 2 summarise the studies by setting. Supplementary material 2 provides detailed information on each study.

Quality assessment

Figure 2 provides details of the methodological quality ratings: three studies were rated as high quality,^{33 35 46} five as medium quality,^{32 34 36 41 47} and 10 as low quality.^{1 37-40 42-45 48} These ratings represent the methodological quality of descriptive studies.

Transmission settings

Quarantine hotels

Two outbreaks of covid-19 in quarantine hotels were identified, both in New Zealand and involving cases part of the same genomic cluster who had quarantined

RESEARCH

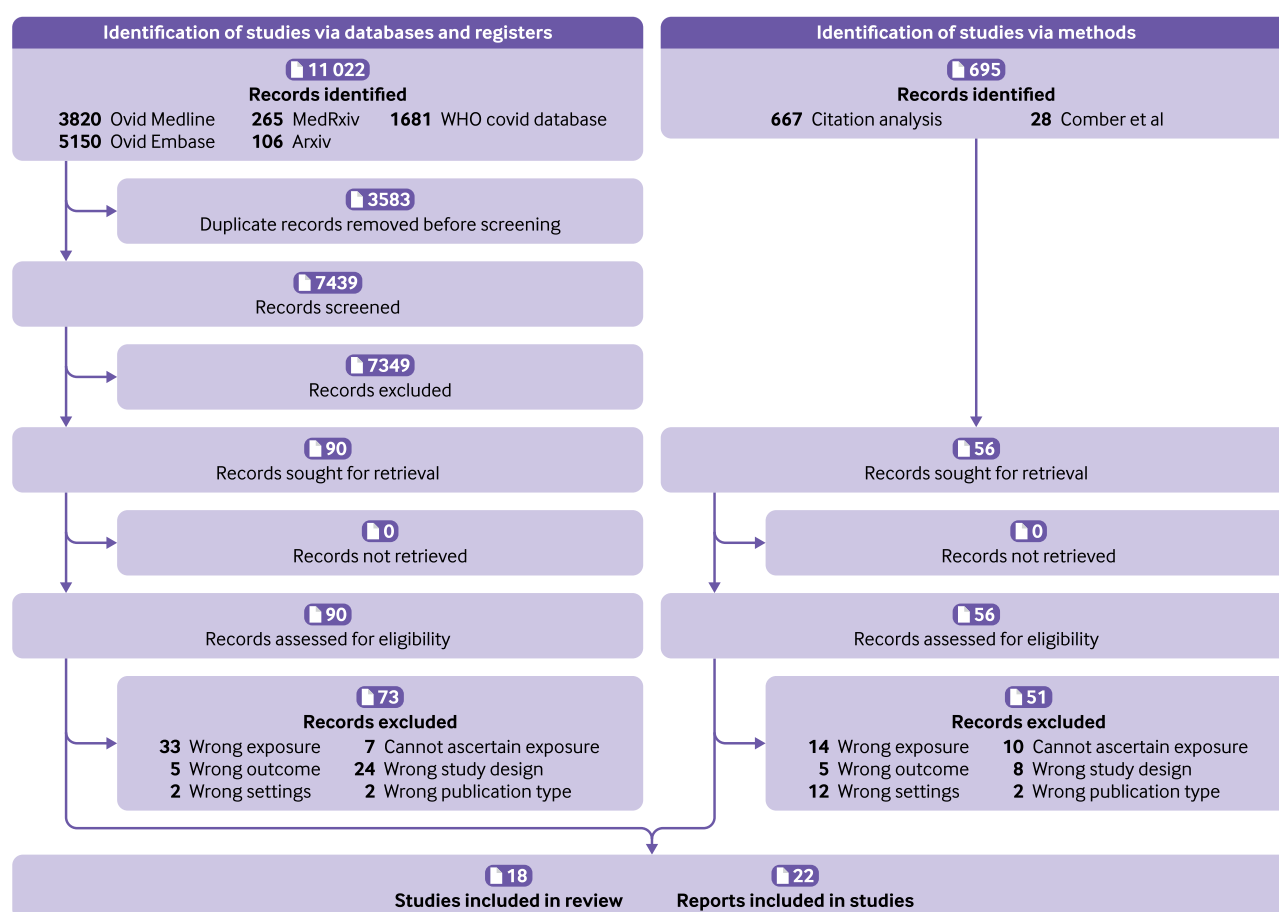


Fig 1 | Flow of articles through the review

in separate rooms. The first outbreak, reported by Eichler et al³² (rated as medium methodological quality) occurred in September 2020, and although primary and secondary cases had travelled on the same flight, transmission is believed to have happened in the hotel on day 12 of quarantine, after the primary case had developed symptoms on day 10. No information was provided on the measures in place at this quarantine hotel (eg, use of face coverings). The second outbreak, reported by Fox-Lewis et al³³ (rated as high methodological quality) occurred in July 2021. The primary case (asymptomatic) and secondary cases had travelled on different flights and arrived at the hotel on different days. Staff members, all vaccinated, wore full personal protective equipment and were regularly tested. Participants were asked to wear surgical masks when opening doors, but this could not be validated in the investigation. None of the cases (primary or secondary) were vaccinated; the only person who was vaccinated tested negative despite being part of the same travel group as the secondary cases.

Close contact and fomite transmission were ruled out by video analysis in both studies, although in the outbreak reported by Eichler et al³² fomite transmission through a communal bin—although unlikely, cannot be ruled out. Video analysis showed that in both outbreaks the doors of the rooms had

been opened simultaneously for a short period during which infected respiratory particles could have moved between rooms. Both investigations included a review of the ventilation systems and found that pressure differences between rooms and corridors could support this hypothesis. Long distance airborne transmission between a primary case and at least one secondary case was therefore considered to be the most likely route in both outbreaks.

Restaurants

Two separate outbreaks of covid-19 in restaurants were identified. The first outbreak, in China in January 2020, was mainly reported by Li et al³⁴ (rated as medium methodological quality), with additional evidence provided in two other reports.^{49 50} This outbreak involved a primary case (with symptom onset later that day) and at least two secondary cases who were seated on tables between 1.4 and 4.6 m away from the primary case. The second outbreak, reported by Kwon et al³⁵ (rated as high methodological quality), occurred in June 2020 in South Korea and involved three people with confirmed covid-19 who belonged to the same genomic cluster. The primary case, which was presymptomatic at the time, sat 6.5 m from one secondary case for five minutes, and 4.8 m from the other secondary cases for 21 minutes, all at different tables.

Table 1 | Summary of included studies, in chronological order by setting: quarantine hotels, restaurants, buses, and apartment blocks

Reference (quality rating)	Transmission event, setting, date	No of cases	Outcome and exposure assessment	Potential for other transmission routes	Potential for airborne transmission >2 m*	Modifying factors
Li et al, ³⁴ Lu et al, ⁴⁹ Zhang et al ⁵⁰ (medium)	Restaurant, China, January 2020	Ten confirmed cases from three tables	No genomic sequencing. Epidemiological data, video recording, on-site visit, design of air conditioning and ventilation system, experiments to assess airflow and ventilation rates	Close contact or fomite transmission unlikely (except for cases in same household). Transmission from outside event possible for some cases	Possible airborne transmission between primary case and at least two secondary cases; up to 1.4 m (53 min) and 4.6 m (75 min) from primary case	Insufficient air replacement. Directional air flow through air circulation units
Shen et al ³⁶ (medium)	Buses, China, January 2020	Twenty four confirmed cases	No genomic sequencing. Questionnaires and interviews, contact tracing data, bus design, and ventilation system	Close contact, fomite transmission, or transmission from outside event possible for some cases	Possible airborne transmission >2 m from primary case (50 min)	Insufficient air replacement. Directional air flow from central heating system
Luo et al, ³⁷ Ou et al ⁵¹ (low)	Buses, China, January 2020	Nine confirmed cases	No genomic sequencing. Epidemiological data, information on loading and unloading stops of all passengers, and seating positions, ventilation systems, tracer gas experiments	Close contact unlikely. Fomite transmission or transmission from outside event possible for some cases	Possible airborne transmission >2 m for some cases (1 hour to 2.5 hours)	Insufficient air replacement. Directional air flow due to exhaust system
Lin et al ³⁸ (low)	Apartment block, China, January 2020	Nine confirmed cases from three households	No whole genome sequencing (partial S gene only). Interviews with cases, CCTV of lift, tracer gas and wind speed experiments	Close contact or fomite transmission unlikely (except for cases in same household); transmission from outside event possible for some cases	Possible airborne transmission between cases in one flat to two different flats (up to 10 floors from flat of primary case)	Insufficient air replacement. Directional air flow through drainage and exhaust system
Kwon et al ³⁵ (high)	Restaurant, South Korea, June 2020	Three confirmed cases	Genomic sequencing. Contact tracing, interviews, credit card records, video recording, mobile phone location data, on-site visits, air flow measurement, environmental sampling	Close contact, fomite transmission, or transmission from outside event unlikely	Possible airborne transmission between cases seated 4.8 m (21 min) and 6.5 m (5 min) from the primary case	Insufficient air replacement. Directional air flow through air circulation units
Hwang et al ³⁹ (low)	Apartment block, South Korea, August 2020	Ten confirmed cases from seven households	No genomic sequencing. Epidemiological data, surface sampling, building assessment	Close contact or fomite transmission unlikely (except for cases in same household). Transmission from outside event possible	Possible airborne transmission through ventilation ducts across floors for some secondary cases	Directional air flow through vertical air duct or floor drain. Insufficient air replacement (unclear)
Eichler et al ³² (medium)	Quarantine hotel, New Zealand, August-September 2020	Nine confirmed cases, with one secondary case considered for long distance transmission	Genomic sequencing. Epidemiological data, surveillance video, review of ventilation system in hotel	Close contact or fomite transmission unclear. Transmission from outside event unlikely	Possible airborne transmission from hotel room of the primary case to doorway or corridor for one secondary case	Insufficient air replacement. Directional air flow
Han et al ⁴⁰ (low)	Apartment block, South Korea, January 2021	Five secondary cases (three households) considered for long distance transmission	Genomic sequencing. Epidemiological data, interviews, mobile phone location tracking, surface sampling	Close contact or fomite transmission unlikely (except for cases in same household). Transmission from outside event unlikely	Possible airborne transmission through floor drains across three floors for two secondary cases	Insufficient air replacement. Directional air flow through vertical floor drain
Fox-Lewis et al ³³ (high)	Quarantine hotel, New Zealand, July 2021	Five confirmed cases in two rooms	Genomic sequencing. Epidemiological data, surveillance video, review of ventilation system in hotel	Close contact, fomite transmission, or transmission from outside of event unlikely	Possible airborne transmission from hotel room of primary case to hotel room for at least one secondary case (2.1 m)	Insufficient air replacement. Directional air flow

This review's assessment of likelihood of airborne transmission of SARS-CoV-2 over distances >2 m is based on likelihood of it occurring in some, but not necessarily all, transmission events.

*Exposure distance and time are stated when known; if not stated they are categorised as not clear or not specified.

After extensive epidemiological and environmental investigations, both studies suggested that the most plausible route was long distance airborne transmission, which could have been facilitated by air circulation units generating a directional air flow from the primary to secondary cases combined with lack of air replacement. In both outbreaks close contact and fomite transmission were ruled out based on video surveillance analysis.

Buses and coaches

Two separate outbreaks of covid-19 on buses in China in January 2020 were identified, one on a journey to

and from a worship event among lay Buddhists³⁶ and one on a long distance journey using a public coach and minibus.^{37 51}

The outbreak at a worship event was reported by Shen et al³⁶ who conducted a retrospective epidemiological investigation with an analytical component (rated as medium methodological quality). Thirty one of the 300 participants tested positive for SARS-CoV-2 of whom seven were likely to have been infected by close contact transmission during the religious event. The other 23 cases had travelled to the event in the same bus as the primary case and were thought to have been mainly infected during the bus journey, throughout

RESEARCH

Table 2 | Summary of included studies, in chronological order by setting: department store, singing events, meat processing plant, fitness facility, courtroom, and office

Reference (quality rating)	Transmission event, setting, date	No of cases	Outcome and exposure assessment	Potential for other transmission routes	Potential for airborne transmission >2 m*	Modifying factors
Jiang et al ⁴⁵ (low)	Department store, China, January 2020	Twenty four cases, with 12 secondary cases considered for long distance transmission	No genomic sequencing. Epidemiological data, surveillance video, assessment of ventilation conditions	Close contact, fomite transmission, or transmission from outside event all possible	Unclear airborne transmission across different sections of the store	Not applicable
Hamner et al, ¹ Miller et al ⁵² (low)	Singing event, USA, March 2020	Fifty two: 32 confirmed cases, 20 probable cases	No genomic sequencing. Telephone interviews	Close contact or transmission from outside event possible for some cases. Fomite transmission unlikely	Possible airborne transmission >2 m for some cases, owing to high secondary attack rate (2.5 hours)	Insufficient air replacement. Increased aerosol emission—singing
Charlotte et al ⁴⁸ (low)	Singing event, France, March 2020	Nineteen: seven confirmed cases, 12 probable cases	No genomic sequencing. Questionnaire and telephone interviews	Close contact possible for some cases. Fomite transmission unlikely. Transmission from outside event possible for at least two cases	Possible airborne transmission >2 m for some cases, owing to high secondary attack rate (2 hours)	Insufficient air replacement. Increased aerosol emission—singing
Gunther et al ⁴¹ (medium)	Meat processing plant, Germany, May-June 2020	Thirty one confirmed cases	Genomic sequencing. On-site visit (work condition and ventilation system) and information provided by employer on housing, commuting, and workplaces of employees	Close contact and fomite transmission possible for some cases. Transmission from outside event unlikely	Possible airborne transmission for some cases on the production line, up to 12 m from the primary case	Insufficient air replacement. Directional air flow from air circulation system. Increased aerosol emission—physical work (unclear)
Groves et al ⁴² (low)	Fitness facility, USA, June 2020	Twenty one confirmed cases, with 10 secondary cases considered for long distance transmission	No genomic sequencing. Questionnaire and on-site assessment	Close contact possible for some cases. Fomite transmission unclear. Transmission from outside event unlikely	Possible airborne transmission >2 m for some cases, owing to high secondary attack rate (1 hour)	Insufficient air replacement. Directional air flow from air fan. Increased aerosol emission—shouting
Katellaris et al ⁴⁶ (high)	Singing event, Australia, July 2020	Thirteen confirmed cases	Genomic sequencing. Interviews with cases, video recording, on-site visit (ventilation system)	Close contact or fomite transmission unlikely (except for five cases in same household). Transmission from outside event unlikely	Possible airborne transmission with secondary cases seated 1-15 m from the primary case (1 hour)	Insufficient air replacement. Increased aerosol emission—singing
Vernez et al ⁴³ (low)	Courtroom, Switzerland, September 2020	Five confirmed cases	No genomic sequencing. Court records, contact tracing data, and field measurements	Close contact cannot be ruled out, especially for the two secondary cases at 1.5 m from the primary case. Fomite transmission unlikely. Transmission from outside event likely for one secondary case	Possible long distance airborne transmission for three secondary cases (1.5-3 m; 3 hours)	Insufficient air replacement
Shah et al ⁴⁷ (medium)	Five singing events, Netherlands, September-October 2020	Fifty: 48 confirmed cases and two probable cases	Genomic sequencing for seven cases. Phone and email correspondence, questionnaires, epidemiological data, aerosol transmission model	Close contact possible for some cases. Fomite transmission unlikely (except for one event). Transmission from outside event possible for some cases, but unlikely in others	Possible airborne transmission >1.5 m for some cases (1 hour to 2.5 hours)	Increased aerosol emission—singing. Directional air flow (unclear). Insufficient air replacement (unclear)
Sarti et al ⁴⁴ (low)	Office, Italy, November 2020	Five confirmed cases	No genomic sequencing. Telephone interviews	Close contact, fomite transmission, or transmission from outside event possible	Unclear airborne transmission between coworkers	Not applicable

The review's assessment of likelihood of airborne transmission of SARS-CoV-2 over distances >2 m is based on likelihood of it occurring in some, but not necessarily all, transmission events.

*Exposure distance and time are stated when known; if not stated they are categorised as not clear or not specified.

which no one wore face coverings. Those travelling on the bus with the primary case were 11 times more likely to develop covid-19 compared with the other participants (relative risk 11.4, 95% confidence interval 5.1 to 25.4; $P < 0.01$) and 42 times more likely compared with those travelling in the other bus (42.2, 2.6 to 679.3; $P < 0.01$). Close contact transmission, fomite transmission, and transmission from outside the event cannot be ruled out for some of the cases but are unlikely to have accounted for all 23 secondary cases.

The second outbreak, reported by Luo et al³⁷ (rated as low methodological quality) with additional environmental investigations conducted by Ou et al,⁵¹ involved one primary case (symptom onset occurred on the day of the event) who had travelled without wearing a face covering on a coach for 2.5 hours with 48 other individuals and then on a minibus for one hour with 12 other individuals. Nine secondary cases were identified, resulting in a secondary attack rate of 15% (95% confidence interval 6% to 24%), with most seated >2 m from the primary case: up to 4.5 m based

Reference	QCC questions*										Quality rating
	1	2†	3†	4	5	6†	7†	8	9	10	
Charlotte 2020 ⁴⁸	Yes	Yes	Not applicable	Yes	Not applicable	No	No	Not applicable	Yes	Yes	Low
Eichler 2021 ³²	Yes	Yes	Not applicable	Not applicable	Not applicable	Unclear	Yes	Not applicable	No	Yes	Medium
Fox-Lewis 2022 ³³	Yes	Yes	Not applicable	Not applicable	Not applicable	Yes	Yes	Not applicable	Yes	Yes	High
Groves 2021 ⁴²	Yes	Yes	Not applicable	Unclear	Not applicable	No	No	Not applicable	Yes	Yes	Low
Gunther 2020 ⁴¹	Yes	Yes	Not applicable	Yes	Not applicable	Unclear	Yes	Not applicable	Yes	Yes	Medium
Hamner 2020 ^{1, 52}	Yes	Yes	Not applicable	Yes	Not applicable	No	No	Not applicable	Yes	Yes	Low
Han 2022 ⁴⁰	Yes	No	Not applicable	Unclear	Not applicable	No	Yes	Not applicable	No	Yes	Low
Hwang 2021 ³⁹	Yes	Yes	Not applicable	Yes	Not applicable	No	No	Not applicable	Yes	Yes	Low
Jiang 2021 ⁴⁵	Yes	Unclear	Not applicable	Not applicable	Not applicable	No	No	Not applicable	No	Yes	Low
Katellaris 2021 ⁴⁶	Yes	Yes	Not applicable	Yes	Not applicable	Yes	Yes	Not applicable	Yes	Yes	High
Kwon 2020 ³⁵	Yes	Yes	Not applicable	Unclear	Not applicable	Yes	Yes	Not applicable	Yes	Yes	High
Li 2021 ^{34, 49, 50}	Yes	Yes	Not applicable	Not applicable	Not applicable	Yes	No	Not applicable	Yes	Yes	Medium
Lin 2021 ³⁸	Yes	No	Not applicable	Unclear	Not applicable	Unclear	Unclear	Not applicable	Yes	Yes	Low
Luo 2020 ^{37, 51}	Yes	Yes	Not applicable	Yes	Not applicable	No	No	Not applicable	Yes	Yes	Low
Sarti 2021 ⁴⁴	Yes	Yes	Not applicable	Yes	Not applicable	No	No	Not applicable	No	Yes	Low
Shah 2021 ⁴⁷	Yes	Yes	Not applicable	Yes	Not applicable	Unclear	Unclear	Not applicable	Yes	Yes	Medium
Shen 2020 ³⁶	Yes	Yes	Yes	Yes	Not applicable	Unclear	No	No	Yes	Yes	Medium
Vernez 2021 ⁴³	Yes	Yes	Not applicable	Not applicable	Not applicable	No	No	Not applicable	Yes	Yes	Low

Yes Unclear No Not applicable

Fig 2 | Quality assessment. *Assessments using quality criteria checklist (QCC) for primary research (see supplementary material 1). †Critical questions: 2 on selection bias, 3 on group comparability, 6 on description of exposure/assessment of transmission routes, and 7 on validity of outcome measurements

on one report³⁷ and up to 9.5 m based on the other report.⁵¹ Genomic sequencing was not performed and, based on symptom onset dates, it is plausible that more than one primary case was present, reducing our confidence in the distances reported. However, even taking into account all potential primary cases, it is possible that airborne transmission occurred for some secondary cases seated >2 m from a primary case. Some passengers wore face coverings, but none of the secondary cases did.

In both outbreaks, insufficient air replacement and directional airflow from the heating system were hypothesised as promoting long distance airborne transmission, supported by tracer gas experiments in the buses involved in one of the outbreaks.⁵¹

Apartment blocks

Three outbreaks of covid-19 in three separate residential apartment blocks were identified. The study by Lin et al³⁸ (rated as low methodological quality) investigated an outbreak involving nine people who tested positive for SARS-CoV-2 in three flats of a 29 storey apartment block in China. The nine cases, identified between 27 January and 13 February 2020, lived in flats that shared drain and sewer pipes connected via an exhaust pipe to the roof. Except for

cases in the same household, close contact and fomite transmission were ruled out based on interviews with the cases and partial video analysis (lift only). Some but not all of the cases reported wearing face coverings in the communal areas of the building.

The two other outbreaks were in South Korea. The first, reported by Hwang et al³⁹ (rated as low methodological quality), occurred in August 2020 in an apartment block of 267 flats and involved 10 cases from seven households located around two ventilation ducts (eight cases around one, two around another). The second outbreak, reported by Han et al⁴⁰ (rated as low methodological quality), occurred in January 2021 in a complex of 260 flats, in which cases located in three flats along the same drainpipe and ventilation duct could not be explained by close contact or fomite transmission. For both outbreaks, transmission routes were mainly investigated through interviews with cases, and therefore recall bias (no video analysis) was possible. All cases reported wearing face coverings in the communal areas of the buildings.

For all three outbreaks, long distance airborne transmission between flats through vertical air ducts or floor drains was deemed possible for at least some of the secondary cases, although environmental investigation (tracer gas experiment) to support this

hypothesis was conducted in only one³⁸ of the three studies. In two of the three studies,^{38 40} the ventilation ducts were found to be malfunctioning, which could have contributed to transmission risk. However, only one of these studies³⁹ tested all residents and only one conducted whole genome sequencing,⁴⁰ which reduces confidence in the results.

Other indoor settings

The other outbreaks identified in this review occurred in a food processing factory,⁴¹ fitness facility,⁴² courtroom,⁴³ office,⁴⁴ and department store.⁴⁵

Gunther et al⁴¹ (rated as medium methodological quality) reported on an outbreak in a meat processing plant in Germany in May and June 2020 in which 31 out of the 140 workers on the same shift had tested positive for SARS-CoV-2 and were part of the same genomic cluster. Although close contact or fomite transmission in other areas of the processing plant and outside the factory (some workers shared accommodation and carpools) was possible for some cases, the spatial distribution of the cases suggested that transmission was likely to have occurred on the processing line at distances up to 12 m from the primary case who was asymptomatic. The authors hypothesised that factors such as increased respiratory rates (from physically demanding work), lack of air replacement, and continuous recirculation of cooled unfiltered air might have promoted long distance airborne transmission, but these were not investigated further. Some covid-19 measures were in place, including increased distance between workers and use of single layer face coverings, but adherence was not assessed as part of the study.

Groves et al⁴² (rated as low methodological quality) reported on an outbreak involving two fitness instructors at classes taught in three different facilities in June and July 2020, although the investigation suggested that close contact and fomite transmission were likely to have occurred in all classes but one. The class in which long distance airborne transmission might have happened was a one hour static cycling class in which bikes were placed at least 1.8 m apart, with doors and windows closed and three large fans directed towards the class participants. The instructor, who had shouted instructions while facing the participants, was identified as being the primary case (with symptom onset the next day) and all 10 class participants had tested positive for SARS-CoV-2 three to six days after the class. Face coverings had not been used during the class.

In an outbreak in a courtroom in Switzerland reported by Vernez et al⁴³ (study rated as low methodological quality), five out of the 10 participants at a three hour hearing held on the 30 September 2020 tested positive for SARS-CoV-2. The use of face coverings was mandatory in the building, but not when seated, and social distancing measures were in place, with a minimum of 1.5 m between each seat. Long distance airborne transmission (1.5-3 m) was likely to have happened between a primary case (with symptom onset on that day) and three secondary cases, although

close contact or fomite transmission after the hearing or in the bathroom cannot be ruled out. The hypothesis that a lack of air replacement (doors and windows were closed and there was no mechanical ventilation) might have promoted long distance airborne transmission was supported by field measurements and modelling.

Sarti et al⁴⁴ (rated as low methodological quality) reported on an outbreak in an office in Italy in which five of six coworkers were identified as cases. One of the five coworkers was identified as the primary case, and transmission happened before symptom onset. The sixth coworker, who was not infected, was not present in the office for the two days before symptom onset of the primary case. This transmission event happened in November and December 2020 when mitigation measures were in place, including social distancing, acrylic panels between desks, hand hygiene, and use of a face covering except when seated at a desk. The office was not well ventilated (no air conditioning and windows were closed), which could have promoted long distance airborne transmission. On the basis of the investigation, however, close contact, fomite transmission, and transmission from outside the event cannot be ruled out, so it is unclear as to whether long distance airborne transmission was the most likely route.

Jiang et al⁴⁵ (rated as low methodological quality) reported on an outbreak linked to a department store that occurred in January 2020 in Tianjin, China, involving 24 cases (six staff and 18 customers). Airborne transmission was considered as the most likely route of transmission between a primary case and 12 secondary cases, which might have been promoted by a lack of air replacement (doors were closed) and high density of people in the store. As genomic sequencing of SARS-CoV-2 was not performed, however, transmission from outside this event cannot be ruled out and, based on symptom onset dates, it is possible that several primary cases were present. On the basis of this investigation, it is unclear whether long distance airborne transmission had occurred in the store.

Singing events

In addition to transmission events associated with specific settings, four epidemiological investigations reporting on outbreaks linked to singing events were identified.

Katellaris et al⁴⁶ (rated as high methodological quality) reported on an outbreak in Sydney, Australia, linked to a series of four church services held between 15 and 17 July 2020. The probable primary case, a choir member, had sung at each of these one hour services, and 12 secondary cases were identified (2.4% secondary attack rate across the four services), who had sat in the same section of the church, between 1 m and 15 m from the primary case. Viral genomic sequencing of the primary case and 10 secondary cases showed a single genomic cluster, suggesting that transmission had occurred during the church services.

The second epidemiological investigation⁴⁷ (rated as medium methodological quality; preprint) reported on five singing events held between September and October 2020 in the Netherlands. At the time, national recommendations were in place to reduce covid-19 transmission, and although singing in groups was allowed, physical distancing (>1.5 m) and ventilation were recommended. Each singing event had between nine and 21 attendees, and attack rates of between 53% and 74% were observed. Fomite transmission was deemed unlikely in all but one event, but close contact transmission was considered possible for some of the secondary cases in three of the five events. However, owing to the high secondary attack rates, it is possible that at least some of the secondary cases had been infected via long distance airborne transmission and, even though ventilation through open doors or windows was reported for all events, air exchange rates were likely to have been low in at least three of the five events.

The two other outbreaks occurred in March 2020—that is, during the early stage of the pandemic when no mitigation measures were in place. One of them (70% attack rate, including probable cases) happened in France during a two hour choral rehearsal in a narrow, indoor, non-ventilated space⁴⁸ (study rated as low methodological quality). The second outbreak (87% secondary attack rate, including probable cases) after a 2.5 hour choral rehearsal on 10 March 2020 in Washington (USA) was initially reported by Hamner et al¹ (rated as low methodological quality) and further discussed by Miller et al.⁵² For both outbreaks, close contact and fomite transmission were only assessed through interviews and cannot be fully ruled out. The high secondary attack rate, however, suggests that long distance airborne transmission might have occurred for at least some of the cases.

The results from the four studies suggest that long distance airborne transmission was likely to have occurred for at least some of the transmission events, and that singing may have increased the amount of aerosol generated by the primary cases, which is consistent with modelling results reported by some of these authors.^{52 53}

Summary and critical analysis of results

Seven of the outbreaks identified^{1 34 36-38 45 48} occurred in the early stage of the pandemic (January-March 2020) when knowledge of covid-19 was limited, especially the incubation period and the extent of asymptomatic or presymptomatic transmission. As a result, most of these studies only conducted symptomatic testing and considered potential secondary cases to be participants with symptom onset soon after the potential exposure event, including the next day. In addition, for the studies conducted in January 2020 in China and in March 2020 in Europe or the US, it is possible that community transmission was higher than perceived at the time.

Therefore, in an outbreak such as the one reported by Luo et al³⁷ where no genomic sequencing was

conducted and three of the nine secondary cases developed symptoms or tested positive for SARS-CoV-2 one or two days after exposure, it is plausible that more than one primary case was present and that transmission occurred through means other than long distance airborne transmission. In two of the studies reporting on singing events,^{1 48} genomic sequencing and asymptomatic testing were not carried out and some of the secondary cases developed symptoms in the days after exposure but because of the high attack rates reported for these outbreaks, it is possible that long distance airborne transmission had happened for at least some of the transmission events. Long distance airborne transmission was also considered possible for two other early studies as a result of detailed epidemiological investigations.^{34 36} However, the plausibility of long distance airborne transmission for the outbreak in the department store was unclear as other transmission routes could not be ruled out.⁴⁵

Among the other studies, four^{33 35 41 46} provided convincing evidence for long distance airborne transmission as a result of detailed epidemiological investigations combined with genomic sequencing. Eichler et al³² also conducted genomic sequencing but their reporting of the epidemiological investigation was not sufficiently exhaustive to exclude other transmission routes (close contact or fomite) for the only secondary cases who could have been infected by long distance airborne transmission. The investigations by Shah et al,⁴⁷ Hwang et al,³⁹ Groves et al,⁴² Han et al,⁴⁰ and Vernez et al⁴³ suggested that long distance airborne transmission was possible for at least some of the transmission events (close contact or fomite could not be fully ruled out), but stronger conclusions could not be drawn owing to methodological limitations (including the absence of genomic sequencing and risk of selection bias). Finally, the likelihood of long distance airborne transmission was unclear in the outbreak in the office reported by Sarti et al⁴⁴ as, despite the covid-19 measures in place, close contact and fomite transmission could not be completely ruled out on the basis of the investigation.

Eleven of the 18 studies reported on the use of face coverings.^{33 35-44} Overall, the information provided was limited, and two of these studies only mentioned that face coverings were compulsory in the settings of interest (quarantine hotel³³ and food processing factory⁴¹) without reporting on adherence or behaviour (eg, whether workers wore face coverings correctly for the duration of their shift). Based on this limited information, we found no evidence of long distance airborne transmission where participants were known to have worn face coverings for the duration of exposure.

Only one of the outbreaks³³ identified occurred at a time when covid-19 vaccines were available, although in this outbreak the primary and secondary cases were not vaccinated.

Grading of the evidence

Table 3 provides the grading of the evidence for each of the primary outcomes: SARS-CoV-2 infection via

airborne transmission at a distance >2 m, insufficient air replacement (modifying factor), directional air flow (modifying factor), and increased aerosol emission when singing, speaking loudly, or doing intense physical work (modifying factor). Assessment of modifying factors was considered not applicable for the two outbreaks where the likelihood of long distance airborne transmission had been judged as unclear.

For all four outcomes, the evidence was judged as having methodological limitations owing to study design and to be at serious risk of imprecision owing to small numbers of participants as well as some risk of bias in exposure or outcome assessment, or both. However, the risks of inconsistency and indirectness were judged as not serious as the results were consistent across studies conducted in a range of settings and with different populations and provide evidence of direct relevance to the public health question of interest. The risk of publication bias was judged to be serious for the outcome of SARS-CoV-2 infection through airborne transmission at a distance >2 m and for the modifying factor of activities associated with increased emission of aerosols, but not serious for the modifying factors of insufficient air replacement and directional air flow. As a result, the certainty of evidence was judged as very low for all outcomes.

Because of high heterogeneity between studies, the additional outcomes of time spent in the transmission setting and distance over which airborne transmission was thought to have occurred could not be summarised or graded using the GRADE framework. Exposure timings ranged from five minutes to three hours, and distances were up to 15 m.

Discussion

Evidence from the outbreak investigations discussed in this review suggests that airborne transmission of SARS-CoV-2 from an infectious individual to others located >2 m away can occur in different indoor non-healthcare settings. The results of this review show that when long distance transmission occurred, one or more factors were thought to have contributed. Modifying factors such as insufficient air replacement and singing are likely to result in an increased concentration of infectious respiratory particles within the indoor space, whereas factors such as directional air flow are likely to allow viable virus to travel further in a certain direction, which could potentially infect someone downstream of a primary case. The results of this review therefore confirm the importance of the role of ventilation to mitigate the risk of long distance aerosol transmission.⁵⁴⁻⁵⁷

A total of eight events (from four studies) in which singing may have contributed to long distance airborne transmission were identified.^{1 46-48} These results are in line with experimental and modelling studies that have reported on singing and aerosol generation, suggesting that more virus-containing respiratory particles tend to be emitted when singing compared with speaking or breathing.^{53 58} More generally, the quantity of respiratory particles emitted increases with

loudness of vocalisation,^{59 60} which was thought to have contributed to long distance aerosol transmission in a fitness facility.⁴²

In 13 out of 18 studies identified,^{33-37 41-48} suspected primary cases were asymptomatic, presymptomatic, or near the time of symptom onset when transmission occurred. This finding is consistent with wider evidence that people with asymptomatic or presymptomatic SARS-CoV-2 infection can contribute to the community spread of covid-19,⁶¹⁻⁶³ including from long distance airborne transmission.

Although the evidence on face coverings was limited, no outbreaks in which participants had been wearing face coverings for the duration of the exposure were identified. Evidence suggests that face coverings can reduce the number of respiratory particles emitted from the nose and mouth.⁶⁴ However, it is not possible to deduce from the evidence assessed in this review if wearing a face covering can prevent or reduce the risk of long distance transmission of SARS-CoV-2.

Most of the outbreaks we identified occurred at a time when population immunity was limited, either naturally acquired or vaccine mediated. This limits the applicability of our findings to the current context, although there is evidence that transmission of SARS-CoV-2 after vaccination does occur.⁶⁵ While the lack of evidence identified in vaccinated populations may to some extent reflect the successes of vaccine rollout, there may also be a time lag in publication of outbreak reports since vaccine programmes were initiated. There may also be less interest in publishing reports on SARS-CoV-2 associated outbreaks over time.

The evidence from our rapid systematic review was deemed to be of very low certainty based on 18 studies. The relatively small number of studies identified could suggest that outbreaks related to long distance airborne transmission are rare, although also likely to result from difficulties in identifying such events or to under-reporting—for example, in countries without sufficient contact tracing. It can also be partly explained by the level of detail needed to assess transmission routes. Indeed, even outbreak investigations that follow reporting guidelines such as the Outbreak Reports and Intervention studies Of Nosocomial infection (ORION) statement published by the Canada Communicable Disease Report⁶⁶ are not necessarily thorough enough to be able to fully rule out other transmission routes. As a result, several outbreaks in which long distance airborne transmission may have happened were excluded on full text, including a few reports on clusters in aeroplanes that did not properly consider transmission routes during boarding and disembarking.⁶⁷⁻⁷⁰ Finally, the wider challenges of the pandemic should be acknowledged, including the limited resources in public health teams to conduct detailed epidemiological investigations.

The outcomes were rated as being of very low certainty using the GRADE framework, although this reflects the principles of GRADE rather than a lack of quality of the included studies because in traditional evidence hierarchies, outbreak investigations are

Table 3 | Summary of findings using Grading of Recommendations, Assessment, Development, and Evaluation approach

Outcome	Effect	No of studies	Certainty in the evidence
SARS-CoV-2 infection through airborne transmission over a distance >2 m	Sixteen studies suggested that long distance airborne transmission was the main transmission route for at least some of the transmission events in the reported outbreaks. Unclear in two studies	18	Very low owing to methodological limitations of the studies and serious risk of imprecision and publication bias
Modifying factor: insufficient air replacement	Fourteen studies suggested that insufficient air replacement had increased the likelihood of long distance airborne transmission. Unclear in two studies	16	Very low owing to methodological limitations of the studies and serious risk of imprecision
Modifying factor: directional air flow	Eleven studies suggested that directional air flow might have increased the likelihood of long distance airborne transmission. Unclear in one study	12	Very low owing to methodological limitations of the studies and serious risk of imprecision
Modifying factor: activities associated with increased emission of aerosols	Five studies (reporting on nine events) suggested that singing and speaking loudly might have increased the likelihood of long distance airborne transmission. Unclear in one study (intense physical work)	6	Very low owing to methodological limitations of the studies and serious risk of imprecision and publication bias

classed as a low level of evidence. However, some of the included studies were well conducted investigations of covid-19 outbreaks and their contribution to this particular research question should not be underestimated—they provide critical insight where other types of study are just not feasible.⁷¹ The GRADE framework was developed to inform clinical practice where randomised controlled trials are feasible, and linear causal pathways are more often the norm. Public health research does not always fit easily within this framework and the question of what level of public health evidence is sufficient to support decision making for a novel infection warrants further consideration.

Comparison with other studies

These findings are an important addition to the wider body of evidence that supports the biological plausibility of airborne transmission as a potentially important route of transmission in certain scenarios. The wider evidence includes experimental evidence from animal studies⁷² as well as experimental studies that have shown that SARS-CoV-2 can remain viable in artificially generated aerosols for up to 16 hours, and that the stability and viability depends on environmental factors such as temperature, humidity, and exposure to sunlight.²² Similarly, biological monitoring studies have shown that SARS-CoV-2 RNA can be detected in exhaled breath and environmental air samples, but the evidence on viable virus remains limited to a few studies that mostly detected infectious virus in air samples collected at <2 m from the infectious individual.²²⁻²⁴ These experimental and biological studies provide evidence that SARS-CoV-2 can be viable in aerosols and therefore support the epidemiological evidence from this rapid review, and from others^{22,23} that suggest that airborne transmission can happen in some settings.

Strengths and limitations of this review

This rapid systematic review critically assessed the likelihood of long distance airborne transmission of SARS-CoV-2 using only direct real world evidence from observational studies from indoor non-healthcare settings. The application of inclusion criteria that focused the critical appraisal on those studies, which involved comprehensive investigations, is a key

strength of our approach: some of these studies not only included epidemiological data, but also genomic analysis, video surveillance, analysis of seating arrangements, and environmental hypothesis testing.

The main limitation of selecting studies of only real world human-to-human transmission events is that scenarios where transmission has not occurred were not included, and likewise where transmission events have not been detected by contact tracing systems, which could be seen as a form of publication bias. All the evidence is from retrospective epidemiological investigations of outbreaks and therefore this review cannot make inferences on the extent to which long distance airborne transmission occurs or the contribution it may have on community rates of transmission: these remain critical questions for policy and practice. In addition, most of the outbreaks occurred before vaccine rollouts and it is unclear how these results apply to populations with a high level of immunity to infection. Finally, and as with all reviews assessing evidence related to covid-19, this rapid review is limited by the fact that the evidence assessed is from an emerging specialty.

Future work and policy implications

Well conducted outbreak investigations continue to be needed to assess the potential for long distance airborne transmission in vaccinated populations, and with more transmissible SARS-CoV-2 variants such as omicron. To assess transmission routes, such outbreak investigations should deploy robust and mixed methods, ranging from genomic analysis to environmental assessment, and they should be conducted as early as possible to reduce recall bias.

The results from this rapid systematic review highlight the need to ensure measures to mitigate SARS-CoV-2 long distance transmission in indoor settings, especially in poorly ventilated spaces. Identification of poorly ventilated public spaces should be undertaken and improvements made. Other factors such as directional air flow or singing that could increase the risk for long distance airborne transmission should also be considered in risk mitigation.

A need also exists to develop a new framework, or to adapt the existing GRADE framework, to support a pragmatic and consistent approach to the collation,

interpretation, and synthesis of epidemiological investigations, especially when other types of studies are not feasible. The question of what level of public health evidence is sufficient to support decision making for a novel infection warrants further consideration.

Conclusion

This rapid review found evidence suggesting that long distance (>2 m) airborne transmission of SARS-CoV-2 might happen in indoor non-healthcare settings, and that it can occur from people who are asymptomatic or presymptomatic. All transmission events identified occurred alongside factors believed to have contributed to this type of transmission, including lack of air replacement (absence or little ventilation with fresh air), directional air flow (mainly through air circulation systems), and activities such as singing that increased aerosol emission. In the review, we found no evidence of long distance airborne transmission occurring without one or more of these factors present.

Based on the results from this review, indoor non-healthcare settings that might be at risk of long distance airborne transmission include hospitality settings such as restaurants, public transport, and workplaces with inadequate ventilation, as well as settings where activities resulting in increased aerosol emission, such as singing or speaking loudly are carried out.

These results highlight the importance of assessing ventilation, especially in indoor spaces where people meet others from outside their household. Particular attention should be given to ventilation in settings with activities that might increase the number of respiratory particles, for example, singing. Where ventilation is assessed to be inadequate, improvements should be made.

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The manuscript's guarantor (RC) affirms that the manuscript is an honest, accurate, and transparent account of the study being

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Dissemination to participants and related patient and public communities: This paper will be shared widely within the UK Health Security Agency and used to inform relevant guidance. It will also be shared with relevant stakeholders, policy makers, and other public health agencies within the United Kingdom and internationally. Further dissemination will include our website <https://ukhsalibrary.koha-ptfs.co.uk/covid19rapidreviews/> and through colleagues working in covid-19 evidence synthesis.

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- Hamner L, Dubbel P, Capron I, et al. High SARS-CoV-2 attack rate following exposure at a choir practice—Skagit County, Washington, March 2020. *MMWR Morb Mortal Wkly Rep* 2020;69:606-10. doi:10.15585/mmwr.mm6919e6
- Shim E, Tariq A, Choi W, Lee Y, Chowell G. Transmission potential and severity of COVID-19 in South Korea. *Int J Infect Dis* 2020;93:339-44. doi:10.1016/j.ijid.2020.03.031
- Morawska L, Milton DK. It is time to address airborne transmission of coronavirus disease 2019 (COVID-19). *Clin Infect Dis* 2020;71:2311-3. doi:10.1093/cid/ciaa939
- Greenhalgh T, Jimenez JL, Prather KA, Tufekci Z, Fisman D, Schooley R. Ten scientific reasons in support of airborne transmission of SARS-CoV-2. *Lancet* 2021;397:1603-5. doi:10.1016/S0140-6736(21)00869-2
- Tang JW, Marr LC, Li Y, Dancer SJ. Covid-19 has redefined airborne transmission. *BMJ* 2021;373:n913. doi:10.1136/bmj.n913
- Tang JW, Bahnfleth WP, Bluyssen PM, et al. Dismantling myths on the airborne transmission of severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2). *J Hosp Infect* 2021;110:89-96. doi:10.1016/j.jhin.2020.12.022
- Samet JM, Prather K, Benjamin G, et al. Airborne Transmission of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2): What We Know. *Clin Infect Dis* 2021;73:1924-6. doi:10.1093/cid/ciab039
- Wang CC, Prather KA, Sznitman J, et al. Airborne transmission of respiratory viruses. *Science* 2021;373:eabd9149. doi:10.1126/science.abd9149
- Shen J, Kong M, Dong B, Birnkrant MJ, Zhang J. Airborne transmission of SARS-CoV-2 in indoor environments: A comprehensive review. *Sci Technol Built Environ* 2021;27:1331-67. doi:10.1080/23744731.2021.1977693
- Randall K, Ewing ET, Marr LC, Jimenez JL, Bourouiba L. How did we get here: what are droplets and aerosols and how far do they go? A historical perspective on the transmission of respiratory infectious diseases. *Interface Focus* 2021;11:20210049. doi:10.1098/rsfs.2021.0049
- Marr LC, Tang JW. A Paradigm Shift to Align Transmission Routes With Mechanisms. *Clin Infect Dis* 2021;73:1747-9. doi:10.1093/cid/ciab722
- Prather KA, Marr LC, Schooley RT, McDiarmid MA, Wilson ME, Milton DK. Airborne transmission of SARS-CoV-2. *Science* 2020;370:303-4. doi:10.1126/science.abf0521
- World Health Organization. Transmission of SARS-CoV-2: implications for infection prevention precautions. 2020. [Cited 14 March 2022] www.who.int/news-room/commentaries/detail/transmission-of-sars-cov-2-implications-for-infection-prevention-precautions.
- Milton DK. A Rosetta Stone for Understanding Infectious Drops and Aerosols. *J Pediatric Infect Dis Soc* 2020;9:413-5. doi:10.1093/jpids/piaa079
- SAGE-EMG. Application of physical distancing and fabric face coverings in mitigating the B117 variant SARS-CoV-2 virus in public, workplace and community setting. 2021. [Cited 14 February 2022] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1008199/S1029-EMG-face-coverings-distancing-13-jan.pdf.
- Tang JW, Marr LC, Milton DK. Aerosols should not be defined by distance travelled. *J Hosp Infect* 2021;115:131-2. doi:10.1016/j.jhin.2021.05.007
- Chen W, Zhang N, Wei J, Yen H-L, Li Y. Short-range airborne route dominates exposure of respiratory infection during close contact. *Build Environ* 2020;176:106859. doi:10.1016/j.buildenv.2020.106859.

- 18 Noorimotlagh Z, Jaafarzadeh N, Martínez SS, Mirzaee SA. A systematic review of possible airborne transmission of the COVID-19 virus (SARS-CoV-2) in the indoor air environment. *Environ Res* 2021;193:110612. doi:10.1016/j.envres.2020.110612
- 19 Ribaric NL, Vincent C, Jonitz G, Hellinger A, Ribaric G. Hidden hazards of SARS-CoV-2 transmission in hospitals: A systematic review. *Indoor Air* 2022;32:e12968. doi:10.1111/ina.12968
- 20 Aghalari Z, Dahms H-U, Sosa-Hernandez JE, Oyervides-Muñoz MA, Parra-Saldivar R. Evaluation of SARS-CoV-2 transmission through indoor air in hospitals and prevention methods: A systematic review. *Environ Res* 2021;195:110841. doi:10.1016/j.envres.2021.110841
- 21 Comber L, O Murchu E, Drummond L. Airborne transmission of SARS-CoV-2 via aerosols. *Rev Med Virol* 2021;31:e2184. doi:10.1002/rmv.2184
- 22 Public Health Agency of Canada. Rapid Review on SARS-CoV-2 Aerosol Transmission, Update 2. 2021. www.nccmt.ca/covid-19/covid-19-evidence-reviews/418.
- 23 Antimicrobial resistance and healthcare associated infection (ARHAI) Scotland. Rapid review of the literature: Assessing the infection prevention and control measures for the prevention and management of COVID-19 in health and care settings (version 25). 2022. [Cited 8 April 2022] www.nipcm.hps.scot.nhs.uk/web-resources-container/rapid-review-of-the-literature-assessing-the-infection-prevention-and-control-measures-for-the-prevention-and-management-of-covid-19-in-healthcare-settings.
- 24 Bak A, Muggleston MA, Ratnaraja NV, et al. SARS-CoV-2 routes of transmission and recommendations for preventing acquisition: joint British Infection Association (BIA), Healthcare Infection Society (HIS), Infection Prevention Society (IPS) and Royal College of Pathologists (RCPath) guidance. *J Hosp Infect* 2021;114:79-103. doi:10.1016/j.jhin.2021.04.027
- 25 Tricco AC, Langlois E, Straus SE. Rapid reviews to strengthen health policy and systems: a practical guide: World Health Organization; 2017. https://apps.who.int/iris/bitstream/handle/10665/258698/9789241512763-eng.pdf.
- 26 Page MJ, McKenzie JE, Bossuyt PM, et al. The PRISMA 2020 statement: An updated guideline for reporting systematic reviews. *PLoS Med* 2021;18:e1003583. doi:10.1371/journal.pmed.1003583
- 27 Palmer J, Pearce-Smith N, Duval D, et al. Airborne transmission of SARS-CoV-2 over distances greater than two metres: a rapid review protocol. *PROSPERO*. 2021;CRD42021236762.
- 28 Shea BJ, Reeves BC, Wells G, et al. AMSTAR 2: a critical appraisal tool for systematic reviews that include randomised or non-randomised studies of healthcare interventions, or both. *BMJ* 2017;358:j4008. doi:10.1136/bmj.j4008
- 29 Ouzzani M, Hammady H, Fedorowicz Z, Elmagarmid A. Rayyan—a web and mobile app for systematic reviews. *Syst Rev* 2016;5:210. doi:10.1186/s13643-016-0384-4
- 30 Academy of Nutrition and Dietetics. Evidence Analysis Manual: Steps in the Academy Evidence Analysis Process. 2016. [Cited 21 February 2022] www.andeanal.org/evidence-analysis-manual.
- 31 Murad MH, Mustafa RA, Schünemann HJ, Sultan S, Santesso N. Rating the certainty in evidence in the absence of a single estimate of effect. *Evid Based Med* 2017;22:85-7. doi:10.1136/ebmed-2017-110668
- 32 Eichler N, Thornley C, Swadi T, et al. Transmission of Severe Acute Respiratory Syndrome Coronavirus 2 during Border Quarantine and Air Travel, New Zealand (Aotearoa). *Emerg Infect Dis* 2021;27:1274-8. doi:10.3201/eid2705.210514
- 33 Fox-Lewis A, Williamson F, Harrower J, et al. Airborne Transmission of SARS-CoV-2 Delta Variant within Tightly Monitored Isolation Facility, New Zealand (Aotearoa). *Emerg Infect Dis* 2022;28:501-9. doi:10.3201/eid2803.212318
- 34 Li Y, Qian H, Hang J, et al. Probable airborne transmission of SARS-CoV-2 in a poorly ventilated restaurant. *Build Environ* 2021;196:107788. doi:10.1016/j.buildenv.2021.107788
- 35 Kwon KS, Park JJ, Park YJ, Jung DM, Ryu KW, Lee JH. Evidence of Long-Distance Droplet Transmission of SARS-CoV-2 by Direct Air Flow in a Restaurant in Korea. *J Korean Med Sci* 2020;35:e415. doi:10.3346/jkms.2020.35.e415
- 36 Shen Y, Li C, Dong H, et al. Community Outbreak Investigation of SARS-CoV-2 Transmission Among Bus Riders in Eastern China. *JAMA Intern Med* 2020;180:1665-71. doi:10.1001/jamainternmed.2020.5225
- 37 Luo K, Lei Z, Hai Z, et al. Transmission of SARS-CoV-2 in Public Transportation Vehicles: A Case Study in Hunan Province, China. *Open Forum Infect Dis*. 2020;7:ofaa430. doi:10.1093/ofid/ofaa430
- 38 Lin G, Zhang S, Zhong Y, et al. Community evidence of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) transmission through air. *Atmos Environ (1994)* 2021;246:118083. doi:10.1016/j.atmosenv.2020.118083
- 39 Hwang SE, Chang JH, Oh B, Heo J. Possible aerosol transmission of COVID-19 associated with an outbreak in an apartment in Seoul, South Korea. 2020. *Int J Infect Dis* 2021;104:73-6. doi:10.1016/j.ijid.2020.12.035
- 40 Han T, Park H, Jeong Y, et al. COVID-19 Cluster Linked to Aerosol Transmission of SARS-CoV-2 via Floor Drains. *J Infect Dis* 2022;225:1554-60. doi:10.1093/infdis/jiab598
- 41 Günther T, Czech-Sioli M, Indenbirken D, et al. SARS-CoV-2 outbreak investigation in a German meat processing plant. *EMBO Mol Med* 2020;12:e13296. doi:10.15252/emmm.202013296
- 42 Groves LM, Usagawa L, Elm J, et al. Community Transmission of SARS-CoV-2 at Three Fitness Facilities - Hawaii, June-July 2020. *MMWR Morb Mortal Wkly Rep* 2021;70:316-20. doi:10.15585/mmwr.mm7009e1
- 43 Vernez D, Schwarz S, Sauvain JJ, Petignat C, Suarez G. Probable aerosol transmission of SARS-CoV-2 in a poorly ventilated courtroom. *Indoor Air* 2021;31:1776-85. doi:10.1111/ina.12866
- 44 Sarti D, Campanelli T, Rondina T, Gasperini B. COVID-19 in Workplaces: Secondary Transmission. *Ann Work Expo Health* 2021;65:1145-51. doi:10.1093/annweh/wxab023
- 45 Jiang G, Wang C, Song L, et al. Aerosol transmission, an indispensable route of COVID-19 spread: case study of a department-store cluster. *Front Environ Sci Eng* 2021;15:46. doi:10.1007/s11783-021-1386-6
- 46 Katelaris AL, Wells J, Clark P, et al. Epidemiologic Evidence for Airborne Transmission of SARS-CoV-2 during Church Singing, Australia, 2020. *Emerg Infect Dis* 2021;27:1677-80. doi:10.3201/eid2706.210465
- 47 Shah AA, Dusseldorp F, Veldhuijzen IK, et al. High SARS-CoV-2 attack rates following exposure during five singing events in the Netherlands, September-October 2020 (v2, July 2021). *medRxiv*. 2021:2021.03.30.21253126. doi:10.1101/2021.03.30.21253126
- 48 Charlotte N. High Rate of SARS-CoV-2 Transmission Due to Choir Practice in France at the Beginning of the COVID-19 Pandemic. *J Voice* 2020;S0892-1997(20)30452-5. doi:10.1016/j.jvoice.2020.11.029
- 49 Lu J, Gu J, Li K, et al. COVID-19 Outbreak Associated with Air Conditioning in Restaurant, Guangzhou, China, 2020. *Emerg Infect Dis* 2020;26:1628-31. doi:10.3201/eid2607.200764
- 50 Zhang N, Chen X, Jia W, et al. Evidence for lack of transmission by close contact and surface touch in a restaurant outbreak of COVID-19. *J Infect* 2021;83:207-16. doi:10.1016/j.jinf.2021.05.030
- 51 Ou C, Hu S, Luo K, et al. Insufficient ventilation led to a probable long-range airborne transmission of SARS-CoV-2 on two buses. *Build Environ* 2022;207:108414. doi:10.1016/j.buildenv.2021.108414
- 52 Miller SL, Nazaroff WW, Jimenez JL, et al. Transmission of SARS-CoV-2 by inhalation of respiratory aerosol in the Skagit Valley Choral superspreading event. *Indoor Air* 2021;31:314-23. doi:10.1111/ina.12751
- 53 Schijven J, Vermeulen LC, Swart A, Meijer A, Duizer E, de Roda Husman AM. Quantitative microbial risk assessment for airborne transmission of SARS-CoV-2 via breathing, speaking, singing, coughing, and sneezing. *Environ Health Perspect* 2021;129:47002. doi:10.1289/EHP7886
- 54 Morawska L, Tang JW, Bahnfleth W, et al. How can airborne transmission of COVID-19 indoors be minimised? *Environ Int* 2020;142:105832. doi:10.1016/j.envint.2020.105832
- 55 Morawska L, Allen J, Bahnfleth W, et al. A paradigm shift to combat indoor respiratory infection. *Science* 2021;372:689-91. doi:10.1126/science.abg2025
- 56 World Health Organization (WHO). Coronavirus disease (COVID-19): How is it transmitted? (last updated 23 December 2021). 2021. [Cited 14 March 2022] www.who.int/news-room/q-a-detail/coronavirus-disease-covid-19-how-is-it-transmitted.
- 57 UK Health Security Agency (UKHSA). COVID-19: ventilation of indoor spaces to stop the spread of coronavirus (published 4 March 2021, updated 15 September 2021). 2021. [Cited 14 March 2022] www.gov.uk/government/publications/covid-19-ventilation-of-indoor-spaces-to-stop-the-spread-of-coronavirus.
- 58 Alsved M, Nygren D, Thuresson S, Medstrand P, Fraenkel C-J, Löndahl J. SARS-CoV-2 in Exhaled Aerosol Particles from COVID-19 Cases and Its Association to Household Transmission. *Clin Infect Dis* 2022;ciac202. Published online Mar 10. doi:10.1093/cid/ciac202/6546685#354016227.
- 59 Gregson FKA, Watson NA, Orton CM, et al. Comparing aerosol concentrations and particle size distributions generated by singing, speaking and breathing. *Aerosol Sci Technol* 2021;55:681-91. doi:10.1080/02786826.2021.1883544.
- 60 Asadi S, Wexler AS, Cappa CD, Barreda S, Bouvier NM, Ristenpart WD. Aerosol emission and superemission during human speech increase with voice loudness. *Sci Rep* 2019;9:2348. doi:10.1038/s41598-019-38808-z
- 61 Alene M, Yismaw L, Assemie MA, et al. Magnitude of asymptomatic COVID-19 cases throughout the course of infection: A systematic review and meta-analysis. *PLoS One* 2021;16:e0249090. doi:10.1371/journal.pone.0249090

- 62 Byambasuren O, Cardona M, Bell K, Clark J, McLaws M-L, Glasziou P. Estimating the extent of asymptomatic COVID-19 and its potential for community transmission: systematic review and meta-analysis. *JAMM* 2020;5:223-34. doi:10.3138/jammi-2020-0030.
- 63 Buitrago-Garcia D, Ipekci AM, Heron L, et al. Occurrence and transmission potential of asymptomatic and presymptomatic SARS-CoV-2 infections: update of a living systematic review and meta-analysis (v2, March 2022). *medRxiv*. 2022:2022.01.20.22269581. doi:10.1101/2022.01.20.22269581.
- 64 Harrison S, Duval D, Walters B, Sadler L, Pearce-Smith N, Clark R. The effectiveness of face coverings to reduce transmission of COVID-19 in community settings - A rapid review (update 2). UKHSA COVID-19 Rapid Evidence Service, 2021. [Cited 28 March 2022] <https://ukhsa.koha-ptfs.co.uk/cgi-bin/koha/opac-retrieve-file.pl?id=cfd006713bdc311c9bc9e4e029fb4f47>.
- 65 Harrison S, Simmons Z, Ghataure A, Pearce-Smith N, Clark R. The effect of vaccination on transmission of COVID-19 - A rapid evidence briefing (update 1). UKHSA COVID-19 Rapid Evidence Service, 2022. [Cited 28 April 2022] <https://ukhsa.koha-ptfs.co.uk/cgi-bin/koha/opac-retrieve-file.pl?id=17de0b088ac2fa00f643b7037ca51665>.
- 66 Stone SP, Cooper BS, Kibbler CC, et al. The ORION statement: guidelines for transparent reporting of outbreak reports and intervention studies of nosocomial infection. *J Antimicrob Chemother* 2007;59:833-40. doi:10.1093/jac/dkm055
- 67 Khanh NC, Thai PQ, Quach H-L, et al. Transmission of SARS-CoV-2 during long-haul flight. *Emerg Infect Dis* 2020;26:2617-24. doi:10.3201/eid2611.203299
- 68 Toyokawa T, Shimada T, Hayamizu T, et al. Transmission of SARS-CoV-2 during a 2-h domestic flight to Okinawa, Japan, March 2020. *Influenza Other Respir Viruses* 2022;16:63-71. doi:10.1111/irv.12913
- 69 Speake H, Phillips A, Chong T, et al. Flight-associated transmission of severe acute respiratory syndrome coronavirus 2 corroborated by whole-genome sequencing. *Emerg Infect Dis* 2020;26:2872-80. doi:10.3201/eid2612.203910
- 70 Swadi T, Geoghegan JL, Devine T, et al. Genomic evidence of in-flight transmission of SARS-CoV-2 despite predeparture testing. *Emerg Infect Dis* 2021;27:687-93. doi:10.3201/eid2703.204714
- 71 Fox MP, Murray EJ, Lesko CR, Sealy-Jefferson S. On the Need to Revitalize Descriptive Epidemiology. *Am J Epidemiol* 2022;kwac056. doi:10.1093/aje/kwac056
- 72 Kutter JS, de Meulder D, Bestebroer TM, et al. SARS-CoV and SARS-CoV-2 are transmitted through the air between ferrets over more than one meter distance. *Nat Commun* 2021;12:1653. doi:10.1038/s41467-021-21918-6

Supplementary information: supplementary material 1: search strategy, quality criteria checklist, and list of excluded studies

Supplementary information: supplementary material 2: data extraction of included studies

Review of Fungal Outbreaks and Infection Prevention in Healthcare Settings During Construction and Renovation

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Hospital construction and renovation activities are an ever-constant phenomenon in healthcare facilities, causing dust contamination and possible dispersal of fungal spores. We reviewed fungal outbreaks that occurred during construction and renovation over the last 4 decades as well as current infection prevention strategies and control measures. Fungal outbreaks still occur in healthcare settings, especially among patients with hematological malignancies and those who are immunocompromised. The causative pathogens of these outbreaks were usually *Aspergillus* species, but Zygomycetes and other fungi were occasionally reported. *Aspergillus* most commonly caused pulmonary infection. The overall mortality of construction/renovation-associated fungal infection was approximately 50%. The minimal concentration of fungal spores by air sampling for acquisition of fungal infections remains to be determined. Performing infection control risk assessments and implementing the recommended control measures is essential to prevent healthcare-associated fungal outbreaks during construction and renovation.

Keywords. fungal outbreaks; *Aspergillus*; healthcare-associated infections; construction; renovation.

Numerous fungal outbreaks have occurred in healthcare settings and have been a serious threat to immunocompromised hosts [1]. Construction and renovation activities can cause serious dust contamination and disperse large amounts of fungal spores, and construction activity has been reported to be an independent risk factor for invasive fungal infections [1,2]. A previous review revealed that construction or renovation activities within the hospital or in surrounding areas accounted for approximately half of the sources of healthcare-associated *Aspergillus* outbreaks [2]. Hospital construction and renovation activities are an ever-constant phenomenon [2], and the cost of hospital construction is expected to be nearly \$200 billion dollars by 2015 in the United

States [3]. It is estimated that 5000 deaths due to construction-related infections occur each year in healthcare settings [4].

The goal of this review article was to (1) examine fungal outbreaks that were related to hospital construction, renovation, and/or demolition over the last 4 decades; and (2) offer infection prevention and control measures in healthcare facilities based on previous experiences, evidence, and guidelines.

SEARCH AND SELECTION CRITERIA

To select relevant articles, we searched the published literature in PubMed using the following keywords [All Fields]: (aspergillosis OR *Aspergillus* OR Zygomycetes OR Mucor OR mycoses OR mycosis OR fungi) AND (hospital OR healthcare OR nosocomial) AND (construction OR renovation) AND (outbreak OR contamination OR infection OR prevention OR control). From 1974 through 2014, 158 references were carefully reviewed. Additional reports were also identified through the references cited. Finally, 49 studies [5–53] were

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selected for the analysis, including all cases of outbreaks that were related to hospital construction, renovation, or demolition. We excluded non-English publications, reported cases of contaminations or *Candida* species only, and reports that did not include human infections. We used each author's definition in the selected articles to classify construction, renovation, demolition, and excavation. Definitive outbreaks (pseudo-outbreaks were not included) are summarized in Table 1.

FUNGAL OUTBREAKS ASSOCIATED WITH CONSTRUCTION AND RENOVATION AT EACH 5-YEAR TIME PERIOD

The trend of outbreaks that were related to construction, renovation, and demolition by 5-year period of publication from 1970 to the present is shown in Figure 1. The first report was published in 1976 [5], and the reported cases of outbreaks increased gradually. There were 7–10 articles of outbreaks associated with construction, renovation, and demolition in each 5-year period during 1985–2009; however, in the last period, 2010–2014, there were only 3 published studies that had been conducted before 2010. This reduction in reported outbreaks may represent improved infection control that resulted in fewer outbreaks or publication bias (by authors or journals) given the large number of previously published outbreaks.

SETTINGS WHERE FUNGAL OUTBREAKS AND INFECTIONS OCCURRED, AND PATIENT POPULATIONS AT RISK

Healthcare-associated fungal outbreaks have been reported throughout the world [2]. In this review of English-language studies that focused on construction and renovation, the United States accounted for 47% (23/49 articles), followed by European countries, including the United Kingdom (8%), Italy (8%), and France (8%). University hospitals were the most common (35%) settings. Tertiary care hospitals and university hospitals have often implemented the most medically advanced treatment in a given era (eg, cancer chemotherapy, immunosuppressive therapy, and transplant), which likely accounts for the overrepresentation of academic centers because of their highly susceptible patient populations.

Susceptible populations for healthcare-associated *Aspergillus* infections included patients with the following characteristics: hematological malignancies, allogeneic hematopoietic stem cell transplant (HSCT), solid organ transplant (renal and liver), high-dose steroid therapy, neonates, other malignancies, chronic lung disease, residing in intensive care units (ICUs), and thoracic surgery [2]. The main risk factors for healthcare-associated mucormycosis were prolonged steroid therapy, solid organ transplant, diabetes mellitus, prematurity, and hematological malignancies [54].

In this review, hematologic malignancies or bone marrow transplant accounted for 53% of reports by underlying diseases, and construction-related fungal infections occurred infrequently among rheumatology patients, patients after surgery, premature infants, and nephrology and dialysis patients (Table 2).

FEATURES OF FUNGAL OUTBREAKS AND INFECTIONS AND THOSE CAUSATIVE PATHOGENS

The primary infection site was mainly lower respiratory tract in healthcare-associated *Aspergillus* outbreaks as air was the major transmission route of fungal spore, whereas surgical site infections and skin infections were rarely described [2]. Of the 41 articles reporting *Aspergillus* infection only, the major site of *Aspergillus* infection was lung only (19 articles [46%]), followed by lung with other sites (8 articles [20%]), skin/wound (3 articles [7%]), sinus with other sites (1 article), eye (1 article), and disseminated (1 article). An outbreak of *Aspergillus fumigatus* endophthalmitis after cataract surgery during construction has been described [32]. The causative pathogens of fungal outbreaks and infections were usually *Aspergillus* species, including *A. fumigatus*, *Aspergillus flavus*, *Aspergillus terreus*, and *Aspergillus niger*, but occasionally Zygomycetes and other fungi, which was similar to a previously published article [55]. Six construction-related cases of healthcare-associated pulmonary mucormycosis due to *Mucor indicus* or *Cunninghamella bertholletiae* have been reported [9, 34], although it was difficult to differentiate healthcare-acquired from community-acquired mucormycosis, as most of those infections in hospitalized patients are sporadic in nature [56].

Furthermore, there were 4 articles of pseudo-outbreaks associated with construction and renovation, including a pseudo-epidemic of *Sporothrix cyanescens* pneumonia due to bronchoscopy material contaminated by dust created during renovation of the bronchoscopy suite [57]; pseudo-fungemia of *Aspergillus* species and *Penicillium* species from contamination of plates that had been inadvertently left open to air on a workbench area connected to locations outside the laboratory during renovation [58]; pseudo-epidemic of *A. niger* cultures traced to specimen contamination in the laboratory during construction [59]; and pseudo-outbreak of *Aspergillus sydowii* keratitis due to environmental contamination of culture media following construction in an ophthalmology ward [60].

Invasive aspergillosis is an independent predictor of mortality, and the overall case-fatality rate among the published reports was 58%, ranging from 25% in cutaneous cases to 88% in disseminated or central nervous system cases [61, 62]. Death attributable to mucormycosis differed from 50% to 100% by each report [54]. This review revealed that the overall mortality of fungal outbreaks and infections associated with construction

Table 1. Characteristics of Fungal Outbreaks and Infections Associated With Construction, Renovation, and Demolition

Author, Year	Patient Population	No. of Patient Infected	No. of Patient Deaths	Type of Infection (Site)	Type of Fungi	Reservoir or Source	Airborne Fungal Level(s)	Molecular Typing	Control Measures
Aisner, 1976 [5]	Cancer patients	8	Unknown	<i>Aspergillus</i> infection (lung, pharyngeal, or maxillary sinus)	<i>Aspergillus</i> spp. (predominantly <i>A. niger</i> , <i>A. flavus</i> , <i>A. fumigatus</i>)	Fireproofing material sprayed wet during construction	Unknown	Unknown	Unknown
Arnou, 1978 [6]	Immunosuppression (renal transplant)	3	1	<i>Aspergillus</i> infection (lung)	<i>A. fumigatus</i> , <i>Aspergillus</i> sp.	Renovation, spores on dust from false ceiling tiles above transplant unit	Airborne spores >200 cfu below renovation	Unknown	Impermeable plastic barriers, immunosuppressed patients moved to other floors, horizontal surfaces, vacuumed, damp mopped, and dusted
Sarubbi, 1982 [8]	Hospitalized patients (acute nonlymphocytic leukemia for 1 infected)	1	1	Invasive <i>Aspergillus</i> infection (lung)	<i>A. flavus</i>	Construction, defective ventilation and air filtration	8 <i>A. flavus</i> /positive room, control 1 <i>A. flavus</i> /positive room-settle plates	Unknown	Pre-filters and filters in ventilation system replaced
Lentino, 1982 [7]	Immunosuppressed patients with renal allograft recipients or hematologic malignancy	10	4	Invasive <i>Aspergillus</i> infection (lung)	<i>Aspergillus</i> sp.	Road construction for access to the new hospital, contaminated window air conditioners in renal transplantation ward	400–2800 <i>Aspergillus</i> spores/cm ² from air conditioner filter	Unknown	Unknown
Krasinski, 1985 [9]	Premature infants	2	2	Fungal infection (lung)	<i>Aspergillus</i> sp., Zygomycetes, <i>Rhizopus indicus</i>	Renovation of adjacent special care unit and demolition of wall, mold in dust above a false ceiling	0.88 fungi per hour per settle plate compared to 0.22 fungi per hour per settle plate in construction free area	Unknown	Patients moved from area of construction, additional dampers placed in air ducts, impervious dust barriers erected, area above false ceiling and ventilation ducts vacuumed, replaced HEPA filters, air ducts and environmental surfaces disinfected
Opal, 1986 [10]	Immunocompromised (lymphoreticular malignancy, high-dose corticosteroid therapy or disseminated carcinoma)	11	11	<i>Aspergillus</i> infection (disseminated)	<i>A. flavus</i> , <i>A. fumigatus</i> , <i>A. niger</i> , <i>Aspergillus</i> sp.	Hospital renovation and construction	5.9 ± 0.7 <i>Aspergillus</i> /m ³ inside construction site compared to 1.2 <i>Aspergillus</i> /m ³ outside construction site	Unknown	Copper-8 quinolinolate, airtight plastic and dry wall barriers about the construction site, HEPA filters in patients room, and negative pressure in construction area
Barnes, 1989 [14]	Children undergoing BMT	6	6	Invasive <i>Aspergillus</i> infection (lung)	Unknown	Building work installing a laminar air flow system to the unit	133 cfu/m ³ of <i>A. fumigatus</i> in the BMT unit during building work	Unknown	Laminar air flow isolation
Humphreys, 1991 [19]	Severe patients in the ITU	2	2	Invasive <i>Aspergillus</i> infection (lung)	<i>A. fumigatus</i> , <i>A. flavus</i>	Building work in an area adjacent to the ITU, disturbance of spores in fibrous insulation material above the perforated metal ceiling	Sampling after building work completed, but no molds isolated	Unknown	Improved hospital design, satisfactory ventilation, thorough regular cleaning of environmental surfaces, and relocation of patients

Table 1 continued.

Author, Year	Patient Population	No. of Patient Infected	No. of Patient Deaths	Type of Infection (Site)	Type of Fungi	Reservoir or Source	Airborne Fungal Level(s)	Molecular Typing	Control Measures
Brincker, 1991 [18]	Acute leukemia	10	4	<i>Aspergillus</i> infection (lung)	Unknown	Indoor building renovation, increased spores in ward locations with heavy traffic of patients and staff	At least 11.2 <i>Aspergillus</i> per 24h-settle plate	Unknown	Unknown
Flynn, 1993 [20]	BMT recipients, acute myeloid leukemia, or disseminated choriocarcinoma	4	4	<i>Aspergillus</i> infection (lung)	<i>A. terreus</i>	Hospital renovation, entry of fungal organisms from corridors, stairwells, elevator, shafts serving the ICU and renovation areas due to the negative air pressure gradient	Fungal spores >71/m ³ at elevator shafts during renovation	Unknown	Reestablished positive pressure and unidirectional airflow
Iwen, 1994 [22]	Neutropenic patients who underwent high-dose chemotherapy	5	Unknown	Invasive <i>Aspergillus</i> infection (unknown)	<i>A. fumigatus</i> , <i>A. flavus</i>	Hospital construction, increase in molds in the air occurred in the patient rooms and corridor adjacent to construction staging area, windows in the adjacent corridor as the most likely source of mold contamination	0.14 cfu fungi per hour per settle plate (before construction) to 0.40 cfu fungi per hour per settle plate (after construction)	Unknown	Special care unit closed to incoming patients, window casements, plumbing penetrations, electrical outlets, and other sources for potential air leaks visually examined and sealed, HEPA filters replaced, each room terminally cleaned with subsequent follow-up testing by air-settling plates
Buffington, 1994 [21]	Acute leukemia or aplastic anemia	7	6	Invasive <i>Aspergillus</i> infection (unknown)	<i>A. flavus</i> , <i>A. fumigatus</i> , <i>Aspergillus</i> sp.	Construction activity, staff and visitors frequently walking through breezeway by the construction	Unknown	Randomly amplified polymorphic DNA (6 different pattern, similar pattern banding from case patient, healthcare worker, and environmental source)	Laminar air flow rooms with HEPA filters, air intake ducts decontaminated with formaldehyde vapor
Loudon, 1994 [23]	Hematologic malignancies (acute lymphoblastic leukemia, acute myeloid leukemia, lymphoma, Hodgkin's disease)	7	5	Invasive <i>Aspergillus</i> infection (lung)	<i>A. fumigatus</i> , <i>A. flavus</i>	Extensive building work was ongoing on the ground floor beneath the hematology unit, <i>Aspergillus</i> for showerhead	Unknown	Silver staining of sodium dodecyl sulphate-immunoblot fingerprinting, and random amplification of polymorphic DNA (3 cases indistinguishable)	Itraconazole prophylaxis

Table 1 continued.

Author, Year	Patient Population	No. of Patient Infected	No. of Patient Deaths	Type of Infection (Site)	Type of Fungi	Reservoir or Source	Airborne Fungal Level(s)	Molecular Typing	Control Measures
Anderson, 1996 [25]	Immunocompromised pediatric patients with leukemia or neuroblastoma	6	Unknown	Nosocomial <i>Aspergillus</i> infection (lung, blood, pericardial fluid, or cardiac vegetation)	<i>A. fumigatus</i> , <i>A. terreus</i> , <i>A. flavus</i> , <i>A. niger</i> , <i>Aspergillus</i> sp.	Defective disposal conduit door and dispersal of contaminated aerosol from the ward vacuum cleaner	62 <i>Aspergillus</i> /m ³ close to vacuum cleaner during use	Unknown	Disposal door sealed, vacuum cleaner replaced by a machine of higher efficiency, itraconazole prophylaxis
Loo, 1996 [28]	Patients with leukemia or BMT	36	17	Nosocomial <i>Aspergillus</i> infection (lung, sinus)	<i>A. flavus</i> , <i>A. fumigatus</i> , <i>A. niger</i>	Archaic ventilation system in hospital which could not filter the <i>Aspergillus</i> spores that were disturbed and dispersed to patient-care areas during construction activity	6.77 <i>Aspergillus</i> sp./m ³ during the epidemic period	Unknown	Portable HEPA filter air purifier units, application of copper-8-quinolinate formulation, windows sealed, existing perforated ceiling tiles replaced with the easy-to-clean, non-perforated tiles, vinyl-faced aluminum tiles, horizontal dust-accumulating blinds replaced with vinyl, opaque, roller shades, ventilation systems meticulously maintained, patient rooms cleaned regularly, patients moved to another area of the hospital and housed in single rooms with doors closed
Thio, 2000 [35]	Patients with leukemia or BMT	21	6	Invasive <i>Aspergillus</i> infection (sinus and other)	<i>A. flavus</i>	Construction of a new building adjacent to the oncology center, negative pressure in the oncology unit	0.8–18 <i>A. flavus</i> /1,000L	Randomly amplified polymorphic DNA (2 of 5 patient samples and 5 environmental samples identical)	Use of wet buffing to clean all floors, N95 masks to protect neutropenic patients outside filtered areas, portable HEPA at entrance, change of traffic patterns into the unit, windows and exterior walls resealed, doors to patient rooms kept closed, hospital construction policy developed, closing central stairwell
Lai, 2001 [37]	Patients undergoing BMT and neutropenia	2	2	Invasive <i>Aspergillus</i> infection (lung)	<i>Aspergillus</i> sp., <i>A. flavus</i>	Construction below the unit, but no link to the construction by air sampling	0.5–5.9/0 <i>Aspergillus</i> cfu/m ³ , 5.9–23.6/0.4–> 11.6 other filamentous fungi cfu/m ³ (precleaning/postcleaning)	Unknown	BMT unit closed, air intake ducts cleaned, HEPA filters replaced, double plastic coverings across the entryways to construction sites, stairwell sealed with negative pressure, carpeting replaced by vinyl flooring, prophylactic amphotericin B
Burwen, 2001 [36]	Neutropenic patients in hematology-oncology ward	6	Unknown	Invasive <i>Aspergillus</i> infection (lung, blood, ear tissue, and other)	<i>A. flavus</i>	Internal construction on a new west wing adjacent to the hematology-oncology ward and renovation of patients' room	Unknown	Randomly amplified polymorphic DNA (patient isolate matched an environmental isolates matched)	Unknown

Table 1 continued.

Author, Year	Patient Population	No. of Patient Infected	No. of Patient Deaths	Type of Infection (Site)	Type of Fungi	Reservoir or Source	Airborne Fungal Level(s)	Molecular Typing	Control Measures
Oren, 2001 [38]	Acute leukemia	31	8	Invasive <i>Aspergillus</i> infection (lung)	<i>Aspergillus</i> sp.	Extensive hospital construction and indoor renovation	15 <i>Aspergillus</i> /m ³ at construction site	Unknown	Amphotericin B prophylaxis, and HEPA system
Read, 2002 [39]	Neutropenic patients with hematologic malignancy	113	Unknown	Nosocomial invasive <i>Aspergillus</i> infection (lung)	<i>A. fumigatus</i> , <i>A. terreus</i> , <i>A. flavus</i>	Hospital construction (low-intensity construction and high-intensity construction)	5–29 fungi/m ³ in outdoor air during low-intensity construction, 1–71 fungi/m ³ in outdoor air during high-intensity construction and 1–2 fungi/m ³ in indoor air	Unknown	Physical barriers using floor-to-ceiling dry wall or plastic barriers, protected environment with laminar air-flow rooms, HEPA filter, use of high-efficiency filtration masks for patients when leaving rooms
Yonemori, 2002 [40]	Acute leukemia	4	0	Invasive fungal infection (lung)	Unknown	Demolition and excavation near new building	65 fungi/m ³ at construction area; 10 fungi/m ³ in patient rooms	Unknown	Windows sealed, use of portable open horizontal laminar-air-flow apparatuses placed at bedside of neutropenic patients, itraconazole prophylaxis
Panackal, 2003 [42]	Renal transplant recipients	4	4	Invasive <i>Aspergillus</i> infection (unknown)	<i>A. fumigatus</i>	Inappropriate barriers between construction site and ward, frequent trafficking of staff between the construction and patient care areas, few respiratory protection	Unknown	Restriction fragment length polymorphism (genotype matched between 2 patients and 2 environmental isolates, but no match between environmental and clinical isolate)	Recommend application of CDC guideline such as: appropriate placement of impermeable barriers, the use of HEPA filters in HVAC, N95 respirator use for patients in contaminated areas, preventing traffic between construction and patient care areas, and elevator for exclusive use of construction workers and debris removal
Ahmad Sarji, 2006 [44]	Child patients with leukemia and other malignancies undergoing chemotherapy	14	9	Fungal infection (lung, blood, sinus, liver, spleen, kidney, skin)	<i>Candida</i> sp., <i>Aspergillus</i> sp., <i>Fusarium</i> sp., <i>Chrysosporium</i> sp., <i>Mycellium</i> sp., <i>Monilia</i> sp., <i>Phaeclomyces</i> sp.	Soil disturbance at adjacent building construction work	659 fungi /m ³ at treatment room	Unknown	Identifying high-risk patients, anti-fungal prophylaxis
Berthelot, 2006 [45]	Highly immunocompromised patients with hematological malignancies	15	8	Invasive <i>Aspergillus</i> infection (lung)	<i>A. flavus</i> , <i>A. fumigatus</i>	Hospital building work and demolition	3.7% - 15.2% (frequency of environmental samples containing <i>A. fumigatus</i> per year)	Unknown	Use of temporary barriers during work, watering of soil during demolition work, reduction of pedestrian traffic in construction areas, maintaining negative pressure, and wearing of high-efficiency filtration masks by immunosuppressed patients

Table 1 continued.

Author, Year	Patient Population	No. of Patient Infected	No. of Patient Deaths	Type of Infection (Site)	Type of Fungi	Reservoir or Source	Airborne Fungal Level(s)	Molecular Typing	Control Measures
Pini, 2008 [50]	Acute leukemia	7	Unknown	Invasive <i>Aspergillus</i> infection (lung)	<i>A. fumigatus</i> , <i>Aspergillus</i> sp.	Renovation work	2.98 <i>A. fumigatus</i> /m ³ corridor between the wards, 0.09 <i>A. fumigatus</i> /m ³ in restricted access rooms	Unknown	Multiple-bed rooms without HEPA filtration but restricted access to visitors and other particular behavioral measures (ban on plants, flowers, and opening windows)
Chang, 2008 [49]	Leukemia, multiple myeloma, and high-grade lymphoma	6	2	Nosocomial invasive <i>Aspergillus</i> infection (lung, mediastinum)	<i>A. fumigatus</i>	Hospital construction in and around the vicinity of the day oncology building	No fungal growth by air sampling in the inpatient facility, day-oncology and pharmacy	Unknown	Unit relocation, impermeable barriers at construction site, face-masking and voriconazole prophylaxis among high-risk patients
Chabrol, 2010 [51]	Acute leukemia	25	6	Invasive <i>Aspergillus</i> infection (lung, sinus, brain, disseminated)	<i>A. fumigatus</i> , <i>A. flavus</i> , <i>A. terreus</i>	Construction or renovation work	1–10 <i>Aspergillus</i> /m ³ (during building work)	Unknown	HEPA filters without any laminar air flow room, and prophylaxis with voriconazole or caspofungin
Pokala, 2014 [53]	Children with acute leukemia	50	10	Invasive fungal diseases (lung, sinus, and other)	<i>Scedosporium</i> sp., <i>Rhizopus</i> sp., <i>Phoma</i> sp., <i>Exosporium</i> sp., <i>Bipolaris</i> sp., <i>Fusarium</i> sp., <i>Aspergillus</i> sp., <i>Candida</i> sp.	Major renovation with excavation of the grounds for construction of a new tower connected to the existing buildings	Unknown	Unknown	Windows of the existing adjacent building re-sealed, education for construction crews, air handling systems optimized using HEPA filters, use of N-95 respirator, valet parking service for all oncology patients immediately adjacent to the hospital entrance, fluconazole or voriconazole prophylaxis

Abbreviations: BMT, bone marrow transplant; CDC, Centers for Disease Control and Prevention; CFU, colony-forming unit; HEPA, high-efficiency particulate air; HVAC, heating, ventilation, and air conditioning; ICU, intensive care unit; ITU, intensive therapy unit.

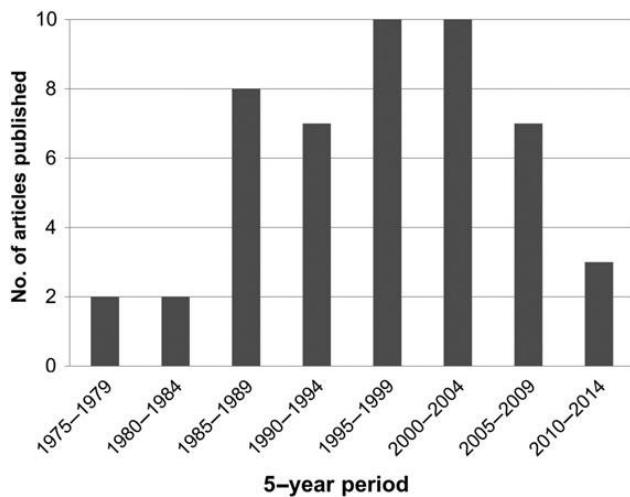


Figure 1. Trend of fungal outbreaks and infections associated with construction, renovation, and demolition.

and renovation among the published reports was 48%, ranging from 12.5% after surgery to 67% in rheumatology patients, premature infants, or nephrology and dialysis patients (Table 2). Thus, the mortality of fungal outbreaks and infections was substantially high but varied greatly according to underlying conditions and infection types.

RESERVOIRS AND SOURCES OF FUNGI OUTBREAKS AND INFECTIONS ASSOCIATED WITH CONSTRUCTION AND RENOVATION

Construction was the most common type of source in this review (38 articles [78%]), followed by renovation (19), demolition (4), and excavation (3). The data on reservoirs and sources are summarized in Table 1. Environmental sources in construction-related settings were described as follows: inflow of unfiltered outside air, backflow of contaminated air, air

filters, fireproofing materials, air conditioners, duct systems, and dust above false ceilings [55], thereby enabling fungal spores to be aerosolized and disseminated throughout hospital areas. *Aspergillus* species can also be isolated from hospital water samples and be involved in invasive aspergillosis [52, 63, 64]. However, it remains unclear how *Aspergillus* species isolated from hospital water contribute to nosocomial waterborne *Aspergillus* infections, and there are no criteria for determining water contamination levels that have been correlated with a risk of fungal infections.

LABORATORY TESTING, AIR SAMPLING, AND MOLECULAR TYPING IN INVESTIGATION OF FUNGAL OUTBREAKS AND INFECTIONS

In the special settings of construction and renovation, several studies described the monitoring of *Aspergillus* species using quantitative polymerase chain reaction (PCR) of air samples [65, 66] or serum *Aspergillus* galactomannan in pediatric patients with allogeneic stem cell transplant [67]. Although *Aspergillus* infections were finally diagnosed at autopsy in many articles reviewed, the diagnosis of invasive aspergillosis during a patient's lifetime remains difficult. Clinical signs and radiological findings for *Aspergillus* infections can be nonspecific, and in less invasive testing methods, there are diagnostic limitations for conventional culture methods and serum biomarkers (eg, galactomannan and [1→3]-β-D-glucan assays) due to the low sensitivities and for clinical implementation of PCR assays because of the potential environmental contamination of *Aspergillus* DNA [68–72]. Recently, detection of *Aspergillus* antigen by the lateral-flow device as a point-of-care test [73] or *Aspergillus* secondary metabolite signature in breath by thermal desorption–gas chromatography/mass spectrometry [72] may be promising, but further investigation is needed.

Air sampling may be used to measure airborne fungal levels inside and outside of hospitals before, during, and after

Table 2. Fungal Infections and Associated Mortality by Each Underlying Disease During Construction, Renovation, or Demolition

Underlying Diseases	No. of Articles Published	No. of Patients Infected	No. of Patients Died	Mortality, No. ^a (%)
Hematologic malignancies or bone marrow transplant	26	414	148	131/288 (45.5)
Other malignancies, transplant, and/or immunosuppressed patients	13	105	38	38/60 (63.3)
Patients in intensive care unit	3	8	2	2/4 (50)
Rheumatology patients	2	6	4	4/6 (66.7)
After surgery	2	8	1	1/8 (12.5)
Premature infant	2	3	2	2/3 (66.7)
Nephrology and dialysis patients	1	3	2	2/3 (66.7)
Total	49	547	197	180/372 (48.4)

^a Articles in which the number of patients infected or died was unknown were excluded for mortality calculation.

Table 3. Bundle of Key Methods for Preventing Filamentous Fungal Infections Associated With Renovation/Construction Activities

1. Hospital epidemiology (infection control) should be notified by plant engineering prior to any renovation/construction activities in the healthcare facility.
2. Conduct an ICRA for all renovation/construction activities: implement recommended prevention strategies as guided by the ICRA.
3. Focus prevention efforts on control of airborne dissemination of fungal spores (eg, barriers, containment, air handling, portable HEPA filters).
4. Consider impact of renovation/construction on the involved hospital unit plus adjacent units on the same floor, and hospital units on floors above and below the renovation/construction activities.
5. Maintain surveillance for healthcare-associated filamentous fungal infections during renovation/construction. Investigate any cases to see if they are related to renovation/construction and determine if prevention efforts need to be revised.
6. Visit renovation/construction sites regularly to assure compliance with recommended prevention activities.

Source: Adapted from the Centers for Disease Control and Prevention. Guidelines for Environmental Infection Control in Health-Care Facilities. Available at: http://www.cdc.gov/hicpac/pdf/guidelines/eic_in_HCF_03.pdf. Accessed 2 January 2015.

Abbreviations: HEPA, high-efficiency particulate air; ICRA, infection control risk assessment.

construction by identifying viable airborne fungal spores [1]. Air sampling may be useful in inspection of ventilation performance, maintenance, and cleaning of airflow systems, construction activities, and epidemiologic investigation and research purposes, but microbiologic air sampling and environmental culture are not routinely recommended [55]. Although air sampling has been performed in many studies, there are no standardized methods that are comparable in terms of performance, data collection and analysis, and interpretation (eg, type of air samplers, sampling sites and time, air volume, airflow rate, ecological condition [1]). In addition, there are only limited studies showing a direct relationship between fungal spore concentration by air sampling and human fungal infections in healthcare settings during construction and renovation [37]. In fact, airborne fungal levels varied greatly, and even <1 colony-forming unit (CFU)/m³ could be associated with an *Aspergillus* outbreak among immunocompromised patients [2]. In this review focused on construction and renovation, 22 of 49 (45%) articles conducted air sampling, and airborne fungal levels ranged from 1 to 659 CFU/m³. Several investigators have provided a time series over several years in which they assessed a relationship between healthcare-associated filamentous fungal infections and construction and renovation [45, 52, 53, 74]. In some cases, an increase in fungal infections with an increase in fungal spores occurred during the time period of renovation and construction [14, 22, 28]. Although renovation and construction can be associated with outbreaks, the correlation is

imperfect (ie, outbreaks may occur without renovation/construction, whereas renovation/construction may occur without an outbreak). An article reported fungal infections despite no fungal growth by air sampling [49]. Thus, the minimal airborne concentration of spores needed for acquisition of fungal infections remains to be determined.

Unlike most bacterial outbreaks in healthcare settings, multiple fungal strains can cause construction-related outbreaks because *Aspergillus* species are ubiquitous in nature [75]. In addition, the incubation period of invasive aspergillosis remains unclear, and thus it is impossible to definitively conclude that *Aspergillus* infections resulted from construction activities. Notably, a recent whole-genome sequencing analysis of serial *A. fumigatus* clinical isolates showed dynamic alterations in the genome within its host [76]. In this review, only 5 (10%) articles applied molecular typing, mostly random amplified polymorphic DNA (4 articles), to their investigations. Furthermore, if molecular typing is performed and reveals multiple distinguishable fungal strains within a patient cluster, the possibility of a nosocomial outbreak cannot be excluded as invasive fungal cases could be caused by a variety of unrelated strains [2]. Therefore, the value of *Aspergillus* typing to facilitate epidemiologic investigations remains undetermined. The lack of genotypic matches between the environmental and clinical isolates may be related to the genetic diversity of *Aspergillus* species in the environment.

INFECTION PREVENTION AND CONTROL MEASURES IN SPECIAL HEALTHCARE SETTINGS OF CONSTRUCTION AND RENOVATION

Infection prevention and control measures used to prevent and terminate outbreaks are summarized in Table 1. Recent guidelines regarding infection prevention and control in construction and renovation activities have been published [77–79]. A multidisciplinary coordination team and elaborate planning are essential to prevent airborne fungal infections before/during/after construction and renovation activities in healthcare facilities [78]. The environmental surveillance for immunocompromised patients and high-risk units during construction and renovation are also recommended by several guidelines [77, 80]. A bundle of preventive measures for fungal infections associated with renovation/construction activities is summarized in Table 3. Construction activities can be safely conducted if a bundle of preventive measures is employed with cooperation and coordination among team members who are involved in infection prevention and control for construction projects [81]. It is important for infection control departments to ensure that hospital engineering staff notify them of the planned work activities and seek advice from them preemptively for all hospital

construction and renovation. Furthermore, education of construction workers, engineers controlling indoor air quality and ventilation, and healthcare personnel caring for high-risk patients is necessary to mitigate dust and moisture intrusion from construction sites into patients' areas. Regular monitoring and feedback on compliance with infection control guidelines in and around construction site are also critical [78].

The risk assessment before construction and renovation is implemented to identify potential exposures of susceptible patients to dust and moisture for prevention of airborne infections and to mitigate potential risks [78]. The infection control risk assessment (ICRA) is a multidisciplinary, organizational, documented process using the risk matrix based on construction project types (eg, type A: small noninvasive and inspection; type D: major demolition and construction) and patient risk groups (eg, low risk: office areas and public areas; highest risk: ICUs, oncology, and transplant units). The matched matrix helps to determine the class of infection control precautions that should be followed. Details of the ICRA are available at http://www.ashe.org/advocacy/organizations/CDC/pdfs/assessment_icra.pdf. Infection control risk mitigation recommendations are developed as specific measures for obviating transmission of airborne biological contaminants in construction activities.

Protective measures include relocating high-risk patients, wet cleaning, sealing off the construction site and avoiding unnecessary traffic, and using air filtration adequately [49, 77]. The Centers for Disease Control and Prevention guideline recommends high-efficiency particulate air (HEPA) for high-risk patients as the HEPA filter system can reduce fungal spore counts from the environment of healthcare facilities during construction and renovation and may help prevent fungal outbreaks in combination with other environmental control measures [1, 77]. However, a meta-analysis revealed no significant improvement of HEPA filtration in the prevention of death among patients with hematological malignancies and severe neutropenia, although there were possible publication bias and limitations that no studies were blinded or had control subjects [82]. Further investigations are needed to clarify whether specific control measures contribute to preventing healthcare-associated fungal infections in construction and renovation.

Because antifungal prophylaxis is recommended by the Infectious Diseases Society of America for immunosuppressed patients, including neutropenic patients and HSCT recipients, under certain conditions [83], physicians are likely to administer antifungal prophylaxis among those patients, whether or not construction and renovation are ongoing. Although the practical use of antifungal drugs for prophylaxis is beyond the scope of this review, pharmacokinetics/pharmacodynamics, spectrums, interactions, and adverse effects should be considered in administering antifungal drugs properly. Several previous

studies described the usefulness of antifungal prophylaxis during construction and renovation [49, 51], but no randomized controlled studies exist in such a special condition. On the other hand, voriconazole prophylaxis did not prevent healthcare-associated environmental mold infections among approximately 40% of pediatric patients with leukemia who had received this prophylaxis and had exposure to hospital construction with excavation that was related to the increased risk of developing mold infections despite the recommended prospective measures, suggesting the need for monitoring compliance with infection preventive strategies [53].

CONCLUSIONS

We reviewed outbreaks and infections with medically important mycotic agents during construction and renovation over the last 4 decades, and summarized current infection prevention and control strategies. Construction-related fungal cases among recently published articles seem to be in decline, presumably due to introduction of guidelines and policies regarding infection prevention and control and dissemination of antifungal prophylaxis, but fungal outbreaks and infections under special circumstances still continue to occur in healthcare settings, especially among patients with hematological malignancies and those who are immunocompromised. Further research is required to address the unresolved issues on air sampling and molecular typing for investigation of sources, and specific control measures. It is important for infectious disease physicians and infection preventionists in collaboration with building contractors and other associated departments to appropriately implement risk assessment and mitigation measures and prevent healthcare-associated fungal outbreaks and infections.

Supplementary Data

Supplementary materials are available at *Clinical Infectious Diseases* online (<http://cid.oxfordjournals.org>). Supplementary materials consist of data provided by the author that are published to benefit the reader. The posted materials are not copyedited. The contents of all supplementary data are the sole responsibility of the authors. Questions or messages regarding errors should be addressed to the author.

Note

Potential conflicts of interest. All authors: No reported conflicts.

All authors have submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest. Conflicts that the editors consider relevant to the content of the manuscript have been disclosed.

References

1. Chang CC, Athan E, Morrissey CO, Slavin MA. Preventing invasive fungal infection during hospital building works. *Intern Med J* **2008**; 38:538–41.
2. Vonberg RP, Gastmeier P. Nosocomial aspergillosis in outbreak settings. *J Hosp Infect* **2006**; 63:246–54.

3. Stichler JF. Enhancing safety with facility design. *J Nurs Adm* **2007**; 37:319–23.
4. Bartley J. Hospital construction: stirring up trouble. *Engineered Systems*, **2007**. Available at: http://www.esmagazine.com/Articles/Feature_Article/BNP_GUID_9-5-2006_A_1000000000000126814. Accessed 6 February 2015.
5. Aisner J, Schimpff SC, Bennett JE, Young VM, Wiernik PH. *Aspergillus* infections in cancer patients. Association with fireproofing materials in a new hospital. *JAMA* **1976**; 235:411–2.
6. Arnow PM, Andersen RL, Mainous PD, Smith EJ. Pulmonary aspergillosis during hospital renovation. *Am Rev Respir Dis* **1978**; 118: 49–53.
7. Lentino JR, Rosenkranz MA, Michaels JA, Kurup VP, Rose HD, Rytel MW. Nosocomial aspergillosis: a retrospective review of airborne disease secondary to road construction and contaminated air conditioners. *Am J Epidemiol* **1982**; 116:430–7.
8. Sarubbi FA Jr, Kopf HB, Wilson MB, McGinnis MR, Rutala WA. Increased recovery of *Aspergillus flavus* from respiratory specimens during hospital construction. *Am Rev Respir Dis* **1982**; 125:33–8.
9. Krasinski K, Holzman RS, Hanna B, Greco MA, Graff M, Bhogal M. Nosocomial fungal infection during hospital renovation. *Infect Control* **1985**; 6:278–82.
10. Opal SM, Asp AA, Cannady PB Jr, Morse PL, Burton LJ, Hammer PG 2nd. Efficacy of infection control measures during a nosocomial outbreak of disseminated aspergillosis associated with hospital construction. *J Infect Dis* **1986**; 153:634–7.
11. Perraud M, Piens MA, Nicoloyannis N, Girard P, Sepetjan M, Garin JP. Invasive nosocomial pulmonary aspergillosis: risk factors and hospital building works. *Epidemiol Infect* **1987**; 99:407–12.
12. Ruutu P, Valtonen V, Tiitonen L, et al. An outbreak of invasive aspergillosis in a haematologic unit. *Scand J Infect Dis* **1987**; 19:347–51.
13. Weems JJ Jr, Davis BJ, Tablan OC, Kaufman L, Martone WJ. Construction activity: an independent risk factor for invasive aspergillosis and zygomycosis in patients with hematologic malignancy. *Infect Control* **1987**; 8:71–5.
14. Barnes RA, Rogers TR. Control of an outbreak of nosocomial aspergillosis by laminar air-flow isolation. *J Hosp Infect* **1989**; 14:89–94.
15. Hopkins CC, Weber DJ, Rubin RH. Invasive aspergillus infection: possible non-ward common source within the hospital environment. *J Hosp Infect* **1989**; 13:19–25.
16. Klimowski LL, Rotstein C, Cummings KM. Incidence of nosocomial aspergillosis in patients with leukemia over a twenty-year period. *Infect Control Hosp Epidemiol* **1989**; 10:299–305.
17. Weber SF, Peacock JE Jr, Do KA, Cruz JM, Powell BL, Capizzi RL. Interaction of granulocytopenia and construction activity as risk factors for nosocomial invasive filamentous fungal disease in patients with hematologic disorders. *Infect Control Hosp Epidemiol* **1990**; 11:235–42.
18. Brincker H, Christensen BE, Schmidt KG, Hornstrup MK. Itraconazole treatment of pulmonary aspergillosis in leukaemia patients during a nosocomial epidemic associated with indoor building renovation. *Mycoses* **1991**; 34:395–400.
19. Humphreys H, Johnson EM, Warnock DW, Willatts SM, Winter RJ, Speller DC. An outbreak of aspergillosis in a general ITU. *J Hosp Infect* **1991**; 18:167–77.
20. Flynn PM, Williams BG, Hetherington SV, Williams BF, Giannini MA, Pearson TA. *Aspergillus terreus* during hospital renovation. *Infect Control Hosp Epidemiol* **1993**; 14:363–5.
21. Buffington J, Reporter R, Lasker BA, et al. Investigation of an epidemic of invasive aspergillosis: utility of molecular typing with the use of random amplified polymorphic DNA probes. *Pediatr Infect Dis J* **1994**; 13:386–93.
22. Iwen PC, Davis JC, Reed EC, Winfield BA, Hinrichs SH. Airborne fungal spore monitoring in a protective environment during hospital construction, and correlation with an outbreak of invasive aspergillosis. *Infect Control Hosp Epidemiol* **1994**; 15:303–6.
23. Loudon KW, Coke AP, Burnie JP, Lucas GS, Liu Yin JA. Invasive aspergillosis: clusters and sources? *J Med Vet Mycol* **1994**; 32:217–24.
24. Alvarez M, Lopez Ponga B, Rayon C, et al. Nosocomial outbreak caused by *Scedosporium prolificans* (*inflatum*): four fatal cases in leukemic patients. *J Clin Microbiol* **1995**; 33:3290–5.
25. Anderson K, Morris G, Kennedy H, et al. Aspergillosis in immunocompromised paediatric patients: associations with building hygiene, design, and indoor air. *Thorax* **1996**; 51:256–61.
26. Ansorg R, van den Boom R, von Heinegg EH, Rath PM. Association between incidence of *Aspergillus* antigenemia and exposure to construction works at a hospital site. *Zentralbl Bakteriol Parasitenkd Infektionskr Hyg* **1996**; 284:146–52.
27. Bryce EA, Walker M, Scharf S, et al. An outbreak of cutaneous aspergillosis in a tertiary-care hospital. *Infect Control Hosp Epidemiol* **1996**; 17:170–2.
28. Loo VG, Bertrand C, Dixon C, et al. Control of construction-associated nosocomial aspergillosis in an antiquated hematology unit. *Infect Control Hosp Epidemiol* **1996**; 17:360–4.
29. Papouli M, Roilides E, Bibashi E, Andreou A. Primary cutaneous aspergillosis in neonates: case report and review. *Clin Infect Dis* **1996**; 22:1102–4.
30. Sessa A, Meroni M, Battini G, et al. Nosocomial outbreak of *Aspergillus fumigatus* infection among patients in a renal unit? *Nephrol Dial Transplant* **1996**; 11:1322–4.
31. Patterson JE, Zidouh A, Minitier P, Andriole VT, Patterson TF. Hospital epidemiologic surveillance for invasive aspergillosis: patient demographics and the utility of antigen detection. *Infect Control Hosp Epidemiol* **1997**; 18:104–8.
32. Tabbara KF, al Jabarti AL. Hospital construction-associated outbreak of ocular aspergillosis after cataract surgery. *Ophthalmology* **1998**; 105: 522–6.
33. Garrett DO, Jochimsen E, Jarvis W. Invasive *Aspergillus* spp infections in rheumatology patients. *J Rheumatol* **1999**; 26:146–9.
34. Rickerts V, Bohme A, Viertel A, et al. Cluster of pulmonary infections caused by *Cunninghamella bertholletiae* in immunocompromised patients. *Clin Infect Dis* **2000**; 31:910–3.
35. Thio CL, Smith D, Merz WG, et al. Refinements of environmental assessment during an outbreak investigation of invasive aspergillosis in a leukemia and bone marrow transplant unit. *Infect Control Hosp Epidemiol* **2000**; 21:18–23.
36. Burwen DR, Lasker BA, Rao N, Durry E, Padhye AA, Jarvis WR. Invasive aspergillosis outbreak on a hematology-oncology ward. *Infect Control Hosp Epidemiol* **2001**; 22:45–8.
37. Lai KK. A cluster of invasive aspergillosis in a bone marrow transplant unit related to construction and the utility of air sampling. *Am J Infect Control* **2001**; 29:333–7.
38. Oren I, Haddad N, Finkelstein R, Rowe JM. Invasive pulmonary aspergillosis in neutropenic patients during hospital construction: before and after chemoprophylaxis and institution of HEPA filters. *Am J Hematol* **2001**; 66:257–62.
39. Raad I, Hanna H, Osting C, et al. Masking of neutropenic patients on transport from hospital rooms is associated with a decrease in nosocomial aspergillosis during construction. *Infect Control Hosp Epidemiol* **2002**; 23:41–3.
40. Yonemori K, Takezako N, Nishimura K, et al. Fungal infection in neutropenic patients in a hospital during construction. *Jpn J Infect Dis* **2002**; 55:126–7.
41. De Rosa FG, Shaz D, Campagna AC, Dellaripa PE, Khetry U, Craven DE. Invasive pulmonary aspergillosis soon after therapy with infliximab, a tumor necrosis factor- α -neutralizing antibody: a possible healthcare-associated case? *Infect Control Hosp Epidemiol* **2003**; 24:477–82.
42. Panackal AA, Dahlman A, Keil KT, et al. Outbreak of invasive aspergillosis among renal transplant recipients. *Transplantation* **2003**; 75:1050–3.
43. Florio M, Marroni M, Morosi S, Stagni G. Nosocomial *Aspergillus flavus* wound infections following cardiac surgery. *Infez Med* **2004**; 12:270–3.

44. Ahmad Sarji S, Wan Abdullah W, Wastie M. Imaging features of fungal infection in immuno-suppressed patients in a local ward outbreak. *Biomed Imaging Interv J* **2006**; 2:e21.
45. Berthelot P, Loulergue P, Raberin H, et al. Efficacy of environmental measures to decrease the risk of hospital-acquired aspergillosis in patients hospitalised in haematology wards. *Clin Microbiol Infect* **2006**; 12:738–44.
46. Kidd F, Buttner C, Kressel AB. Construction: a model program for infection control compliance. *Am J Infect Control* **2007**; 35:347–50.
47. Nataloni S, Gabbanelli V, Rossi R, Donati A, Pantanetti S, Pelaia P. Successful early voriconazole treatment of *Aspergillus* infection in two non immunocompromised patients in intensive care unit. *Minerva Anestesiol* **2007**; 73:371–5.
48. Raviv Y, Kramer MR, Amital A, Rubinovitch B, Bishara J, Shitrit D. Outbreak of aspergillosis infections among lung transplant recipients. *Transpl Int* **2007**; 20:135–40.
49. Chang CC, Cheng AC, Devitt B, et al. Successful control of an outbreak of invasive aspergillosis in a regional haematology unit during hospital construction works. *J Hosp Infect* **2008**; 69:33–8.
50. Pini G, Faggi E, Donato R, Sacco C, Fanci R. Invasive pulmonary aspergillosis in neutropenic patients and the influence of hospital renovation. *Mycoses* **2008**; 51:117–22.
51. Chabrol A, Cuzin L, Huguet F, et al. Prophylaxis of invasive aspergillosis with voriconazole or caspofungin during building work in patients with acute leukemia. *Haematologica* **2010**; 95:996–1003.
52. Garnaud C, Brenier-Pinchart MP, Thiebaut-Bertrand A, et al. Seven-year surveillance of nosocomial invasive aspergillosis in a French university hospital. *J Infect* **2012**; 65:559–67.
53. Pokala HR, Leonard D, Cox J, et al. Association of hospital construction with the development of healthcare associated environmental mold infections (HAEMI) in pediatric patients with leukemia. *Pediatr Blood Cancer* **2014**; 61:276–80.
54. Rammaert B, Lanternier F, Zahar JR, et al. Healthcare-associated mucormycosis. *Clin Infect Dis* **2012**; 54(suppl 1):S44–54.
55. Haiduvén D. Nosocomial aspergillosis and building construction. *Med Mycol* **2009**; 47(suppl 1):S210–6.
56. Richardson M. The ecology of the Zygomycetes and its impact on environmental exposure. *Clin Microbiol Infect* **2009**; 15(suppl 5):2–9.
57. Jackson L, Klotz SA, Normand RE. A pseudoepidemic of *Sporothrix cyanescens* pneumonia occurring during renovation of a bronchoscopy suite. *J Med Vet Mycol* **1990**; 28:455–9.
58. Hruszkewycz V, Ruben B, Hypes CM, Bostic GD, Staszkiwicz J, Band JD. A cluster of pseudofungemia associated with hospital renovation adjacent to the microbiology laboratory. *Infect Control Hosp Epidemiol* **1992**; 13:147–50.
59. Laurel VL, Meier PA, Astorga A, Dolan D, Brockett R, Rinaldi MG. Pseudoepidemic of *Aspergillus niger* infections traced to specimen contamination in the microbiology laboratory. *J Clin Microbiol* **1999**; 37:1612–6.
60. Freeman J, Rogers K, Roberts S. Pseudo-outbreak of *Aspergillus* keratitis following construction in an ophthalmology ward. *J Hosp Infect* **2007**; 67:104–5.
61. Lin SJ, Schranz J, Teutsch SM. Aspergillosis case-fatality rate: systematic review of the literature. *Clin Infect Dis* **2001**; 32:358–66.
62. Vandewoude KH, Blot SI, Benoit D, Colardyn F, Vogelaers D. Invasive aspergillosis in critically ill patients: attributable mortality and excesses in length of ICU stay and ventilator dependence. *J Hosp Infect* **2004**; 56:269–76.
63. Warris A, Klaassen CH, Meis JF, et al. Molecular epidemiology of *Aspergillus fumigatus* isolates recovered from water, air, and patients shows two clusters of genetically distinct strains. *J Clin Microbiol* **2003**; 41:4101–6.
64. Anaissie EJ, Stratton SL, Dignani MC, et al. Pathogenic *Aspergillus* species recovered from a hospital water system: a 3-year prospective study. *Clin Infect Dis* **2002**; 34:780–9.
65. Morrison J, Yang C, Lin KT, Haugland RA, Neely AN, Vesper SJ. Monitoring *Aspergillus* species by quantitative PCR during construction of a multi-storey hospital building. *J Hosp Infect* **2004**; 57:85–7.
66. Goebes MD, Baron EJ, Mathews KL, Hildemann LM. Effect of building construction on *Aspergillus* concentrations in a hospital. *Infect Control Hosp Epidemiol* **2008**; 29:462–4.
67. Hovi L, Saxen H, Saarinen-Pihkala UM, Vettenranta K, Meri T, Richardson M. Prevention and monitoring of invasive fungal infections in pediatric patients with cancer and hematologic disorders. *Pediatr Blood Cancer* **2007**; 48:28–34.
68. Hope WW, Walsh TJ, Denning DW. Laboratory diagnosis of invasive aspergillosis. *Lancet Infect Dis* **2005**; 5:609–22.
69. Pfeiffer CD, Fine JP, Safdar N. Diagnosis of invasive aspergillosis using a galactomannan assay: a meta-analysis. *Clin Infect Dis* **2006**; 42:1417–27.
70. Koo S, Bryar JM, Page JH, Baden LR, Marty FM. Diagnostic performance of the (1→3)- β -D-glucan assay for invasive fungal disease. *Clin Infect Dis* **2009**; 49:1650–9.
71. Harrison E, Stalherger T, Whelan R, et al. *Aspergillus* DNA contamination in blood collection tubes. *Diagn Microbiol Infect Dis* **2010**; 67:392–4.
72. Koo S, Thomas HR, Daniels SD, et al. A breath fungal secondary metabolite signature to diagnose invasive aspergillosis. *Clin Infect Dis* **2014**; 59:1733–40.
73. Hoenigl M, Prattes J, Spiess B, et al. Performance of galactomannan, beta-D-glucan, *Aspergillus* lateral-flow device, conventional culture, and PCR tests with bronchoalveolar lavage fluid for diagnosis of invasive pulmonary aspergillosis. *J Clin Microbiol* **2014**; 52:2039–45.
74. Hansen D, Blahout B, Benner D, Popp W. Environmental sampling of particulate matter and fungal spores during demolition of a building on a hospital area. *J Hosp Infect* **2008**; 70:259–64.
75. Hajjeh RA, Warnock DW. Counterpoint: invasive aspergillosis and the environment—rethinking our approach to prevention. *Clin Infect Dis* **2001**; 33:1549–52.
76. Hagiwara D, Takahashi H, Watanabe A, et al. Whole-genome comparison of *Aspergillus fumigatus* strains serially isolated from patients with aspergillosis. *J Clin Microbiol* **2014**; 52:4202–9.
77. Centers for Disease Control and Prevention. Guidelines for environmental infection control in health-care facilities: recommendations of CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC). *MMWR Recomm Rep* **2003**; 52(No. RR-10): 1–48.
78. Sehulster LM, Chinn RYW, Arduino MJ, et al. Guidelines for environmental infection control in health-care facilities. Recommendations from CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC). Chicago, IL: American Society for Healthcare Engineering/American Hospital Association, **2004**.
79. Facility Guidelines Institute. Guidelines for design and construction of hospitals and outpatient facilities. Chicago, IL: American Society for Healthcare Engineering of the American Hospital Association, **2014**.
80. French Society for Medical Mycology and the French Society for Hospital Hygiene. Risk of fungal infections, and construction work in hospitals, **2011**. Available at: http://www.sf2h.net/SF2H_english/SF2H-SFMM_fungal-infections-guidelines-2011.pdf. Accessed 2 March 2015.
81. Berger J, Willinger B, Diab-Elschahawi M, et al. Effectiveness of preventive measures for hemato-oncologic patients undergoing stem cell transplantation during a period of hospital construction. *Am J Infect Control* **2011**; 39:746–51.
82. Eckmanns T, Ruden H, Gastmeier P. The influence of high-efficiency particulate air filtration on mortality and fungal infection among highly immunosuppressed patients: a systematic review. *J Infect Dis* **2006**; 193:1408–18.
83. Freifeld AG, Bow EJ, Sepkowitz KA, et al. Clinical practice guideline for the use of antimicrobial agents in neutropenic patients with cancer: 2010 update by the Infectious Diseases Society of America. *Clin Infect Dis* **2011**; 52:427–31.



EVIDENCE SUPPORTS THE HIGH BARRIER TO RESISTANCE OF DOVATO UP TO 5 YEARS¹⁻³

CONFIDENCE IN DOVATO ACROSS TREATMENT SETTINGS⁴⁻⁹

Treatment-naïve resistance rates, with up to **3 years of evidence**⁵⁻⁷

0%
(n=0/1,885)^{*4}
REAL-WORLD EVIDENCE

0.1%
(n=1/953)^{*4,11,12,13}
RANDOMISED CONTROLLED TRIALS

Treatment-experienced resistance rates, with up to **5 years of evidence**¹⁻³

0.03%
(n=10/35,888)^{*4}
REAL-WORLD EVIDENCE

0%
(n=0/615)^{11,12,13}
RANDOMISED CONTROLLED TRIALS

>300,000 PEOPLE LIVING WITH HIV HAVE BEEN TREATED WITH DOVATO GLOBALLY¹⁰

DOVATO is supported by a wealth of evidence, with the outcomes of **>40,000** people living with HIV captured within clinical trials and real-world evidence, including those with:^{4-9,11,12}



NO PRIOR TREATMENT EXPERIENCE¹³



NO BASELINE RESISTANCE TESTING¹³

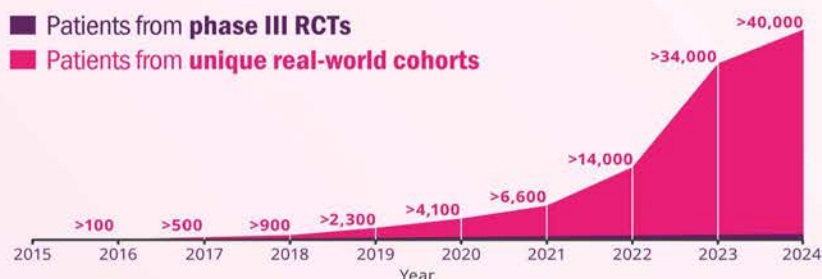


HIGH BASELINE VIRAL LOAD
(>100,000 copies/mL and even >1M copies/mL)^{6,13}



LOW CD4+ COUNT
(≤200 cells/mm³)¹³

■ Patients from **phase III RCTs**
■ Patients from **unique real-world cohorts**



IS IT TIME TO RECONSIDER THE VALUE OF THE 2ND NRTI?

LEARN MORE ➔

DOVATO is indicated for the treatment of Human Immunodeficiency Virus type 1 (HIV-1) infection in adults and adolescents above 12 years of age weighing at least 40 kg, with no known or suspected resistance to the integrase inhibitor class, or lamivudine.¹³

Adverse events should be reported. Reporting forms and information can be found at <https://yellowcard.mhra.gov.uk/> or search for MHRA Yellowcard in the Google Play or Apple App store. Adverse events should also be reported to GSK on 0800 221441

REFERENCES

1. Maggiolo F et al. BMC Infect Dis 2022; 22(1): 782.
2. Taramasso L et al. AIDS Patient Care STDs 2021; 35(9): 342-353.
3. Ciccullo A et al. JAIDS 2021; 88(3): 234-237.
4. ViiV Healthcare. Data on File. REF-223795. 2024.
5. Cahn P et al. AIDS 2022; 36(1): 39-48.
6. Rolfe C et al. Open Forum Infect Dis 2023; 10(3): ofad101.
7. Cordova E et al. Poster presented at 12th IAS Conference on HIV Science. 23-26 July 2023. Brisbane, Australia. TUPEB02.
8. De Wit S et al. Slides presented at HIV Glasgow. 23-26 October 2022. Virtual and Glasgow, UK. M041.
9. Llibre J et al. Clin Infect Dis 2023; 76(4): 720-729.
10. ViiV Healthcare. Data on File. REF-220949. 2024.
11. Rolfe C et al. Poster presented IDWeek. 11-15 October 2023. Virtual and Boston, USA. 1603.
12. Slim J et al. Abstract presented IDWeek. 11-15 October 2023. Virtual and Boston, USA. 1593.
13. DOVATO. Summary of Product Characteristics. June 2023.

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ABBREVIATIONS

3TC, lamivudine; **CD4**, cluster of differentiation 4; **DTG**, dolutegravir; **FDA**, United States Food and Drug Administration; **FTC**, emtricitabine; **HIV**, human immunodeficiency virus; **ITT-E**, intention-to-treat exposed; **NRTI**, nucleoside/nucleotide reverse transcriptase inhibitor; **RCT**, randomised controlled trial; **RNA**, ribonucleic acid; **TAF**, tenofovir alafenamide fumarate; **TDF**, tenofovir disoproxil fumarate; **XTC**, emtricitabine.

FOOTNOTES

*Data extracted from a systematic literature review of DTG+3TC real-world evidence. Overlap between cohorts cannot be fully excluded.

**The reported rate reflects the sum-total of resistance cases calculated from GEMINI I and II (n=1/716, through 144 weeks), STAT (n=0/131, through 52 weeks), and D2ARLING (n=0/106, through 24 weeks).⁵⁻⁷

†GEMINI I and II are two identical 148-week, phase III, randomised, double-blind, multicentre, parallel-group, non-inferiority, controlled clinical trials testing the efficacy of DTG/3TC in treatment-naïve patients. Participants with screening HIV-1 RNA ≤500,000 copies/mL were randomised 1:1 to once-daily DTG/3TC (n=716, pooled) or DTG + TDF/FTC (n=717, pooled). The primary endpoint of each GEMINI study was the proportion of participants with plasma HIV-1 RNA <50 copies/mL at Week 48 (ITT-E population, snapshot algorithm).¹³

‡STAT is a phase IIb, open-label, 48-week, single-arm pilot study evaluating the feasibility, efficacy, and safety of DTG/3TC in 131 newly diagnosed HIV-1 infected adults as a first line regimen. The primary endpoint was the proportion of participants with plasma HIV-1 RNA <50 copies/mL at Week 24.⁶

§D2ARLING is a randomised, open-label, phase IV study designed to assess the efficacy and safety of DTG/3TC in treatment-naïve people with HIV with no available baseline HIV-1 resistance testing. Participants were randomised in a 1:1 ratio to receive DTG/3TC (n=106) or DTG + TDF/XTC (n=108). The primary endpoint was the proportion of participants with plasma HIV-1 RNA <50 copies/mL at Week 48. Results at week 24 of the study.

|| The reported rate reflects the sum-total of resistance cases calculated from TANGO (n=0/369, through 196 weeks) and SALSA (n=0/246, through 48 weeks).^{8,9}

¶TANGO is a randomised, open-label, trial testing the efficacy of DOVATO in virologically suppressed patients. Participants were randomised in a 1:1 ratio to receive DOVATO (n=369) or continue with TAF-containing regimens (n=372) for up to 200 weeks. At Week 148, 298 of those on TAF-based regimens switched to DOVATO. The primary efficacy endpoint was the proportion of subjects with plasma HIV-1 RNA ≥50 copies/mL (virologic non-response) as per the FDA Snapshot category at Week 48 (adjusted for randomisation stratification factor).^{8,13}

#SALSA is a phase III, randomised, open-label, non-inferiority clinical trial evaluating the efficacy and safety of switching to DTG/3TC compared with continuing current antiretroviral regimens in virologically suppressed adults with HIV. Eligible participants were randomised 1:1 to switch to once-daily DTG/3TC (n=246) or continue current antiretroviral regimens (n=247). The primary endpoint was the proportion of subjects with plasma HIV-1 RNA ≥50 copies/mL at Week 48 (ITT-E population, snapshot algorithm).⁹

REVIEW

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Recognition of aerosol transmission of infectious agents: a commentary

Raymond Tellier¹, Yuguo Li², Benjamin J. Cowling³ and Julian W. Tang^{4,5*}

Abstract

Although short-range large-droplet transmission is possible for most respiratory infectious agents, deciding on whether the same agent is also airborne has a potentially huge impact on the types (and costs) of infection control interventions that are required.

The concept and definition of aerosols is also discussed, as is the concept of large droplet transmission, and airborne transmission which is meant by most authors to be synonymous with aerosol transmission, although some use the term to mean either large droplet or aerosol transmission.

However, these terms are often used confusingly when discussing specific infection control interventions for individual pathogens that are accepted to be mostly transmitted by the airborne (aerosol) route (e.g. tuberculosis, measles and chickenpox). It is therefore important to clarify such terminology, where a particular intervention, like the type of personal protective equipment (PPE) to be used, is deemed adequate to intervene for this potential mode of transmission, i.e. at an N95 rather than surgical mask level requirement.

With this in mind, this review considers the commonly used term of 'aerosol transmission' in the context of some infectious agents that are well-recognized to be transmissible via the airborne route. It also discusses other agents, like influenza virus, where the potential for airborne transmission is much more dependent on various host, viral and environmental factors, and where its potential for aerosol transmission may be underestimated.

Keywords: Aerosol, Airborne, Droplet, Transmission, Infection

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Background

The classification of an infectious agent as airborne and therefore ‘aerosol-transmissible’ has significant implications for how healthcare workers (HCWs) need to manage patients infected with such agents and what sort of personal protective equipment (PPE) they will need to wear. Such PPE is usually more costly for airborne agents (i.e. aerosol-transmissible) than for those that are only transmitted by large droplets or direct contact because of two key properties of aerosols: a) their propensity to follow air flows, which requires a tight seal of the PPE around the airways, and b) for bioaerosols, their small size, which calls for an enhanced filtering capacity.

Several recent articles and/or guidance, based on clinical and epidemiological data, have highlighted the potential for aerosol transmission for Middle-East Respiratory Syndrome-associated coronavirus (MERS-CoV) [1, 2] and Ebola virus [3, 4]. Some responses to the latter have attempted to put these theoretical risks in a more practical light [4], and this nicely illustrates the quandary of how to classify such emerging or re-emerging pathogens into either the large droplet (short-range) versus airborne (short and possibly long-range) transmission categories. However, this delineation is not black and white, as there is also the potential for pathogens under both classifications to be potentially transmitted by aerosols between people at close range (i.e. within 1 m).

Definitions

Strictly speaking, ‘aerosols’ refer to particles in suspension in a gas, such as small droplets in air. There have been numerous publications classifying droplets using particle sizes over the years [5–10]. For example it is generally accepted that: i) small particles of $< 5\text{--}10\text{ }\mu\text{m}$ aerodynamic diameter that follow airflow streamlines are potentially capable of short and long range transmission; particles of $< 5\text{ }\mu\text{m}$ readily penetrates the airways all the way down to the alveolar space, and particles of $< 10\text{ }\mu\text{m}$ readily penetrates below the glottis (7) ii) large droplets of diameters $> 20\text{ }\mu\text{m}$ refer to those that follow a more ballistic trajectory (i.e. falling mostly under the influence of gravity), where the droplets are too large to follow inhalation airflow streamlines. For these particle sizes, for example, surgical masks would be effective, as they will act as a direct physical barrier to droplets of this size that are too large to be inhaled into the respiratory tract around the sides of the mask (which are not close-fitting); iii) ‘intermediate particles’ of diameters $10\text{--}20\text{ }\mu\text{m}$, will share some properties of both small and large droplets, to some extent, but settle more quickly than particles $< 10\text{ }\mu\text{m}$ and potentially carry a smaller infectious dose than large ($> 20\text{ }\mu\text{m}$) droplets.

‘Aerosols’ would also include ‘droplet nuclei’ which are small particles with an aerodynamic diameter of $10\text{ }\mu\text{m}$ or less, typically produced through the process of rapid

desiccation of exhaled respiratory droplets [5, 6]. However, in some situations, such as where there are strong ambient air cross-flows, for example, larger droplets can behave like aerosols with the potential to transmit infection via this route (see next section below).

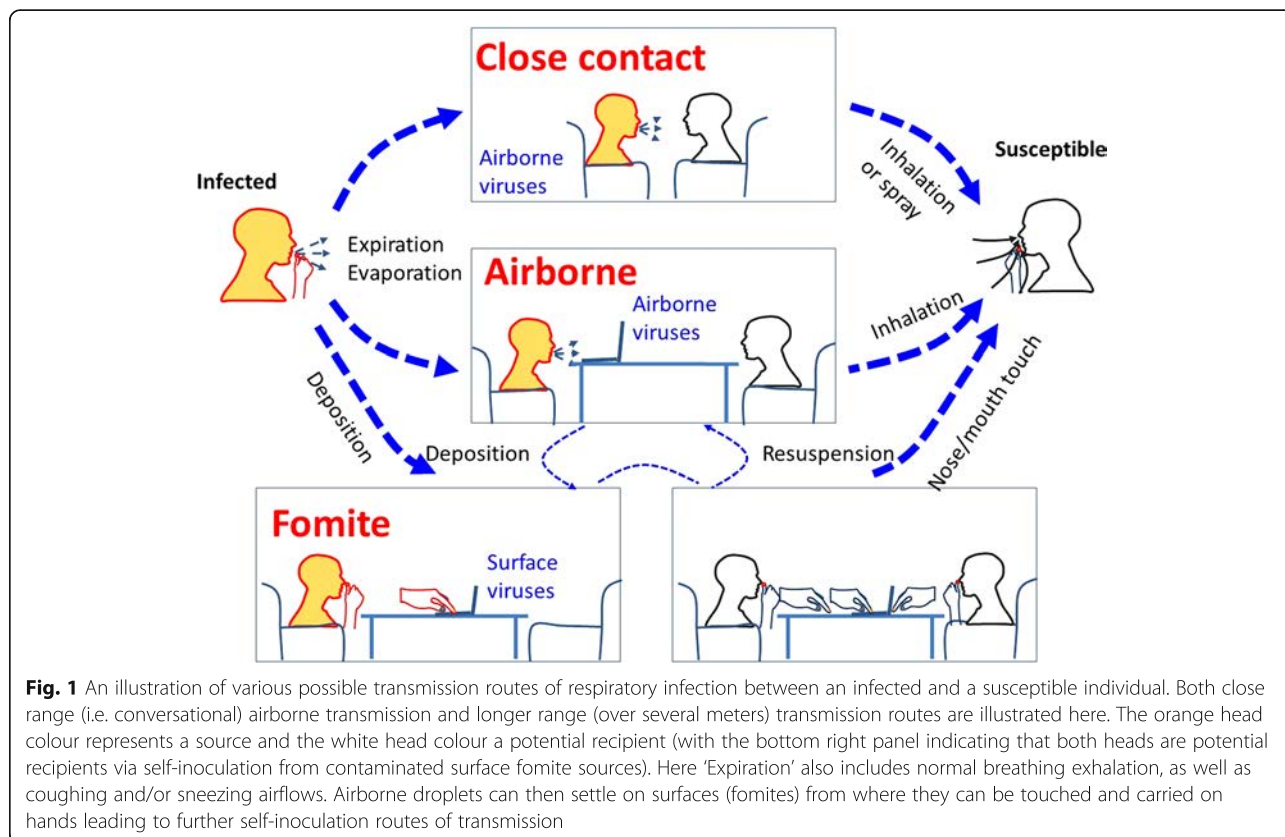
Several properties can be inferred from this, for example the penetration of the lower respiratory tract (LRT), as at greater than $10\text{ }\mu\text{m}$ diameter, penetration below the glottis rapidly diminishes, as does any potential for initiating an infection at that site. Similarly, any such potential for depositing and initiating an LRT infection is less likely above a droplet diameter of $20\text{ }\mu\text{m}$, as such large particles will probably impact onto respiratory epithelial mucosal surfaces or be trapped by cilia before reaching the LRT [6].

The Infectious Diseases Society of America (IDSA) has proposed a scheme that is essentially equivalent [7], defining “respirable particles” as having a diameter of $10\text{ }\mu\text{m}$ or less; and “inspirable particles” as having a diameter between $10\text{ }\mu\text{m}$ and $100\text{ }\mu\text{m}$, nearly all of which are deposited in the upper airways. Some authors have proposed the term “fine aerosols”, consisting of particles of $5\text{ }\mu\text{m}$ or less, but this has been in part dictated by constraints from measurement instruments [8]. Several authors lump together transmission by either large droplets or aerosol-sized particles as “airborne transmission” [9], or use “aerosol transmission” to describe pathogens that can cause disease via inspirable particles of any size [10].

However, we think that it is important to maintain a distinction between particles of $< 10\text{ }\mu\text{m}$ and larger particles, because of their significant qualitative differences including suspension time, penetration of different regions of the airways and requirements for different PPE. In this commentary, we use the common convention of “airborne transmission” to mean transmission by aerosol-size particles of $< 10\text{ }\mu\text{m}$.

If the infected patients produce infectious droplets of varying sizes by breathing, coughing or sneezing, transmission between individuals by both short-range large droplets and airborne small droplet nuclei are both possible, depending on the distance from the patient source. Figure 1 illustrates these potential routes of short and long-range airborne transmission, as well as the downstream settling of such droplets onto surfaces (fomites). From such fomites, they may be touched and transported by hands to be self-inoculated into mucosal membranes e.g. in the eyes, nose and mouth) to cause infection, depending on the survival characteristics of individual pathogens on such surfaces, and the susceptibility (related to available, compatible cell receptors) of the different exposed tissues to infection by these pathogens.

For example, when the infectious dose (the number of infectious agents required to cause disease) of an organism is low, and where large numbers of pathogen-laden droplets are produced in crowded conditions with poor



ventilation (in hospital waiting rooms, in lecture theatres, on public transport, etc.), explosive outbreaks can still occur, even with pathogens whose airborne transmission capacity is controversial, e.g. the spread of influenza in a grounded plane where multiple secondary cases were observed in the absence of any ventilation [11].

The more mechanistic approaches (i.e. arguing from the more fundamental physical and dynamic behavior of small versus larger particle and droplet sizes in the absence of any biological interactions) to classifying which pathogens are likely to transmit via the airborne route have been published in various ways over the years [12–17], but may have to be considered in combination with epidemiological and environmental data to make a convincing argument about the potential for the airborne transmissibility of any particular agent – and the number of possible potential exposure scenarios is virtually unlimited).

The importance of ambient airflows and the of aerosols

One should note that “aerosol” is essentially a relative and not an absolute term. A larger droplet can remain airborne for longer if ambient airflows can sustain this suspension for longer, e.g. in some strong cross-flow or natural ventilation environments, where ventilation-induced airflows can propagate suspended pathogens effectively enough to cause infection at a considerable distance away from the source.

One of the standard rules (Stoke's Law) applied in engineering calculations to estimate the suspension times of droplets falling under gravity with air resistance, was derived assuming several conditions including that the ambient air is still [13–17]. So actual suspension times will be far higher where there are significant cross-flows, which is often the case in healthcare environments, e.g. with doors opening, bed and equipment movement, and people walking back and forth, constantly. Conversely, suspension times, even for smaller droplet nuclei, can be greatly reduced if they encounter a significant downdraft (e.g. if they pass under a ceiling supply vent). In addition, the degree of airway penetration, for different particle sizes, also depends on the flow rate.

In the field of dentistry and orthopedics, where high-powered electric tools are used, even bloodborne viruses (such as human immunodeficiency virus – HIV, hepatitis B and hepatitis B viruses) can become airborne when they are contained in high velocity blood splatter generated by these instruments [18, 19]. Yet, whether they can cause efficient transmission via this route is more debatable. This illustrates another point, that although some pathogens can be airborne in certain situations, they may not necessarily transmit infection and cause disease via this route.

Outline

Over time, for a pathogen with a truly predominant airborne transmission route, eventually sufficient numbers of published studies will demonstrate its true nature [13]. If there are ongoing contradictory findings in multiple studies (as with influenza virus), it may be more likely that the various transmission routes (direct/indirect contact, short-range droplet, long-, and even short-range airborne droplet nuclei) may predominate in different settings [16, 20], making the airborne route for that particular pathogen more of an opportunistic pathway, rather than the norm [21]. Several examples may make this clearer.

The selected pathogens and supporting literature summarized below are for illustrative purposes only, to demonstrate how specific studies have impacted the way we consider such infectious agents as potentially airborne and ‘aerosol-transmissible’. It is not intended to be a systematic review, but rather to show how our thinking may change with additional studies on each pathogen, and how the acceptance of “aerosol transmission” for different pathogens did not always followed a consistent approach.

Results and discussion

Chickenpox

Chickenpox is a febrile, vesicular rash illness caused by varicella zoster virus (VZV), a lipid-enveloped, double-stranded DNA virus, and a member of the *Herpesviridae* family.

For chickenpox, the evidence appears to be mainly epidemiological and clinical, though this has appeared to be sufficient to classify varicella zoster virus (VZV) as an airborne agent. Studies on VZV have shown that the virus is clearly able to travel long distances (i.e. up to tens of meters away from the index case, to spread between isolation rooms and other ward areas connected by corridors, or within a household) to cause secondary infections and/or settle elsewhere in the environment [22–24]. In addition, Tang et al. [25] showed that airborne VZV could leak out of isolation rooms transported by induced environmental airflows to infect a susceptible HCW, most likely via the direct inhalation route.

Measles

Measles (also known as rubeola) is a febrile, rash illness caused by the measles virus, a lipid-enveloped, single-stranded, negative-sense RNA virus, and a member of the *Paramyxoviridae* family.

For measles several studies examined a more mechanistic airflow dynamical explanation (i.e. based upon the fundamental physics and behaviour of airborne particles) for the main transmission route involved in several measles outbreaks [26], including that of Riley and colleagues who used the concept of ‘quanta’ of infection [27]. Later, two other outbreaks in outpatient clinics included retrospective

airflow dynamics analysis, providing more evidence for the transmissibility of measles via the airborne route [28, 29].

Tuberculosis

Tuberculosis is a localized or systemic, but most often respiratory bacterial illness caused by mycobacteria belonging to the *Mycobacterium tuberculosis* complex.

For tuberculosis (TB), definitive experimental evidence of airborne transmission being necessary and sufficient to cause disease was provided in a series of guinea-pig experiments [30, 31], which has been repeated more recently in a slightly different clinical context [32]. Numerous other outbreak reports have confirmed the transmissibility of TB via the airborne route [33–35], and interventions specifically targeting the airborne transmission route have proven effective in reducing TB transmission [36].

Smallpox

Smallpox is a now eradicated, febrile, vesicular rash and disseminated illness, caused by a complex, double-stranded DNA orthopoxvirus (*Poxviridae* family), which can present clinically in two forms, as variola major or variola minor.

For smallpox, a recent comprehensive, retrospective analysis of the literature by Milton has suggested an important contribution of the airborne transmission route for this infection [37]. Although various air-sampling and animal transmission studies were also reviewed, Milton also emphasized clinical epidemiological studies where non-airborne transmission routes alone could not account for all the observed smallpox cases.

At least one well-documented hospital outbreak, involving 17 cases of smallpox, could only be explained by assuming the aerosol spread of the virus from the index case, over several floors. Retrospective smoke tracer experiments further demonstrated that airborne virus could easily spread to patients on different floors via open windows and connecting corridors and stairwells in a pattern roughly replicating the location of cases [38].

Emerging coronaviruses: Severe acute respiratory syndrome (SARS), middle-east respiratory syndrome (MERS)

Coronaviruses are lipid-enveloped, single-stranded positive sense RNA viruses, belong to the genus *Coronavirus* and include several relatively benign, seasonal, common cold viruses (229E, OC43, NL63, HKU-1). They also include two new more virulent coronaviruses: severe acute respiratory syndrome coronavirus (SARS-CoV), which emerged in the human population in 2003; and Middle-East Respiratory Syndrome coronavirus (MERS-CoV), which emerged in humans during 2012.

For SARS-CoV, several thorough epidemiological studies that include retrospective airflow tracer investigations are

consistent with the hypothesis of an airborne transmission route [39–41]. Air-sampling studies have also demonstrated the presence of SARS-CoV nucleic acid (RNA) in air, though they did not test viability using viral culture [42].

Although several studies compared and contrasted SARS and MERS from clinical and epidemiological angles [43–45], the predominant transmission mode was not discussed in detail, if at all. Several other studies do mention the potential for airborne transmission, when comparing potential routes of infection, but mainly in relation to super-spreading events or “aerosolizing procedures” such as broncho-alveolar lavage, and/or a potential route to take into consideration for precautionary infection control measures [46–48]. However, from the various published studies, for both MERS and SARS, it is arguable that a proportion of transmission occurs through the airborne route, although this may vary in different situations (e.g. depending on host, and environmental factors). The contribution from asymptomatic cases is also uncertain [49].

For both SARS and MERS, LRT samples offer the best diagnostic yield, often in the absence of any detectable virus in upper respiratory tract (URT) samples [50–52]. Furthermore, infected, symptomatic patients tend to develop severe LRT infections rather than URT disease. Both of these aspects indicate that this is an airborne agent that has to penetrate directly into the LRT to preferentially replicate there before causing disease.

For MERS-CoV specifically, a recent study demonstrated the absence of expression of dipeptidyl peptidase 4 (DPP4), the identified receptor used by the virus, in the cells of the human URT. The search for an alternate receptor was negative [53]. Thus, the human URT would seem little or non-permissive for MERS-CoV replication, indicating that successful infection can only result from the penetration into the LRT via direct inhalation of appropriately sized ‘droplet nuclei’-like particles. This makes any MERS-CoV transmission leading to MERS disease conditional on the presence of virus-containing droplets small enough to be inhaled into the LRT where the virus can replicate.

Influenza

Influenza is a seasonal, often febrile respiratory illness, caused by several species of influenza viruses. These are lipid-enveloped, single-stranded, negative-sense, segmented RNA viruses belonging to the *Orthomyxoviridae* family. Currently, influenza is the only common seasonal respiratory virus for which licensed antiviral drugs and vaccines are available.

For human influenza viruses, the question of airborne versus large droplet transmission is perhaps most controversial [54–57]. In experimental inoculation experiments on human volunteers, aerosolized influenza

viruses are infectious at a dose much lower than by nasal instillation [58]. The likely answer is that both routes are possible and that the importance and significance of each route will vary in different situations [16, 20, 21].

For example, tighter control of the environment may reduce or prevent airborne transmission by: 1) isolating infectious patients in a single-bed, negative pressure isolation room [25]; 2) controlling environmental relative humidity to reduce airborne influenza survival [59]; 3) reducing exposure from aerosols produced by patients through coughing, sneezing or breathing with the use of personal protective equipment (wearing a mask) on the patient (to reduce source emission) and/or the healthcare worker (to reduce recipient exposure) [60]; 4) carefully controlling the use and exposure to any respiratory assist devices (high-flow oxygen masks, nebulizers) by only allowing their use in designated, containment areas or rooms [61]. The airflows being expelled from the side vents of oxygen masks and nebulisers will contain a mixture of patient exhaled air (which could be carrying airborne pathogens) and incoming high flow oxygen or air carrying nebulized drugs. These vented airflows could then act as potential sources of airborne pathogens.

Numerous studies have shown the emission of influenza RNA from the exhaled breath of naturally influenza-infected human subjects [62–66] and have detected influenza RNA in environmental air [67–69]. More recently, some of these studies have shown the absence of [70], or significantly reduced numbers of viable viruses in air-samples with high influenza RNA levels (as tested by PCR) [66, 71, 72]. The low number of infectious particles detected is currently difficult to interpret as culture methods are inherently less sensitive than molecular methods such as PCR, and the actual operation of air-sampling itself, through shear-stress related damage to the virions, also causes a drop in infectivity in the collected samples. This may lead to underestimates of the amount of live virus in these environmental aerosols.

An additional variable to consider is that some animal studies have reported that different strains of influenza virus may vary widely in their capacity for aerosol transmission [73].

In some earlier articles that discuss the predominant mode of influenza virus transmission [74–78], these same questions are addressed with mixed conclusions. Most of the evidence described to support their views was more clinical and epidemiological, and included some animal and human volunteer studies, rather than physical and mechanistic. Yet, this mixed picture of transmission in different circumstances is probably the most realistic.

It is noteworthy that several infections currently accepted as airborne-transmitted, such as measles, chickenpox or TB present, in their classical form, an unmistakable and pathognomonic clinical picture. In

contrast the clinical picture of influenza virus infection has a large overlap with that of other respiratory viruses, and mixed outbreaks have been documented [79]. Thus, a prevalent misconception in the field has been to study ‘respiratory viruses’ as a group. However, given that these viruses belong to different genera and families, have different chemical and physical properties and differing viral characteristics, it is unwise and inaccurate to assume that any conclusions about one virus can be applied to another, e.g. in a Cochrane review of 59 published studies on interventions to reduce the spread of respiratory viruses, there were actually only two studies specifically about influenza viruses [80]. As the authors themselves pointed out, no conclusion specific to influenza viruses was possible.

While many airborne infections are highly contagious, this is not, strictly speaking, part of the definition. Even so, the lower contagiousness of influenza compared to, say, measles has been invoked as an argument against a significant contribution of airborne transmission. Yet, it should be noted that a feature of influenza virus infections is that the incubation time (typically 1–2 days) is much shorter than its duration of shedding. This allows for the possibility that a susceptible person will be exposed during an outbreak to several different infectious cases belonging to more than one generation in the outbreak. This multiple exposure and telescoping of generations may result in an underestimate of influenza virus transmissibility, as fewer secondary cases will be assigned to a known index case, when in fact the number of secondary cases per index could be much higher. For example, it is known that in some settings a single index case can infect a large number of people, e.g. 38 in an outbreak on an Alaska Airlines flight [11].

Ebola

Ebola is a viral hemorrhagic fever associated with a very high mortality, caused by the Ebola viruses; these are enveloped single-strand, negative-sense RNA viruses comprising five species within the family *Filoviridae*. Four Ebola species have been implicated in human diseases; the most widespread outbreak, also the most recent, was caused by Ebola Zaire in West Africa in 2013–2016. The transmission of Ebola viruses has been reviewed in depth by Osterholm et al. [4]. These authors noted the broad tissue tropism, as well as the high viral load reached during illness and the low infectious dose, from which it appears inescapable that more than one mode of transmission is possible.

Regarding aerosol transmission, concerns are raised by several documented instances of transmission of Ebola Zaire in laboratory settings between animals without direct contact [81, 82] (also reviewed in [4]). Experimental infections of Rhesus monkeys by Ebola Zaire using aerosol infection has been shown to be highly effective [83, 84] and

this experimental procedure has in fact been used as infectious challenge in Ebola vaccine studies [85, 86]. Rhesus monkeys infected by aerosol exposure reliably developed disseminated, fatal infection essentially similar to that caused by parenteral infection with the addition of involvement of the respiratory tract. Autopsies showed pathological findings in the respiratory tract and respiratory lymphoid system in animals infected by the aerosol route that are not found in animals infected parenterally [83, 84].

Such respiratory pathological lesions have not been reported in human autopsies of Ebola cases, but as noted by Osterholm et al. [4], there have been few human autopsies of Ebola cases, arguably too few to confidently rule out any possibility of disease acquired by the aerosol route. The precautionary principle would therefore dictate that aerosol precautions be used for the care of infected patients, and especially considering that infection of the respiratory tract in such patients is not necessary to create an aerosol hazard: Ebola viruses reach a very high titer in blood or other bodily fluids during the illness [87, 88] and aerosolization of blood or other fluids would create a significant airborne transmission hazard.

Conclusions

In summary, despite the various mechanistic arguments about which organisms can be potentially airborne and therefore aerosol-transmissible, ultimately, the main deciding factor appears to be how many studies using various differing approaches: empirical (clinical, epidemiological), and/or experimental (e.g. using animal models), and/or mechanistic (using airflow tracers and air-sampling) methods, reach the same consensus opinion. Over time, the scientific community will eventually form an impression of the predominant transmission route for that specific agent, even if the conclusion is one of mixed transmission routes, with different routes predominating depending on the specific situations. This is the case for influenza viruses, and is likely the most realistic.

Some bacterial and viral infections that have more than one mode of transmission are also *anisotropic*, like anthrax, plague, tularemia and smallpox: the severity of the disease varies depending on the mode of transmission [37, 89]. Older experimental infection experiments on volunteers suggest that this is the case for influenza, with transmission by aerosols being associated with a more severe illness [14, 90], and some more recent field observations are consistent with this concept [57]. For anisotropic agents, even if a mode of transmission (e.g. aerosols) accounts for only a minority of cases, interruption of that route of transmission may be required if it accounts for the most severe cases.

Abbreviations

LRT: lower respiratory tract; MERS-CoV: Middle East Respiratory Syndrome-associated coronavirus; PCR: polymerase chain reaction; RNA: ribonucleic

acid; SARS-CoV: severe acute respiratory syndrome-associated coronavirus; TB: tuberculosis; URT: upper respiratory tract; VZV: varicella zoster virus

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All studies cited/discussed are already published and in the public domain – some require the relevant journal subscriptions for access.

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Authors' contributions

JWT, RT, BJC developed the original concept and outline of the article; YL contributed the figures and some additional related text; all authors critically reviewed the final version of the manuscript. All authors read and approved the final manuscript.

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References

- CIDRAP (Center for Infectious Disease Research and Policy). Commentary: Protecting health workers from airborne MERS-CoV—learning from SARS <https://www.cdc.gov/coronavirus/mers/infection-prevention-control.html>. Accessed 9 August 2017.
- Kim SH, Chang SY, Sung M, et al. Extensive viable Middle East respiratory syndrome (MERS) coronavirus contamination in air and surrounding environment in MERS isolation wards. *Clin Infect Dis*. 2016;63:363–9.
- CIDRAP (Center for Infectious Disease Research and Policy). Commentary: Health workers need optimal respiratory protection for Ebola <https://www.cdc.gov/vhf/ebola/healthcare-us/ppe/guidance.html>. Accessed 9 August 2017.
- Osterholm MT, Moore KA, Kelley NS, Brosseau LM, Wong G, Murphy FA, et al. Transmission of Ebola viruses: what we know and what we do not know. *MBio*. 2015;6:e00137.
- Cole EC, Cook CE. Characterization of infectious aerosols in health care facilities: an aid to effective engineering controls and preventive strategies. *Am J Infect Control*. 1998;26:453–64.
- Hinds WC. *Aerosol technology*. 2nd ed. New York: John Wiley & Sons; 1999.
- Infectious Diseases Society of America (ISDA). Preventing Transmission of Pandemic Influenza and Other Viral Respiratory Diseases: Personal Protective Equipment for Healthcare Personnel: Update 2010. Chapter: 2 Understanding the Risk to Healthcare Personnel. 2010. <https://www.nap.edu/read/13027/chapter/4#30>
- Yan J, Grantham M, Pantelic J, Bueno de Mesquita PJ, Albert B, Liu F, et al. Infectious virus in exhaled breath of symptomatic seasonal influenza cases from a college community. *Proc Natl Acad Sci U S A*. 2018;115:1081–86.
- Herfst S, Schrauwen EJ, Linster M, Chutinimitkul S, de Wit E, Munster VJ, et al. Airborne transmission of influenza a/H5N1 virus between ferrets. *Science*. 2012;336:1534–41.
- Centers for Disease Control and prevention (CDC). Approaches to Better Understand Human Influenza Transmission. 2010. <https://www.cdc.gov/influenza/transmissionworkshop2010/>
- Moser MR, Bender TR, Margolis HS, Noble GR, Kendal AP, Ritter DG. An outbreak of influenza aboard a commercial airliner. *Am J Epidemiol*. 1979;110:1–6.
- Tang JW, Li Y, Eames I, Chan PK, Ridgway GL. Factors involved in the aerosol transmission of infection and control of ventilation in healthcare premises. *J Hosp Infect*. 2006;64:100–14.
- Xie X, Li Y, Chwang AT, Ho PL, Seto WH. How far droplets can move in indoor environments—revisiting the Wells evaporation-falling curve. *Indoor Air*. 2007;17:211–25.
- Li Y, Leung GM, Tang JW, Yang X, Chao CY, Lin JZ, et al. Role of ventilation in airborne transmission of infectious agents in the built environment - a multidisciplinary systematic review. *Indoor Air*. 2007;17:2–18.
- Jones RM, Brosseau LM. Aerosol transmission of infectious disease. *J Occup Environ Med*. 2015;57:501–8.
- Liu L, Li Y, Nielsen PV, Wei J, Jensen RL. Short-range airborne transmission of expiratory droplets between two people. *Indoor Air*. 2017;27:452–62.
- Aliabadi AA, Rogak SN, Bartlett KH, Green SI. Preventing airborne disease transmission: review of methods for ventilation Design in Health Care Facilities. *Adv Prev Med*. 2011;2011:124064.
- Jewett DL, Heinsohn P, Bennett C, Rosen A, Neuilly C. Blood-containing aerosols generated by surgical techniques: a possible infectious hazard. *Am Ind Hyg Assoc J*. 1992;53:228–31.
- Harrel SK, Molinari J. Aerosols and splatter in dentistry: a brief review of the literature and infection control implications. *J Am Dent Assoc*. 2004;135:429–37.
- Wei J, Li Y. Airborne spread of infectious agents in the indoor environment. *Am J Infect Control*. 2016;44(9 Suppl):S102–8.
- Roy CJ, Milton DK. Airborne transmission of communicable infection—the elusive pathway. *N Engl J Med*. 2004;350:1710–2.
- Asano Y, Iwayama S, Miyata T, Yazaki T, Ozaki T, Tsuzuki K, et al. Spread of varicella in hospitalized children having no direct contact with an indicator zoster case and its prevention by a live vaccine. *Biken J*. 1980;23:157–61.
- Gustafson TL, Lavelly GB, Brawnner ER Jr, Hutcheson RH Jr, Wright PF, Schaffner W. An outbreak of airborne nosocomial varicella. *Pediatrics*. 1982;70:550–6.
- Suzuki K, Yoshikawa T, Ihira M, Ohashi M, Suga S, Asano Y. Spread of varicella-zoster virus DNA to the environment from varicella patients who were treated with oral acyclovir. *Pediatr Int*. 2003;45:458–60.
- Tang JW, Eames I, Li Y, Taha YA, Wilson P, Bellingan G, et al. Door-opening motion can potentially lead to a transient breakdown in negative-pressure isolation conditions: the importance of vorticity and buoyancy airflows. *J Hosp Infect*. 2005;61:283–6.
- Wells WF, Wells WM, Wilder TS. The environmental control of epidemic contagion. I. An epidemiologic study of radiant disinfection of air in day schools. *Am J Hyg*. 1942;35:97–121.
- Riley EC, Murphy G, Riley RL. Airborne spread of measles in a suburban elementary school. *Am J Epidemiol*. 1978;107:421–32.
- Bloch AB, Orenstein WA, Ewing WM, Spain WH, Mallison GF, Herrmann KL, et al. Measles outbreak in a pediatric practice: airborne transmission in an office setting. *Pediatrics*. 1985;75:676–83.
- Remington PL, Hall WN, Davis IH, Herald A, Gunn RA. Airborne transmission of measles in a physician's office. *JAMA*. 1985;253:1574–7.
- Riley RL, Mills CC, Nyka W, Weinstock N, Story PB, Sultan LU, Riley MC, Wells WF. Aerial Dissemination of pulmonary tuberculosis a two year study of contagion in a tuberculosis ward. *Am J Hyg*. 1959;70:185–96.

31. Riley RL, Mills CC, O'Grady F, Sultan LU, Wittstadt F, Shivpuri DN. Infectiousness of air from a tuberculosis ward. Ultraviolet irradiation of infected air: comparative infectiousness of different patients. *Am Rev Respir Dis*. 1962;85:511–25.
32. Escombe AR, Moore DA, Gilman RH, Pan W, Navincopa M, Ticona E, et al. The infectiousness of tuberculosis patients coinfecting with HIV. *PLoS Med*. 2008;5:e188.
33. Houk VN. Spread of tuberculosis via recirculated air in a naval vessel: the Byrd study. *Ann N Y Acad Sci*. 1980;353:10–24.
34. Hutton MD, Stead WW, Cauthen GM, Bloch AB, Ewing WM. Nosocomial transmission of tuberculosis associated with a draining abscess. *J Infect Dis*. 1990;161:286–95.
35. Kenyon TA, Walway SE, Ihle WW, Onorato IM, Castro KG. Transmission of multidrug-resistant *Mycobacterium tuberculosis* during a long airplane flight. *N Engl J Med*. 1996;334:933–8.
36. Escombe AR, Moore DA, Gilman RH, Navincopa M, Ticona E, Mitchell B, et al. Upper-room ultraviolet light and negative air ionization to prevent tuberculosis transmission. *PLoS Med*. 2009;6:e43.
37. Milton DK. What was the primary mode of smallpox transmission? Implications for biodefense *Front Cell Infect Microbiol*. 2012;2:150.
38. Wehrle PF, Posch J, Richter KH, Henderson DA. An airborne outbreak of smallpox in a German hospital and its significance with respect to other recent outbreaks in Europe. *Bull World Health Organ*. 1970;43:669–79.
39. Wong TW1, Lee CK, Tam W, Lau JT, Yu TS, Lui SF, et al. Cluster of SARS among medical students exposed to single patient, Hong Kong. *Emerg Infect Dis*. 2004;10:269–276.
40. Olsen SJ, Chang HL, Cheung TY, Tang AF, Fisk TL, Ooi SP, et al. Transmission of the severe acute respiratory syndrome on aircraft. *N Engl J Med*. 2003;349:2416–22.
41. Yu IT, Li Y, Wong TW, Tam W, Chan AT, Lee JH, et al. Evidence of airborne transmission of the severe acute respiratory syndrome virus. *N Engl J Med*. 2004;350:1731–9.
42. Booth TF1, Kournikakis B, Bastien N, Ho J, Kobasa D, Stadnyk L, et al. Detection of airborne severe acute respiratory syndrome (SARS) coronavirus and environmental contamination in SARS outbreak units. *J Infect Dis*. 2005;191:1472–1477.
43. Assiri A1, Al-Tawfiq JA, Al-Rabeeh AA, Al-Rabiah FA, Al-Hajjar S, Al-Barrak A, et al. Epidemiological, demographic, and clinical characteristics of 47 cases of Middle East respiratory syndrome coronavirus disease from Saudi Arabia: a descriptive study. *Lancet Infect Dis*. 2013;13:752–761.
44. Hui DS, Memish ZA, Zumla A. Severe acute respiratory syndrome vs. the Middle East respiratory syndrome. *Curr Opin Pulm Med*. 2014;20:233–41.
45. Al-Tawfiq JA, Zumla A, Memish ZA. Coronaviruses: severe acute respiratory syndrome coronavirus and Middle East respiratory syndrome coronavirus in travelers. *Curr Opin Infect Dis*. 2014;27:411–7.
46. Guery B, Poissy J, el Mansouf L, Séjourné C, Ettahar N, Lemaire X, et al. Clinical features and viral diagnosis of two cases of infection with Middle East respiratory syndrome coronavirus: a report of nosocomial transmission. *Lancet*. 2013;381:2265–72.
47. Mailles A, Blanckaert K, Chaud P, van der Werf S, Lina B, Caro V, et al. First cases of Middle East Respiratory Syndrome Coronavirus (MERS-CoV) infections in France, investigations and implications for the prevention of human-to-human transmission, France, May 2013. *Euro Surveill*. 13; 18(24).
48. Chowell G, Abdizak F, Lee S, Lee J, Jung E, Nishiura H, et al. Transmission characteristics of MERS and SARS in the healthcare setting: a comparative study. *BMC Med*. 2015;13:210.
49. Omrani AS, Matin MA, Haddad Q, Al-Nakhli D, Memish ZA, Albarrak AM. A family cluster of Middle East respiratory syndrome coronavirus infections related to a likely unrecognized asymptomatic or mild case. *Int J Infect Dis*. 2013;17:e668–72.
50. Peiris JS, Chu CM, Cheng VC, Chan KS, Hung IF, Poon LL, et al. Clinical progression and viral load in a community outbreak of coronavirus-associated SARS pneumonia: a prospective study. *Lancet*. 2003;361:1767–72.
51. Poissy J, Goffard A, Parmentier-Decrucq E, Favory R, Kaut M, Kipnis E, et al. Kinetics and pattern of viral excretion in biological specimens of two MERS-CoV cases. *J Clin Virol*. 2014;61:275–8.
52. Memish ZA, Al-Tawfiq JA, Makhdoom HQ, Assiri A, Alhakeem RF, Albarrak A, et al. Respiratory tract samples, viral load, and genome fraction yield in patients with Middle East respiratory syndrome. *J Infect Dis*. 2014;210:1590–4.
53. Widagdo W, Raj VS, Schipper D, Kolijn K, van Leenders GJ, Bosch BJ, et al. Differential expression of the MERS-coronavirus receptor in the upper respiratory tract of humans and dromedary camels. *J Virol*. 2016; 90:4838–42.
54. Tellier R. Review of aerosol transmission of influenza a virus. *Emerg Infect Dis*. 2006;12:1657–62.
55. Tellier R. Aerosol transmission of influenza a virus: a review of new studies. *J R Soc Interface*. 2009;6(Suppl 6):S783–90.
56. Cowling BJ. Airborne transmission of influenza: implications for control in healthcare and community settings. *Clin Infect Dis*. 2012;54:1578–80.
57. Cowling BJ, Ip DK, Fang VJ, Suntarattiwong P, Olsen SJ, Levy J, et al. Aerosol transmission is an important mode of influenza a virus spread. *Nat Commun*. 2013;4:1935.
58. Alford RH, Kasel JA, Gerone PJ, Knight V. Human influenza resulting from aerosol inhalation. *Proc Soc Exp Biol Med*. 1966;122:800–4.
59. Tang JW. The effect of environmental parameters on the survival of airborne infectious agents. *J R Soc Interface*. 2009;6(Suppl 6):S737–46.
60. US Centers for Disease Control and Prevention (CDC). Interim Guidance for the Use of Masks to Control Influenza Transmission. <https://www.cdc.gov/flu/professionals/infectioncontrol/maskguidance.htm>. Accessed 9 August 2017.
61. O'Neil CA, Li J, Leavey A, Wang Y, Hink M, Wallace M, et al. Characterization of Aerosols Generated During Patient Care Activities. *Clin Infect Dis*. 2017; doi: [10.1093/cid/cix535](https://doi.org/10.1093/cid/cix535)
62. Fabian P, McDevitt JJ, DeHaan WH, Fung RO, Cowling BJ, Chan KH, et al. Influenza virus in human exhaled breath: an observational study. *PLoS One*. 2008;3:e2691.
63. Stelzer-Braid S, Oliver BG, Blazey AJ, Argent E, Newsome TP, Rawlinson WD, et al. Exhalation of respiratory viruses by breathing, coughing, and talking. *J Med Virol*. 2009;81:1674–9.
64. Lindsley WG, Noti JD, Blachere FM, Thewlis RE, Martin SB, Othumpangat S, et al. Viable influenza a virus in airborne particles from human coughs. *J Occup Environ Hyg*. 2015;12:107–13.
65. Lindsley WG, Blachere FM, Beezhold DH, Thewlis RE, Noorbakhsh B, Othumpangat S, et al. Viable influenza a virus in airborne particles expelled during coughs vs. Exhalations Influenza Other Respir Viruses. 2016;10:404–13.
66. Yan J, Grantham M, Pantelic J, Bueno de Mesquita PJ, Albert B, Liu F, Ehrman S, Milton DK. EMIT Consortium Infectious virus in exhaled breath of symptomatic seasonal influenza cases from a college community. *Proc Natl Acad Sci U S A*. 2018;115:1081–6.
67. Yang W, Elankumaran S, Marr LC. Concentrations and size distributions of airborne influenza a viruses measured indoors at a health Centre, a day-care Centre and on aeroplanes. *J R Soc Interface*. 2011;8:1176–84.
68. Bischoff WE, Swett K, Leng I, Peters TR. Exposure to influenza virus aerosols during routine patient care. *J Infect Dis*. 2013;207:1037–46.
69. Leung NH, Zhou J2, Chu DK, Yu H, Lindsley WG, Beezhold DH, et al. Quantification of Influenza Virus RNA in Aerosols in Patient Rooms *PLoS One* 2016;11:e0148669.
70. Tang JW, Gao CX, Cowling BJ, Koh GC, Chu D, Heilbronn C, et al. Absence of detectable influenza RNA transmitted via aerosol during various human respiratory activities—experiments from Singapore and Hong Kong. *PLoS One*. 2014;9:e107338.
71. Milton DK, Fabian MP, Cowling BJ, Grantham ML, McDevitt JJ. Influenza virus aerosols in human exhaled breath: particle size, culturability, and effect of surgical masks. *PLoS Pathog*. 2013;9:e1003205.
72. Hatagishi E, Okamoto M, Ohmiya S, Yano H, Hori T, Saito W, et al. Establishment and clinical applications of a portable system for capturing influenza viruses released through coughing. *PLoS One*. 2014; 9:e103560.
73. Koster F, Gouveia K, Zhou Y, Lowery K, Russell R, MacInnes H, et al. Exhaled aerosol transmission of pandemic and seasonal H1N1 influenza viruses in the ferret. *PLoS One*. 2012;7:e33118.
74. Goldmann DA. Transmission of viral respiratory infections in the home. *Pediatr Infect Dis J*. 2000;19(10 Suppl):S97–102.
75. Goldmann DA. Epidemiology and prevention of pediatric viral respiratory infections in health-care institutions. *Emerg Infect Dis*. 2001; 7:249–53.
76. Salgado CD, Farr BM, Hall KK, Hayden FG. Influenza in the acute hospital setting. *Lancet Infect Dis*. 2002;2:145–55.
77. Bridges CB, Kuehnert MJ, Hall CB. Transmission of influenza: implications for control in health care settings. *Clin Infect Dis*. 2003;37:1094–101.

78. Hall CB. The spread of influenza and other respiratory viruses: complexities and conjectures. *Clin Infect Dis*. 2007;45:353–9.
79. Mathur U, Bentley DW, Hall CB. Concurrent respiratory syncytial virus and influenza A infections in the institutionalized elderly and chronically ill. *Ann Intern Med*. 1980;93:49–52.
80. Jefferson T, Del Mar CB, Dooley L, Ferroni E, Al-Ansary LA, Bawazeer GA, et al. Physical intervention to interrupt and reduce the spread of respiratory viruses: a Cochrane review. *Health Technol Assess*. 2010;14:347–476.
81. Jaax N, Jarhlig P, Gesibert T, Geisbert S, Steele K, McKee K, et al. Transmission of Ebola virus (Zaire strain) to uninfected control monkeys in a biocontainment laboratory. *Lancet*. 1995;346:1669–71.
82. Weingartl HM, Embury-Hyatt C, Nfon C, Leung A, Smith G, Kobinger G. Transmission of Ebola virus from pigs to non-human primates. *Sci Rep*. 2012. <https://doi.org/10.1038/srep00811>.
83. Twenhafel NA, Mattix ME, Johnson JC, Robinson CG, Pratt WD, Cashman KA, et al. Pathology of experimental aerosol Zaire ebolavirus infection in rhesus macaques. *Vet Pathol*. 2012;50:514–29.
84. Johnson E, Jaax N, White J, Jahrling P. Lethal experimental infections of rhesus monkeys by aerosolized Ebola virus. *Int J Exp Path*. 1995;76:227–36.
85. Herbert AS, Kuehne AI, Barth JF, Ortiz RA, Nichols DK, Zak SE, et al. Venezuelan equine encephalitis virus replicon particle vaccine protects nonhuman primates from intramuscular and aerosol challenge with ebolavirus. *J Virol*. 2013;87:4952–64.
86. Pratt WD, Wang D, Nichols DK, Luo M, Woraratanadham J, Dye JM, et al. Protection of nonhuman primates against two species of Ebola virus infection with a single complex adenovirus vector. *Clin Vaccine Immunol*. 2010;17:572–81.
87. Towner JS, Rollin PE, Bausch DG, Sanchez A, Cray SM, Vincent M, et al. Rapid diagnosis of Ebola hemorrhagic fever by reverse transcription-PCR in an outbreak setting: an assessment of patient viral load as a predictor of outcome. *J Virol*. 2004;78:4330–41.
88. Kreuels B, Wichmann D, Emmerich P, Schmidt-Chanasit J, de Heer G, Kluge S, et al. A case of severe Ebola virus infection complicated by gram-negative septicemia. *N Engl J Med*. 2014;371:2394–401.
89. Franz DR, Jahrling PB, Friedlander AM, McClain DJ, Hoover DL, Bryne WR, et al. Clinical recognition and management of patients exposed to biological warfare agents. *JAMA*. 1997;278:399–411.
90. Little JW, Douglas RG Jr, Hall WJ, Roth FK. Attenuated influenza produced by experimental intranasal inoculation. *J Med Virol*. 1979;3:177–88.

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The physics of human breathing: flow, timing, volume, and pressure parameters for normal, on-demand, and ventilator respiration

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Abstract

Normal breathing for healthy humans is taken for granted; it occurs without conscious effort using ambient (1-atmosphere) pressure with 21% oxygen (O₂) concentration. The body automatically adjusts for stress, exercise, altitude, and mild disease by increasing the volume and frequency of breathing. Longer term adaptations for exercise and altitude include increases in red blood cell counts and higher concentrations of capillaries in muscle tissue. When more challenging external environmental conditions or pulmonary illnesses exceed the capability for these adaptations, the human system requires technology to maintain sufficient ventilation to preserve life. On the environmental side there are two conditions to be addressed: toxicity of the surrounding atmosphere and changes in external pressure and O₂ concentration. On the medical side, mechanisms for assisting breathing include O₂ supplementation at ambient pressure, positive pressure/flow without additional O₂, or a combination of both. This overview describes the various technologies applied to maintaining a safe breathing environment. Topics for environmental intervention include filter-based and flowing air-supply masks for toxic environments (occupational and laboratory protection), and on-demand gas supply systems for firefighters, self-contained underwater breathing apparatus (SCUBA) divers, and altitude (high performance aircraft, spacecraft) applications. The topics for medical intervention include nasal cannula, continuous positive airway pressure (CPAP), and medical ventilators. The primary purpose of this article is to provide a basic understanding of normal human breathing and the adaptation of breathing in different environments using available technologies.

OVERVIEW

The topic of human breathing mechanics and support has come to the forefront of public awareness due to the current COVID-19 crisis. Wearing hospital masks or improvised facial

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coverings was broadly implemented to protect against spreading infectious aerosols (Pleil et al. 2020a, Eikenberry et al. 2020). At the outset of the pandemic, the news media reported on the availability and use of medical ventilators as well as oxygen (O₂) supplementation via less invasive nasal cannulas or masks to help patients recover from pulmonary disease (Kliff 2020, Ranney et al. 2020). Additionally, breathing protection, supplementation, and therapy appear in the media with respect to firefighters battling wildfires, pilots flying high-performance military aircraft, recreational self-contained underwater breathing apparatus (SCUBA) and professional divers, and medical and laboratory researchers.

This commentary describes normal breathing functionality and strives to put human breathing into context with the modern technologies used to extend the safety envelope beyond sea-level pressure and O₂ concentration to support life in situations ranging from extreme pressures in diving, to low pressures in aviation. Herein we discuss all manner of human breathing parameters and how different support systems work. The article describes the current understanding of the physics of breathing and the processes for distributing O₂ from the air to the human tissues, organs, and the brain.

The discussions are grouped by the level of intervention; consider that a simple hospital mask only serves to filter particles but does not affect O₂ concentration, gas flow, or ambient pressure, whereas a hospital ventilator can take complete control of the human breathing system and dictate timing, flow, volume, and level of oxygen. Between these extremes are applications that address specific parameters. Some common examples are flow-through masks that receive clean air flow from outside to protect the wearer from an indoor contaminated environment, the nasal cannula that provides additional ambient air enriched with O₂ for a patient with respiratory distress, the standard respirator that protects the wearer from organic volatile chemicals, and various “on-demand” mask systems that replace ambient air using a separate source.

The mission of this commentary is to provide a basic understanding of human breathing under different scenarios and to present a baseline of breathing parameters that are required to maintain human life. Examples and data are drawn directly from the authors’ research and expertise, as well as being supplemented with the peer-reviewed literature. This article expands on the understanding of the physics parameters of pressure, flow, volume, and timing under different conditions encountered by humans to further the concepts of breath research beyond the chemistry of metabolism (Pleil et al. 2020b).

NORMAL BREATHING

Humans descended from the superfamily Hominoidea (10–20 million years ago); the earliest fossil records for hominids (earliest direct ancestors) date back 4–5 million years (Andrews 1992), and modern homo sapiens date back approximately 200,000 years (Stringer 2016). Over 2.3 billion years ago, early cyanobacteria began emitting O₂ via photosynthesis (Kasting and Siefert 2002). Considering that the earth’s atmosphere stabilized at ~21% O₂ and ~78% nitrogen (N₂) about 550 million years ago (Berner 1999), it is safe to say that modern humans evolved to efficiently use this atmosphere for “normal” breathing (Liem 1988).

Normal breathing is defined here as the movement of air in and out of the lungs in an environment with infinite volume and stable external pressure. Normal breathing is an autonomous function performed without conscious effort, although humans can take conscious control for actions such as breath-holding, talking, singing, swimming, and exercise. The physics of normal breathing are based on differential pressure between the lungs and the ambient atmosphere. As the diaphragm and ribcage expand and contract due to muscle action, air flows in and out to balance pressure. During inhalation, the fresh oxygenated air flows into branching progressively smaller airways to ultimately inflate the alveoli (small membranous air sacs) and exchange O₂ for carbon dioxide (CO₂), a waste product of cellular energy production. CO₂ is expelled upon exhalation and the cycle begins anew. Humans do not absorb all of the inhaled O₂ for metabolism; inhaled air contains 21% O₂ while exhaled breath contains approximately 16% O₂ and 5% CO₂.

Oxygen transport

Oxygen transport begins at the mouth/nose, continues into the lungs, consisting of progressively smaller branching airways, ending in alveoli or air sacs where oxygen is transferred to the red blood cells. It is then delivered to the systemic blood flow and ultimately into the various cells by capillaries and diffusion. The first effects of reduced O₂ are felt by the brain; in fact, even minor reductions (mild hypoxia) can manifest as disorientation, confusion, and reduced higher executive function. Longer term O₂ deprivation can also cause organ damage, especially to the heart and kidneys, but practically, the brain is the organ of primary concern. In a recent National Aeronautics and Space Administration (NASA) Pilot Breathing Assessment (PBA) study of jet fighter pilots, detailed analyses of breathing response, spirometry, and blood oxygenation have shown that there are losses in O₂ transport along the way from the face to the organs despite 100% O₂ in the breathing gas (NASA PBA Report 2020). A study of environmental contamination has shown that pulmonary function can be lost even when the O₂ content and pressure in the air are nominal (sea level) due to pulmonary inflammation (Stiegel et al. 2017). As an example, Figure 1 shows the conceptual model for O₂ transport related to jet aircraft life support systems.

Breathing frequency, tidal volume, and pulmonary pressure

At complete rest, the typical adult male exchanges approximately 0.5 L (500 mL; 400 mL for female) of air per breath (tidal volume) at a rate of 12 times per minute, resulting in a minute ventilation rate of about 6 L of air per minute. Certainly, there are individual variations due to size, age, gender, and health-state, but these parameters are considered robust default values. Of note is that the first 0.15 L (150 mL) volume of each breath, referred to as the tracheal dead volume, does not participate in O₂/CO₂ exchange but only fills the trachea and branching airways. In calm, at-rest breathing, the body generates a modest ± 3 mmHg pressure swing to create inhalation and exhalation flow. For context, imagine one is blowing up a balloon or drinking a thick milkshake through a straw; there is a maximum amount of positive or negative pressure one can exert, after which the activity fails. According to the literature, the diaphragm and related thoracic muscles can exert maximum exhalation pressures of 44 to 88 mmHg and maximum inhalation pressures of negative 29 to 74 mmHg (Lausted et al. 2006, Evans and Whitelaw 2009). As such, normal

at-rest breathing only requires minimal muscle effort compared to the maximum possible exertion.

The human body is highly adaptable and as metabolic need increases for activity, exercise, and warmth, the cardio-pulmonary (heart-lung) system has mechanisms to increase blood flow and O₂ perfusion. Heart rate, respiration rate, and tidal volume increase to provide the necessary cellular resources to support energy production. With moderate exercise, normal adults can sustain 30 breaths/minute with 3.5 L/breath, and depending on fitness, age, and other health factors, individuals can adapt to higher needs for O₂ perfusion. Pulmonary function tests (PFTs) measure the absolute maximum for a single breath (forced vital capacity, FVC) in the range of 4 to 5.5 L/breath, but such levels are not sustainable, and so this limits human activity. Again, normal at-rest breathing only uses a small amount of the total resources possible.

Table 1 shows the normal breathing parameters for healthy adults. Certainly, individuals can vary greatly depending on cardiovascular fitness, anxiety, inflammatory status, genotype, and phenotype. The values in the table are illustrative and show the potential adaptability of the human system to increased workload. Notably, all measurements of breathing require masks or other devices to measure flows and pressures, and so there is a caveat that these numbers are not exactly “normal breathing.” However, modern measurement technology has evolved to minimize pressure drops and flow restrictions so that such measurements can be taken at face-value. The values in the table are considered “nominal” in that they are generally accepted by the medical community and found in various public websites (e.g., Wikipedia, Mayo Clinic, and Johns Hopkins). Certainly, ranges or slightly different values may also be found, including adjustments for gender or physical size, but the values in Table 1 represent a consensus for normal breathing for healthy adults. More detailed statistical analyses of human breathing have been published by the U.S. Environmental Protection Agency (EPA 2011).

Figure 2 below shows pulmonary function testing with laboratory instrumentation and a handheld device that can be used in the field (US EPA and NASA).

Oxygen saturation

The amount of O₂ in the blood, or blood O₂ saturation level, is defined as the fraction of O₂-saturated hemoglobin in red blood cells compared to the total amount of hemoglobin. Invasive medical tests can be used to measure arterial blood gases (ABG) very accurately; however, standard practice is to estimate peripheral oxygen saturation (SpO₂) non-invasively with pulse oximetry using a colorimetric light sensor attached to a finger. SpO₂ between 95 and 100% is considered normal; readings between 90 and 95% are considered mildly hypoxic, and a level of 90% or below indicates a serious medical condition called hypoxemia that needs to be treated quickly. The human body can adapt slightly to lower levels of SpO₂, but generally this engenders feelings of fatigue and shortness of breath (Hoiland et al. 2016, Hardt et al. 2015).

Altitude adaptation

The default values mentioned above apply for sea-level atmospheric pressure and O₂ levels. However, as altitude increases, the percentage (mass fraction) of O₂ remains the same but the partial pressure decreases proportionally with total pressure, as such the number of O₂ molecules within each breath is proportionally lower. Humans have adapted to elevation as evidenced by major population centers at higher altitudes. In the short term, for visitors to higher altitudes, breathing frequency and tidal volume increase to provide more O₂ to the systems biology. Long-term and natural selection adaptations include the increase in red-blood cells, capillary density, and higher efficiencies in hemoglobin transport.

At sea-level, the partial pressure of oxygen (ppO₂) is 0.21 atmospheres and normal “at-rest” breathing results with O₂ blood perfusion levels of ~98%. At higher elevations, ppO₂ decreases; for context, Table 2 shows some examples for major cities, their populations, elevation, and ppO₂. For example, one of the biggest cities in the world, Mexico City, Mexico (population ~22 million), has an elevation of 7,350 feet, resulting in ppO₂ of 0.16 atm, which represents an O₂ density 60% of sea-level. Anecdotally, some newcomers to Mexico City experience some breathing discomfort, headache, mild hypoxia, and elevated respiration; however, they generally adapt within a few days. Likewise, while “altitude training” has served as an intermittent fad in endurance athletes, practical experience has shown that physiological adaptations from training at altitude generally revert to normal within a few days of returning to sea level conditions. As a comparison, Table 2 shows the typical commercial airliner, which cruises at ~36,000 to 40,000 feet altitude with cabin pressurization set to an equivalent altitude of about 8,000 feet (0.16 ppO₂ atm) as mandated in the U.S. by Federal Regulation 14 CFR 25.831 (Federal Aviation Administration (FAA) 2002); as such, the typical airliner cabin ppO₂ is close to that of Mexico City. The FAA general aviation guidelines further require supplemental O₂ supply if cabin pressure drops to 12,500 feet equivalent (0.13 ppO₂ atm) for more than 30 minutes and always above 14,000 feet cabin altitude (0.12 ppO₂ atm).

Table 2 also includes two mountains: Denali, Alaska, USA, and Mt. Everest, Nepal for additional context. Climbers of Denali (elevation ~20,000 feet) can adapt to the summit altitude with prior aerobic training and acclimation over a few weeks’ time. Very few climbers of Mt. Everest (summit elevation ~29,000 feet) have ever achieved summiting without supplemental O₂. The altitude tipping point for unassisted breathing in very fit individuals (mountain climbers) is around 26,000 feet. The values presented are for illustration only; they are gleaned from consensus of various Wikipedia and other internet sources, as well as published references (e.g., Peacock 1998, West 2000).

Concentration adaptation to CO₂ (artificial atmospheres)

Like the adaptations to activity and ambient pressure, the human body also has some leeway in adapting to different concentrations of O₂ and CO₂. In the previous section, we discussed changes brought about by pressure with constant percentages of constituent gases. Here, we consider only standard pressure, but with different concentrations of CO₂ resulting from the buildup from exhalations.

When breathing normally, humans inhale fresh air with 21% O₂ along with a negligible amount of ambient CO₂ (0.04%), and exhale ~16% O₂ and ~5% CO₂. Medically, ambient concentrations above 19.5% O₂ are considered safe, but there are reported minor adverse effects (e.g., headache, irritability, and confusion) from inhalation of CO₂ starting at ~1,000 ppm (0.1%), with increasing adverse effects up to ~20,000 ppm (2%) concentration. Beyond this level, it becomes more difficult for the body to expel metabolic waste CO₂, and CO₂ concentrations of 100,000 ppm and above can cause loss of consciousness and asphyxiation (National Research Council 2007). Because O₂ and CO₂ in a confined space represent a zero-sum (add up to 20.95% in dry air), excess CO₂ ultimately displaces available O₂. Studies have shown that humans can tolerate more CO₂ for short periods of time, but from a public health perspective, humans in general are not well-adapted to chronic (indoor) exposures to CO₂ beyond 0.1%. Various studies of CO₂ inhalation effects are available in the literature (e.g., Shriram et al. 2019, National Research Council 2007, Satish et al. 2012), and recently the use of CO₂ breath measurements (capnography) has been discussed (Pleil and Christensen 2021).

Consumption of O₂ and production of CO₂ (artificial atmospheres)

Unlike open air breathing, the act of breathing in confined space environments consumes the available O₂ and increases the CO₂ concentration. As such, sustaining normal breathing in closed environments requires some form of ventilation to stabilize the gas mixture. Fully sealed spaces such as submarines, spacecraft, underwater habitats, and hyperbaric/hyperoxic chambers, have engineering systems that continually scrub exhaled CO₂ and add replacement O₂ as needed. More porous environments such as aircraft, cars, large office buildings, crowded auditoriums, and large ships rely on external air exchange via passive or pumped ventilation from the surrounding environment to balance O₂ and CO₂ levels. In the special cases of aircraft flying at altitude and hyperbaric chambers, the supplemental air must be pressurized as well.

In general, artificial atmospheres cannot cost-effectively maintain a perfect ambient atmosphere with 20.95% O₂ and 0.041% CO₂. Depending on ventilation, indoor spaces with human occupancy always have lower O₂ and higher CO₂ than outdoor air. The acceptable American Society of Heating and Air-Conditioning Engineers (ASHRAE) standard for CO₂ in offices is 800 ppm (0.08%); however, levels as high as 4,000 to 5,000 ppm (0.4 to 0.5%) have been measured (Zhang et al. 2017). Measurements in cars stopped in traffic using recirculated conditioned air have shown CO₂ levels reaching 2,500 ppm (0.25%) in a few minutes and continuing to rise (Angelova et al. 2019). In many cases, the practical tradeoff is temperature control vs. CO₂ buildup.

Enclosed spaces such as spacecraft, the International Space Station (ISS) or military submarines always rely on totally artificial atmospheres and maintain a tightly controlled atmospheric gas mixture. Therefore, CO₂ levels in these enclosed spaces are higher than the ambient CO₂ concentration on earth (0.3 mmHg, 400 ppm, or 0.04% of Earth's atmosphere). CO₂ levels in spacecraft typically range from 2.3 to 5.4 mmHg, with the highest recording of 14.9 mmHg on Apollo 13 (Law et al. 2014). NASA's spacecraft maximum allowable concentrations (SMACs) for CO₂ for 1-h and 24-h exposure were set at 13,000 ppm, but

recently the CO₂ SMAC was removed and acceptable levels for CO₂ in spacecraft are currently under review (National Research Council 2007, NASA 2020).

CO₂ levels of more than 10,000 ppm have been reported in nuclear-powered submarines. The U.S. Navy's emergency and continuous exposure guidance levels for CO₂ were evaluated in 2007. The 1-h and 24-h emergency exposure guidance levels of 40,000 ppm were proposed to be lowered to 30,000 ppm and 15,000 ppm, respectively, compared to the National Research Council (NRC) inhalation exposure recommendation of 25,000 ppm for both 1-h and 24-h exposure levels. The 90-day continuous exposure guidance level of 5,000 ppm was proposed to be increased to 7,000 ppm, compared to the 8,000 ppm NRC recommendation (National Research Council 2007).

At complete rest at sea level, a single human consumes approximately 8.6 m³ of air per day of which 5% is exhaled as metabolic CO₂, producing approximately 785 gm of CO₂. According to the U.S. EPA's Exposure Factors Handbook (EPA 2011), an adult male of normal weight with moderate activity for 16 hours and rest for 8 hours consumes ~22.8 m³ of air per day with 99th percentile of 23.7 m³. For calculations, this is generally rounded to 24 m³ or 1 m³ per hour as the default assumption and equates to an exhalation of approximately 2.2 kg of CO₂ per day.

Using the ISS as an example with ~950 m³ interior volume, a crew of seven astronauts (with moderate activity) is expected to produce a volume of 8.4 m³ of CO₂ gas per day. Left uncontrolled, the ISS atmosphere would reach 0.09% CO₂ concentration in 24 hours. Empirically, this does not happen in the ISS environment presumably because the astronauts are not working against gravity and produce only about 1 kg CO₂ per day. Regardless, the closed environment requires removal of CO₂ and supplementation of O₂. As such, the environmental control systems onboard the ISS remove approximately 7 kg of CO₂ each day to maintain a viable atmosphere and continually replenish the air with O₂ that is produced via hydrolysis of water. Figure 3 illustrates space mission environments with the individual space suit, the "shirtsleeve" environment inside the ISS, and an exterior shot of the loneliness of the self-contained human ISS habitat. Within the individual suit, and the whole of the ISS, CO₂ is regularly removed and O₂ is added to maintain a sustainable atmosphere (photos from NASA archives).

Normal breathing in contaminated air environments

There are many situations where there is sufficient O₂ in the air, but contaminants including particulate matter (PM) and dusts, virulent aerosols, gas-phase carcinogens, and adverse odors can make the breathing air unsafe. Typically, these are occupational hazards that require specific respirators or masks; however, now in the era of the COVID-19 pandemic, the general public is also routinely wearing masks to help prevent the spread of the disease (Pleil et al. 2020a).

Respirators: Breathing protection comes in different forms depending on the expected contaminants. The most common occupational respirators are designed to scrub toxic gases and vapors generally using half-face or full-face masks with adsorbent (chemical) or molecular sieve cartridges. Although there is always some small flow restriction from

such cartridges, generally the respirators are very close to normal breathing. Typically, the additional pressure required for inhalation across modern activated carbon filters (ACF) is in the range from 1.5 to 3 mmHg. As such, normal breathing with typical respirators requires ~4.5 to 6 mmHg pulmonary pressure, which is well below the upper limits that are around 40 mmHg (Balanay and Lungu 2016).

Hospital masks: Many environments need only protection against aerosols and particles; for these scenarios, different levels of physical filter materials are used. Standard medical protection masks like the well-known N-95 mask have a tight fit on the face using a double mesh/cloth layer that forces all air through the filter material. In these masks, the inhalation restriction is ~ 0.025 mmHg, which is negligible compared to normal at rest breathing (Skaria and Smaldone 2014). More conventional hospital (paper/polypropylene) masks are loose-fitting and rely more on aerosol and particle kinetics rather than direct filtration; these masks, like improvised facial coverings (bandanas and scarves), have no measurable pressure drops.

Free-flow air supplies: In some confined-space scenarios, outside air is pumped directly into a face shield or mask in the breathing zone at a rate high enough to continually displace the microenvironmental air. There is no pressure drop experienced by the worker; in fact, this style of respiratory protection provides a secondary benefit in that the free-flowing external air provides cooling as well. Such air supplies are common in occupational settings, including aircraft systems maintenance and chemical laboratories.

Figure 4 shows some examples of common protective masks that all support safe “normal” breathing. They include simple facial coverings, face shields, as well as half- and full-face respirators.

Normal breathing with medical O₂ enrichment

In some cases, individuals with moderate lung or heart disease require additional O₂ to maintain oxygenation; this could be a temporary recovery solution in the hospital, or a longer-term solution for ambulatory outpatient maintenance. This “O₂ therapy” can be low- or high-flow. In low-flow O₂ therapy, a small tube provides O₂ enriched flow to a nasal cannula or mask from a cylinder or a portable O₂ generator at up to 15 L per minute (LPM). Of note, low-flow O₂ therapy can only deliver up to ~80% fraction of inspired oxygen. In high-flow O₂ therapy, flows of more than 15 LPM are delivered to a mask or nasal cannula, typically through larger bore tubing. In low- and high-flow O₂ therapy applications, the flow rates and O₂ concentrations delivered are tailored to the needs of the patient.

A common current practice uses high-flow nasal cannula (HFNC) to delivery respiratory support. HFNC can deliver up to 60 LPM and range up to 100% O₂ (Ward 2013, Helviz and Einav 2018). HFNC is a non-invasive alternative to mask-based O₂ therapy and mechanical ventilation; the supplementation remains in the realm of normal breathing in the sense that there is no measured forcing pressure.

Normal breathing in spacesuits and other sealed protective gear

The most esoteric situations for normal breathing involve protective gear that allows independent movement, yet still seals the person completely off from the external environment. The best examples are spacesuits and certain types of HazMat suits. In these configurations, clean air is provided into the suit, especially around the head, without a sealed mask on the face. CO₂ is constantly scrubbed and replaced with an equivalent amount of O₂ in periodic bursts to maintain a viable atmosphere; the most recent advances in space suit design can be found in the literature (e.g., Goldfarb and Hodgson, 2001, Southern and Moisey, 2019).

Extreme adaptation

There are some people that are adapted or trained for extreme situations focused on breath holding and breathing control. The largest groups are found in the free-diving community and in certain types of meditation. The normal healthy human can hold their breath between 30 to 60 seconds. With some practice and coaching, breath hold times can be quickly improved to about 2 minutes or more. Free divers, without prior oxygen loading, can routinely hold their breath for 10 minutes or more and dive unassisted to 300 feet depth, corresponding to about 10 atmospheres pressure. These extreme activities carry risks for acute injury to tissues and airways, as well as for permanent damage or even death. The book “Deep: Freediving, Renegade Science, and What the Ocean Tells Us about Ourselves” describes extreme adaptation not only for humans but also for creatures in the depths of the ocean (Nestor 2014). The human record for breath holding with O₂ loading is 24 minutes 37 seconds achieved by Budimir Šobat in Sisak, Croatia in March 2021; new attempts are ongoing ([Guinnessworldrecords.com](https://www.guinnessworldrecords.com)).

ON-DEMAND BREATHING

There are scenarios in human breathing experience that require more than just adaptation or passive filtration, but instead employ non-rebreathing devices to bring clean air directly to the nose/mouth. These systems operate through “on-demand” mechanics; as the person begins to inhale, the slight pressure drop opens a valve, which in turn triggers delivery of an airstream for inhalation. As the person begins to exhale, the pressure increases, shuts off the inhalation valve and flow, and opens the exhalation valve to allow air out. This type of system has the advantage of conserving resources by only providing air when needed. The challenge is to respond properly with the correct flow, concentration, speed, timing, and volume required to sustain life. All on-demand breathing systems work at the ambient pressure (or maybe a tiny bit higher) that surrounds the human.

SCUBA open-circuit breathing

The first practical applications for “on-demand” breathing were for underwater exploration and recreation. Termed self-contained underwater breathing apparatus (SCUBA), this engineering advance replaced the hardhat suits that were tethered to large surface compressors and pumped with air continuously at high flow rates. With SCUBA gear, the diver could now bring along his own breathing gas in a compressed air cylinder and be completely independent of the surface. Although Jacques Cousteau (of underwater filming

fame) is credited for developing the Aqua-Lung (twin hose scuba equipment) in France for commercial and recreational diving circa 1945 (Richardson 1999), the original concept of the on-demand regulator and use in a diving suit was developed and patented by Benoît Rouquayrol in 1860 (Siermontowski et al. 2016).

Standard SCUBA uses open-circuit breathing wherein the inlet side from the air supply is pressurized and sealed but the outlet (exhalation) side is expelled directly into the water by a diaphragm valve. The basic configuration has a compressed gas cylinder with a two-stage on-demand regulator system that includes a first stage, which regulates the raw cylinder pressure down to a more practical intermediate pressure proportional to depth, and a second stage (typically held by the mouth) that supplies gas from the reference pressure on-demand to the user. The lips provide the seal; standard SCUBA is mouth breathing only and the nose is sealed into the diving mask airspace to allow the sinus volume to equalize to the breathing pressure. Normal swimming goggles cannot be used as they do not allow pressure equalization of the airspace. A variant is the full-face mask that combines visual and breathing needs. This arrangement seals from the forehead around the face down to the chin which allows both mouth and nose breathing, as well as radio communication.

The most important issue with breathing underwater is the wide range of positive pressures encountered. Each additional 33 feet (10 meters) of seawater depth adds one atmosphere of pressure. Typical recreational (vacation) diving has a maximum of 130 feet (40 meters) and is defined as “no-decompression” diving in that it is possible to ascend to the surface in an emergency without obligatory decompression stops. In general, descents and ascents are done slowly to allow the body, especially sinuses and ear channels, to come to equilibrium with the water pressure, and to allow the dissolved gasses in body tissues time to dissipate. Each breath is delivered at the pressure at that depth; so, when breathing at a depth of 33 feet for example, there are twice as many O₂ molecules per L as at the surface. This is not an advantage for conserving volume, however. The body triggers the breathing response based on the build-up of blood CO₂, and so the additional O₂ is not helpful for metabolism. As such, at 33 feet depth (2 atm), one uses the available air in the cylinder twice as fast as at the surface; at 66 feet depth (3 atm) air is used three times as fast, etc. (Loske 2013).

The standard recreational SCUBA tank is referred to as an “Aluminum 80,” which refers to the material and cubic volume of air in cubic feet when pressurized to 3,000 psi. Standard SCUBA breathing for an individual is defined as a surface air consumption (SAC) rate. This depends mostly on the proficiency of the diver; new divers may have anxiety or difficulty with buoyancy control and breathe up to 1 cubic foot per minute (cfm), whereas experienced divers that are calmer and more efficient underwater may have SAC rates of 0.5 cfm or lower. SAC rate, depth, and tank volume are used to estimate the time available for an individual to remain underwater safely. A new diver with a SAC rate of 1 cfm and an Aluminum 80 can expect no more than ~30 minutes of diving on a reef at 33 feet depth and still maintain a safety margin of ~500 to 800 psi residual volume upon surfacing. Experienced divers generally dive recreational profiles for an hour or more with an Aluminum 80, depending on depth. It is common for recreational SCUBA divers to use O₂ enriched mixtures, commonly referred to as “Nitrox”, to increase the partial pressure of O₂ and thus lower the partial pressure of N₂ in the breathing gas. Common Nitrox

mixes range from 28–36% O₂. Use of Nitrox generally allows recreational divers to stay down longer with lower accumulated N₂ in their tissues, due to the proportionally lower N₂ fraction in the breathing gas.

Beyond recreational SCUBA diving there is a complex realm of technical diving using multiple tanks, gas mixtures, long dives, and depths down to 300 feet or more. The most common groups of tech-divers are shipwreck explorers, cave divers, and divers supporting industrial work such as undersea telecommunications, undersea construction, and mining for fossil fuels. Becoming certified in different aspects of technical diving requires years of training, and unlike recreational diving, carries much higher risk. Because human metabolism dissolves N₂ into the bloodstream, increased N₂ is dissolved into the blood and body tissues at the elevated pressures associated with diving. If the diver were to immediately return to the surface, this dissolved N₂ would rapidly come out of solution in the body's blood and tissues, causing a painful and potentially dangerous condition commonly known as "the bends" or decompression sickness (DCS). DCS is commonly called "the bends" because emerging gas often first manifests as pain and immobility in the body's joints, leading the sufferer to "bend" themselves in an attempt to alleviate this joint pain. In order to avoid DCS, divers who spend longer times at depth must "decompress" toward the end of the dive, making periodic stops as they ascend to allow the dissolved gasses to dissipate from their tissues at a manageable rate. Because diving at depth for prolonged periods of time requires proportionally longer decompression times, industrial divers will often live "at pressure" continuously for several months at a time, living, eating, and sleeping in a pressurized vessel matched to the working pressure of their diving environment. This so-called "Saturation Diving" allows divers to work effectively at significant depths of 300 feet or more for months at a time. At the end of this period, saturation divers undergo multiple days of decompression at steadily declining pressures before they can return to the ambient surface environment.

While O₂ is crucial to the human metabolic process, too much O₂ is toxic to humans, and elevated O₂ from pressurized breathing at depth carries significant risk of O₂ toxicity. Symptoms of O₂ toxicity include sudden seizure, convulsion, and sudden loss of consciousness. For obvious reasons, these symptoms, if experienced while diving underwater, can be extremely dangerous or even immediately fatal. Thus, significant care must be taken by divers to account for the elevated pressure of O₂ that they are breathing. Pure O₂ can become toxic to a human at depths as shallow as 6 meters/19.6 feet, while a typical atmospheric air mixture of 21% O₂ can become toxic below 66 meters/216.5 feet.

Tech-divers customize their gear to particular dive scenarios. For long dives above ~120 feet, the typical configuration may be twin back-mounted Steel 120 tanks providing a total of 240 cfm air. Deep dives from 120 to ~300 feet require multiple tanks and specific gas mixtures depending on depth. Typically, these divers use air as a travel gas from the surface down to ~120 feet and then below that level switch to an oxygen-helium-nitrogen (O₂-He-N₂) "trimix" that has reduced O₂ concentration at 10 to 20%, 50% He, and balance N₂. For very deep commercial applications (below 330 feet), divers may use a mixture of 79–90% He and 10–21% O₂ "heliox," which eliminates the N₂ component entirely. These mixtures are carefully chosen such that the effective ppO₂ at depth does not risk becoming toxic to the

user. At 330 feet depth, the body experiences ~11 atmospheres of pressure, so each breath has 11 times as many O₂ molecules as the same breath on the surface. With a concentration of 10% O₂, heliox provides the equivalent of 1.1 ppO₂ atm O₂. O₂ concentration can be adjusted below 10% to accommodate deeper dives without excess risk of O₂ toxicity. The deepest commercial dives replace some of the He with hydrogen (H) and may have as little as 2% O₂ (Loske 2013). Upon returning to the surface, it is common to switch back to travel gas (air) at 120 feet, ascend very slowly with decompression stops at 90, 60, and 30 feet, and then switch to an O₂ enriched mixture (80%) for the final decompression stop at ~20 feet. It is common for technical divers to carry four or more tanks on a single open-water or wreck dive and to stage tanks along the way in caves to use on the return.

The diving industry has many additional mixtures of gases available or custom mixed. The recreational diver may be familiar with “Nitrox” or “EANx” which are O₂-N₂ blends with 32/68 or 36/64 ratios. These are designed for long-term shallow diving (above 100 feet depth). The lower level of N₂ reduces the risk of developing nitrogen narcosis and decompression illness. Nitrox is a popular choice for vacation SCUBA in warm climates.

SCUBA closed-circuit breathing

During open circuit breathing, exhaled breath is wasted by exhaling directly into the water. Consider that humans breathe out most of the O₂ they inhale; at the surface they breathe in 21% and exhale 16% O₂ and 5% CO₂. At depth, this wastage increases proportionally because the mass amount of O₂ metabolized into CO₂ stays the same. The advent of closed-circuit breathing technology recovers the exhalation volume, scrubs out the metabolic CO₂, adds O₂ as needed, and recycles this air back into the breathing circuit. This extends the time underwater by a factor of five or more depending on the configuration. An additional advantage is that there are no expended bubbles, which is important in overhead environments (wrecks and caves) where debris could be dislodged and obscure visibility. Rebreathers are also very quiet, which offers obvious advantages for observing wildlife or in military applications where stealth is important. The one caveat to closed-circuit breathing is the high complexity of the system and numerous potential points of failure, including loss of CO₂ removal, flooding or poisoning of the scrubber, O₂ sensor error, or battery brownout.

Firefighting SCBA gear

The standard turnout gear for firefighters provides protection against heat, abrasion, and airborne toxicity. Breathing gas is provided by a self-contained breathing apparatus (SCBA), which is similar to SCUBA gear in operation. Unlike SCUBA, however, the tanks tend to be smaller and constructed with reinforced carbon fiber wrapped around a thin-walled aluminum shell to reduce weight. As compensation, the tanks are filled to ~4,500 psi and contain 45 cubic feet of air. Another difference is that the regulator/mask assembly is simplified because it works against constant ambient pressure rather than the wide pressure ranges found underwater. However, in contrast to diving in neutral buoyancy, firefighting activity is very strenuous. The protective and breathing gear weigh more than 60 lbs without the advantage of water buoyancy, and the firefighters drag heavy hoses, climb ladders, wield axes, and sometimes carry victims out of buildings. As such, SCBA gear needs to accommodate much higher demands as firefighters generally work near their aerobic

threshold. A standard 45 cfm tank is specified for a maximum work cycle of 30 minutes, which is approximately 3-times the “at rest” air demand. For safety, firefighters typically work for 10–20 minute bouts with 5 minute interim periods for recovery to exchange air cylinders (Kesler et al. 2018).

Firefighter masks seal the whole face and use the open-circuit breathing design described above. Rebreather technology (closed circuit design) that requires a small pure O₂ cylinder is considered too risky for live-fire environments.

High-performance aircraft (military jetfighters)

Healthy humans can easily and safely breathe ambient air to ~8,000 feet elevation even with moderate exercise. Above that, the reduced ppO₂ becomes noticeable, and depending on acclimatization and aerobic demand, the breathing air needs to be enriched with O₂ in accordance with altitude. As discussed above, commercial aircraft are pressurized to the equivalent of 8,000 feet elevation for this reason. External air is compressed using jet engine (turbine) bleed air and a constant internal cabin environment is maintained. Passengers breathe normally, although a subset may experience ear pain on ascent and descent.

Cabin pressure—In contrast to commercial aviation, high performance military aircraft generally have only one or two occupants, and so it is more effective to provide breathing air directly with a mask/regulator system much like it is done for divers and firefighters. The main difference from SCUBA or firefighting activity is that the surroundings are at sub-ambient pressures, and aircraft altitude ranges up to ~50,000 feet where the ambient pressure is 0.11 atm, with a ppO₂ of 0.023 atm. Although high performance aircraft do not expose the pilot to the actual ambient pressure, in U.S. fighter jets, the cabin pressure is adjusted based on an altitude schedule. From sea level to 8,000 feet, the cabin pressure is ambient, from 8,000 to 23,000 feet the air pressure is held constant, and above 23,000 feet, the cabin pressure is maintained to be 5 psi higher than the ambient pressure. As such, the cabin pressure schedule provides some amount of safety up to 23,000 feet in that the pilot could breathe cabin air if necessary; however, above this altitude O₂ supplementation is absolutely required. In general, military regulations always require pilots to wear their breathing gear, regardless of altitude in the event of cabin pressure loss.

Oxygen schedule—There are basically two mask/regulator/supply systems used in high performance aircraft in U.S. jetfighter aircraft, pure O₂ “pressure demand” and mixed gas “diluter demand”; other possible systems are beyond the scope of this article. In short, the system either provides pure O₂ regardless of altitude or air enriched with some level of O₂ adjusted for cabin pressure. From a mechanical perspective, it is simplest to supply pure O₂ all the time, but at lower altitudes it is not necessary and may engender oxidative stress in the pilot. In addition, this method of delivery wastes a fair amount of O₂, especially at lower altitudes. A more conservative approach is to adjust the breathing air to provide a ppO₂ close to sea level and only increase the relative concentration to accommodate lower cabin pressures as altitude increases. Referred to as “diluter demand”, this method is more technically complex, but does a better job at providing only as much O₂ as needed by the pilot, and thus also conserves O₂ resources. Figure 5 shows representative pictures of

respiratory protection/supplementation for scuba, firefighting, aircraft maintenance and jet pilots drawn from the authors' field studies.

Breathing system disruptions (BSDs)

One of the most difficult challenges to breathing when using on-demand technology occurs with respect to mechanical delays in valve and regulator response. Termed "breathing system disruptions" (BSDs), these have different (but related) indications. The most common is referred to as "hysteresis" wherein the combination of very brief delays between inhalation, the start of gas flow, and delayed shut-off for exhalation create excess pressure demands on the human. As most of the breathing systems previously discussed use mechanically triggered valves, this is a normal characteristic of on-demand systems, and generally, divers, firefighters and pilots adapt quickly, and mild hysteresis is not noticed. When adapting to such delays results in conscious effort, maintenance is required.

A second BSD indication is "pressure no flow", a more severe condition wherein the regulator and/or mask valves malfunction to the extent that breathing is interrupted noticeably. This is more likely in SCUBA and high-performance jets systems where the system is referenced to varying external pressures. This has been found particularly important in jet fighters where supply pressure, cabin pressure, and mask pressure all interact. A related phenomenon called "free flow" occurs more often in SCUBA diving wherein pressure balance is lost when the second-stage regulator exhalation valve fails and remains open.

The most subtle of the BSDs occur due to high frequency pressure pulses. A recent study of pilot on-demand breathing showed that adaptive pressure controls can "chatter" or "modulate" and at times have a frequency spectrum similar to that of human breathing. Even modest cycling in mask pressure during inhalation (decrease) or during exhalation (increase) may overwhelm the pressures capable of the human system (NASA PBA Report 2020).

Dissolved inert gases

There are additional physics wrinkles in breathing pressurized air based on the thermodynamics of gases dissolved into the body tissues. These are primarily of concern for SCUBA diving where the ambient pressure varies severely, adding one full atmosphere for every 33 feet of depth, but could also affect high-performance aircraft operation, especially during rapid decompression of the cockpit.

Under higher pressures, inert gases (mostly N₂) slowly dissolve into the blood and tissues; because these inert gases are not metabolized like O₂, they can only leave the system in a reverse process as pressure is reduced. If the ambient pressure drops too quickly, interstitial bubbles can form that may damage the surrounding tissues, leading to DCS. Mild DCS can cause fatigue and malaise while more severe cases can affect the lungs and central nervous system, requiring treatment at a recompression facility (Newton et al. 2001). In SCUBA diving, DCS is avoided by slow ascents, and intermittent decompression stops based on dive tables designed to minimize bubble formation. However, more than 50% of DCS cases occur after no-decompression dives, and factors such as hypothermia, fatigue, dehydration,

alcohol, health conditions, and older age can contribute to the risk of developing DCS (Newton et al. 2001).

Inert gas narcosis is another issue that can affect the human system. As inert gases (typically N₂) dissolve into cellular membranes, especially those of the central nervous system, they can disrupt the normal function of neurological signaling analogous to anesthesia or alcohol inebriation, leading to symptoms of light-headedness, euphoria, poor judgement, overconfidence, hallucinations, and possibly loss of consciousness. Narcosis typically happens when diving at deeper depths and during rapid descents. This is a physical effect that quickly resolves upon relief of positive pressure (Rocco et al. 2019).

As discussed in the SCUBA section above, He is sometimes used as an inert balance gas to offset nitrogen narcosis and bubble formation. Although less likely to cause DCS or narcosis, He has six times the thermal conductivity of N₂ and so has a noticeable systemic cooling effect, removing body heat during exhalation.

POSITIVE PRESSURE VENTILATOR BREATHING

The most invasive level of breathing support technology is used when the pulmonary system cannot sustain adequate ventilation. Medical ventilators literally breathe for the patient. They can be used invasively or non-invasively. Non-invasive ventilation (NIV) is relatively simple as ventilation is provided through a mask that is sealed to the nose and mouth externally. When NIV only provides one continuous pressure setting to a spontaneously breathing patient, this is called continuous positive airway pressure (CPAP); when there is one pressure for inhalation (IPAP) and a lower pressure for exhalation (EPAP) a respiratory rate is provided; this is called bi-level positive airway pressure (BiPAP), since there is a different pressure during inhalation and exhalation. NIV is indicated to help patients who can protect their own airway but need assistance oxygenating and/or ventilating. However, hospital ventilators as used in intensive care units (ICUs) commonly require the patient to be intubated wherein a breathing tube is inserted through the mouth or neck and into the trachea. During this invasive ventilation, the tubing is sealed off and the system periodically inflates the lungs. Breathing frequency and parameters to regulate tidal volume are set specifically for each patient.

Indications for controlled invasive mechanical ventilation

The criteria used to decide to place a spontaneously breathing patient on mechanical ventilation varies, particularly for patients with chronic respiratory diseases, but is typically based on the following five criteria related to breathing stress:

1. Inability to protect one's airway
2. Respiration rate is increasing beyond 30 breaths/minute
3. O₂ saturation rate is no longer maintained above 90% despite supplementation above 60% O₂
4. Blood is trending towards acidic, dropping below pH 7.20
5. ppCO₂ exceeds 50 mmHg

Certainly, there are more immediate conditions that require ventilation, including trauma from chest injuries, collapsed lung, heart failure, head injury/coma, and severe pulmonary infection. Ventilators are also used during surgery to maintain breathing under anesthesia and in postoperative recovery.

During the early stages of the COVID-19 pandemic, ventilators were the primary mechanism to preserve life and maintain oxygenation and ventilation in the setting of acute respiratory distress syndrome while the patient's immune system geared up to fight the infection. Since then, antiviral treatments and other early interventions such as nasal cannulas and early prone positioning have reduced the need for invasive ventilation. Figure 6 shows two examples of patients on hospital ventilator equipment; the left panel shows a BiPAP system that provides positive pressure when needed and the right panel shows a patient in an ICU.

Methods for controlled invasive mechanical ventilation

Modern mechanical ventilators are programmable and feedback-regulated to achieve appropriate life support. They have various functions, including volumetric cycling, pressure cycling, flow cycling, and combinations of all three, and are controllable for O₂ concentration, frequency of breathing, and inspiratory flow rate. Traditional adult positive pressure ventilators are typically set for 10–30 breaths/minute, but neonatal ventilators are often used with high frequency (300–1200 breaths/min) coupled with low volumes referred to as high-frequency oscillatory ventilation (HFOV) to accommodate complex respiratory diseases of premature infants with small tidal volumes.

Typically, controlled ventilation starts with 60% O₂, which may be reduced over time as the patient stabilizes to avoid potential complications from oxidative stress. Modern ventilators can accommodate spontaneous breathing response as the patient improves and ultimately return to an “on-demand” hybrid mode.

Ventilator parameter settings

Adjustable ventilator settings differ with mode and patient demand but generally include the following adjustable parameters and their normal settings (in parentheses):

1. Respiratory rate (12–20 breaths/min)
2. Tidal volume (500 mL, or 4–8 mL/kg body mass, depending upon disease pathophysiology)
3. Trigger sensitivity (adjustable for spontaneous breathing response)
4. Flow rate (adjustable from 60 to 100 L/min)
5. Pressure profile - waveform
6. Inspiratory/expiratory (I/E) time ratio (1/2)
7. O₂ concentration (21–100%)
8. Positive End Expiratory Pressure (PEEP, 5–10 cmH₂O)

These parameters are set based on the patient's health state, physical size, age, and ventilation needs to approximate "normal breathing" as discussed previously. Based on health state, there are accommodations for restrictions in the airway (lower flow rates), there may be lower tidal volumes with respectively higher frequency used to adapt for trauma or disease, and there may be a decrease in the I/E ratio from 1/2 to 1/4 to allow for longer exhalation in response to compromised pulmonary flexibility. The waveform parameter is a relatively new concept and may be adjusted to adapt to the patient's particular physiology.

SUMMARY

Human breathing is a complex function that occurs automatically to provide O₂ needed by cells and tissues. Although humans have evolved to breathe 1-atmosphere with 21% O₂, the human systems biology is adaptable to the immediate environment (altitude, pressure, and CO₂). Humans can quickly adapt to small changes in external conditions or O₂ demand unconsciously and can also consciously modify breathing for singing, swimming, breath holding, and coughing. However, if something goes awry, lack of pulmonary ventilation becomes life threatening in a few minutes.

Technology has been developed to protect humans from inhaling contaminants in the air, to provide adequate air flow and concentrations for flight, travel, and sport activities, and for medical supplementation of O₂ within the construct of normal breathing for trauma or disease intervention. Although much of contemporary breathing research involves the chemistry and metabolism of breathing, the physics of breathing described herein is also an important factor in the preservation of human life.

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REFERENCES

- Andrews P Evolution and environment in the Hominoidea. *Nature*. 1992;360(6405):641–6. [PubMed: 1465127]
- Angelova RA, Markov DG, Simova I, Velichkova R, Stankov P. Accumulation of metabolic carbon dioxide (CO₂) in a vehicle cabin. *In* IOP Conference Series: Materials Science and Engineering. IOP Publishing. 2019;664(1):012010.
- Balanay JA, Lungu CT. Determination of pressure drop across activated carbon fiber respirator cartridges. *Journal of Occupational and Environmental Hygiene*. 2016;13(2):141–7. [PubMed: 26513199]
- Berner RA. Atmospheric oxygen over Phanerozoic time. *Proceedings of the National Academy of Sciences*. 1999;96(20):10955–7.
- Eikenberry SE, Mancuso M, Iboi E, Phan T, Eikenberry K, Kuang Y, Kostelich E, Gumel AB. To mask or not to mask: Modeling the potential for face mask use by the general public to curtail the COVID-19 pandemic. *Infectious Disease Modelling* 2020;5:293–308. [PubMed: 32355904]
- EPA. Exposure Factors Handbook, Edition (Final Report). Chapter 6 "Inhalation Rates" U.S. Environmental Protection Agency, Washington, DC, EPA/600/R-09/052F. 2011.

- Evans JA, Whitelaw WA. The assessment of maximal respiratory mouth pressures in adults. *Respiratory Care*. 2009;54(10):1348–1359. [PubMed: 19796415]
- FAA. Federal Regulation 14 CFR 25.831. Federal Aviation Administration, Department of Transportation, Title 14 - Aeronautics and Space. 2002. https://www.faa.gov/documentLibrary/media/Advisory_Circular/AC_25-20.pdf
- Goldfarb JD, Hodgson EW. Advanced, Lightweight, Space Suit Primary Life Support System for Mars Exploration. SAE Technical Paper. 2001. <https://ttu-ir.tdl.org/bitstream/handle/2346/84710/ICES-2019-26.pdf?sequence=1>
- Guinnessworldrecords.com. [https://www.guinnessworldrecords.com/world-records/longest-timebreath-held-voluntarily-\(male\)](https://www.guinnessworldrecords.com/world-records/longest-timebreath-held-voluntarily-(male)), accessed 5/03/21.
- Hardt DJ, James RA, Gut CP Jr, McInturf SM, Sweeney LM, Erickson RP, Gargas ML. Evaluation of submarine atmospheres: effects of carbon monoxide, carbon dioxide and oxygen on general toxicology, neurobehavioral performance, reproduction and development in rats. I. Subacute exposures. *Inhalation toxicology* 2015;27(2):83–99. [PubMed: 25600219]
- Helviz Y, Einav S. A systematic review of the high-flow nasal cannula for adult patients. *Annual Update in Intensive Care and Emergency Medicine* 2018. 2018:177–91.
- Hoiland RL, Bain AR, Rieger MG, Bailey DM, Ainslie PN. Hypoxemia, oxygen content, and the regulation of cerebral blood flow. *American Journal of Physiology-Regulatory, Integrative and Comparative Physiology* 2016;310(5):R398–413.
- Kasting JF, Siefert JL. Life and the evolution of Earth's atmosphere. *Science*. 2002;296(5570):1066–8. [PubMed: 12004117]
- Kesler RM, Deetjen GS, Bradley FF, Angelini MJ, Petrucci MN, Rosengren KS, Horn GP, Hsiao-Weckler ET. Impact of SCBA size and firefighting work cycle on firefighter functional balance. *Applied ergonomics* 2018;69:112–119. [PubMed: 29477318]
- Kliff S, Satariano A, Silver-Greenberg J, Kulish N. There Aren't Enough Ventilators to Cope with the Coronavirus The New York Times. 2020;18.
- Lausted CG, Johnson AT, Scott WH, Johnson MM, Coyne KM, Coursey DC. Maximum static inspiratory and expiratory pressures with different lung volumes. *Biomedical Engineering OnLine*. 2006;5(1):29. [PubMed: 16677384]
- Law J, Van Baalen M, Foy M, Mason SS, Mendez C, Wear ML, Meyers VE, Alexander D. Relationship between carbon dioxide levels and reported headaches on the international space station. *Journal of occupational and environmental medicine*. 2014;56(5):477–83. [PubMed: 24806559]
- Liem KF. Form and function of lungs: the evolution of air breathing mechanisms. *American Zoologist*. 1988;28(2):739–59.
- Loske A. Fundamentals of SCUBA-diving physics. *International Journal of Sports Science*. 2013;3(2):37–45.
- National Research Council. Emergency and continuous exposure guidance levels for selected submarine contaminants: Volume 1, Chapter 3, Carbon Dioxide. National Academies Press. 2007;1(3).
- NASA. Spacecraft Maximum Allowable Concentrations for Airborne Contaminants. NASA, Human Health and Performance Directorate. JSC 20584. Revision A. 2020.
- NASA PBA Report. Pilot Breathing Assessment, NESC Document #: NESC-RP-18-01320. 2020. https://www.nasa.gov/sites/default/files/atoms/files/nesc-rp-18-01320_v.1.2_nesc_pba_vol.1_11-19-20_nrb_rp_final-.pdf
- Newton HB. Neurological complications of scuba diving. *American family physician*. 2001;63(11):2211. [PubMed: 11417773]
- Peacock AJ. Oxygen at high altitude. *British Medical Journal*. 1998;317(7165):1063–6. [PubMed: 9774298]
- Pleil JD, Beauchamp JD, Risby TH, Dweik RA. The scientific rationale for the use of simple masks or improvised facial coverings to trap exhaled aerosols and possibly reduce the airborne spread of COVID-19. *Journal of breath research*. 2020a;14(3):030201 [PubMed: 32303016]

- Pleil JD, Beauchamp JD, Dweik RA, Risby TH. A special issue: Flow, pressure, volume and time as dependent variables in breath analysis. *Journal of breath research*. 2020b;15(1):010201. [PubMed: 33084604]
- Pleil JD and Christensen LE, 2021. Rationale for developing tunable laser spectroscopy (TLS) technology for high resolution real-time carbon dioxide monitoring (capnography) in human breath, *Journal of Breath research* (in press)
- Ranney ML, Griffeth V, Jha AK. Critical supply shortages—the need for ventilators and personal protective equipment during the Covid-19 pandemic. *New England Journal of Medicine*. 2020;382(18):e41.
- Richardson D A brief history of scuba diving in the United States. *SPUMS Journal*. 1999;29:173–176.
- Rocco M, Pelaia P, Di Benedetto P, Conte G, Maggi L, Fiorelli S, Mercieri M, Balestra C, De Blasi RA, ROAD Project Investigators.. Inert gas narcosis in scuba diving, different gases different reactions. *European journal of applied physiology*. 2019;119(1):247–255. [PubMed: 30350155]
- Satish U, Mendell MJ, Shekhar K, Hotchi T, Sullivan D, Streufert S, Fisk WJ. Is CO₂ an indoor pollutant? Direct effects of low-to-moderate CO₂ concentrations on human decision-making performance. *Environmental health perspectives*. 2012;120(12):1671–7. [PubMed: 23008272]
- Shriram S, Ramamurthy K, Ramakrishnan S. Effect of occupant-induced indoor CO₂ concentration and bioeffluents on human physiology using a spirometric test. *Building and Environment*. 2019;149:58–67.
- Siermontowski P, Zieliński E, Olszański R. Hyperbary-the common roots of treatment of people and exploration of sea depths. *Archives of Physiotherapy & Global Researches* 2016;20(3):13–17.
- Skaria SD, Smaldone GC. Respiratory source control using surgical masks with nanofiber media. *Annals of occupational hygiene* 2014;58(6):771–81.
- Southern TC, Moiseev NA. Commercial EVA Space Suit System Development. *International Conference on Environmental Systems, ICES* 2019;26:1–18.
- Stiegel MA and Pleil JD, Sobus JR, Stevens T, Madden MC. Linking physiological parameters to perturbations in the human exposome: environmental exposures modify blood pressure and lung function via inflammatory cytokine pathway. *Journal of Toxicology and Environmental Health A*. 2017;80(9):485–501.
- Stringer C The origin and evolution of Homo sapiens. *Philosophical Transactions of the Royal Society B: Biological Sciences* 2016;371(1698):20150237.
- Ward JJ. High-flow oxygen administration by nasal cannula for adult and perinatal patients. *Respiratory Care*. 2013;58(1):98–122. [PubMed: 23271822]
- West JB. Human limits for hypoxia: the physiological challenge of climbing Mt. Everest. *Annals of the New York Academy of Sciences*. 2000;899(1):15–27. [PubMed: 10863526]
- Zhang X, Wargocki P, Lian Z. Physiological responses during exposure to carbon dioxide and bioeffluents at levels typically occurring indoors. *Indoor Air*. 2017;27(1):65–77. [PubMed: 26865538]

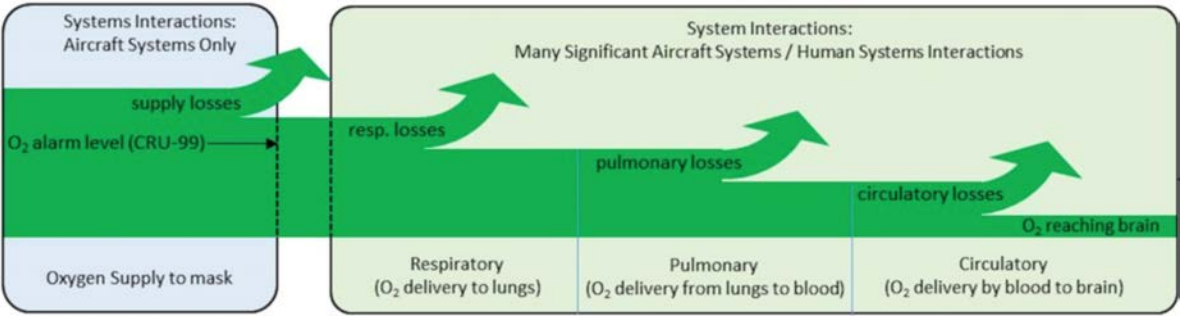


Figure 1. Conceptual diagram of O₂ transport from the face to the brain as adapted from NASA PBA study. Despite adequate input air, there are potential losses from various physiological factors including bronchoconstriction, pulmonary inflammation, and impaired circulation (NASA PBA Report 2020).



Figure 2:
Examples of pulmonary function testing in the laboratory and in the field drawn from US EPA and NASA studies.



Figure 3:
NASA photos of space mission environments with the individual space suit, the “shirtsleeve” environment inside the International Space Station, and an exterior shot of the loneliness of the self-contained human ISS habitat.



Figure 4:
Examples of common protective masks used for safe breathing in various settings. (from US Government archives).



Figure 5:
Examples of respiratory protection/supplementation for scuba, firefighting, aircraft maintenance and jet pilots drawn from the authors' field studies.



Figure 6:
Examples of hospital ventilators that either supplement breathing (left panel), or fully control breathing (right panel) (from <https://commons.wikimedia.org/>).

Table 1:

Nominal values for normal human adult breathing at sea-level

Condition	Rate (Breaths/min)	Tidal Volume (L/breath)	Minute Ventilation (L/min)
Nominal At-Rest	12	0.5	6
Normal Activity	16	1	16
Moderate Exercise	20	2	40
Stress Test	35	3	140
Maximum PFT *	NA	4.5	NA

* standard pulmonary function test (PFT)

NA: not applicable.

Table 2:

Examples of large human populations adapted to breathing normally at different altitudes. As elevation increases, ppO_2 decreases and the human adapts with various mechanisms.

Location	Metropolitan Population (estimate in millions)	Altitude (feet)	Air Pressure (atm)	ppO_2 (atm)
New York City, NY, USA	18.83	33	1.00	0.21
Delhi, India	30.33	709	0.97	0.20
Santiago, Chile	6.77	1615	0.94	0.20
Denver, CO, USA	3.21	5000	0.83	0.17
Kabul, Afghanistan	4.27	5602	0.81	0.17
Mexico City, Mexico	21.78	7350	0.76	0.16
Commercial Airline Cabin	NA	8000	0.74	0.16
El Alto/La Paz, Bolivia	2.91	13600	0.60	0.13
Denali Summit, AK, USA	NA	20208	0.48	0.10
Mount Everest Summit, Nepal	NA	29000	0.31	0.07

* NA: Not applicable

Influenza Aerosols in UK Hospitals during the H1N1 (2009) Pandemic – The Risk of Aerosol Generation during Medical Procedures

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Abstract

Background: Nosocomial infection of health-care workers (HCWs) during outbreaks of respiratory infections (e.g. Influenza A H1N1 (2009)) is a significant concern for public health policy makers. World Health Organization (WHO)-defined 'aerosol generating procedures' (AGPs) are thought to increase the risk of aerosol transmission to HCWs, but there are presently insufficient data to quantify risk accurately or establish a hierarchy of risk-prone procedures.

Methodology/Principal Findings: This study measured the amount of H1N1 (2009) RNA in aerosols in the vicinity of H1N1 positive patients undergoing AGPs to help quantify the potential risk of transmission to HCWs. There were 99 sampling occasions (windows) producing a total of 198 May stages for analysis in the size ranges 0.86–7.3 μm . Considering stages 2 (4–7.3 μm) and 3 (0.86–4 μm) as comprising one sample, viral RNA was detected in 14 (14.1%) air samples from 10 (25.6%) patients. Twenty three air samples were collected while potential AGPs were being performed of which 6 (26.1%) contained viral RNA; in contrast, 76 May samples were collected when no WHO 2009 defined AGP was being performed of which 8 (10.5%) contained viral RNA (unadjusted OR = 2.84 (95% CI 1.11–7.24) adjusted OR = 4.31 (0.83–22.5)).

Conclusions/Significance: With our small sample size we found that AGPs do not significantly increase the probability of sampling an H1N1 (2009) positive aerosol (OR (95% CI) = 4.31 (0.83–22.5)). Although the probability of detecting positive H1N1 (2009) positive aerosols when performing various AGPs on intensive care patients above the baseline rate (i.e. in the absence of AGPs) did not reach significance, there was a trend towards hierarchy of AGPs, placing bronchoscopy and respiratory and airway suctioning above baseline (background) values. Further, larger studies are required but these preliminary findings may be of benefit to infection control teams.

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Introduction

In 2003, at least 284 healthcare workers (HCWs) were infected with SARS-Coronavirus during the severe acute respiratory

syndrome epidemic [1]. Nosocomial infection was the primary accelerator of infection accounting for 72% of cases in Toronto and 55% of probable cases in Taiwan [2,3]. Aerosol generating procedures (AGPs) performed on infected patients were implicated

as the source of outbreaks among Health Care Workers (HCWs), however no direct evidence for this mode of transmission was demonstrated. [4].

Several medical procedures have been reported to generate aerosols and to increase the risk of pathogen transmission [5]. In response to these concerns the World Health Organization (WHO) produced guidelines on infection control procedures and personal protective equipment in 2007, which were refined in 2009 (Table 1) [6,7]. The guidelines incorporated the available data relating to the infective potential of AGPs but many of the studies contained methodological flaws that precluded the use of their conclusions to draw recommendations, and it was accepted that the level of understanding of the aerobiology of AGPs may evolve. In particular the risks associated with individual AGPs have not been quantified nor has a risk hierarchy been established.

Despite their scientific limitations these guidelines have been used to plan infection control during subsequent pandemics. In addition, controversy remains about the importance of aerosol transmission of influenza in the absence of AGPs [8,9,10]. This ongoing uncertainty was reflected in the diverse approaches adopted by different countries in relation to the recommendations for the use of surgical face masks (SFM) and respirators by HCWs during the 2009 pandemic [11,12,13].

WHO guidance states that standard and droplet precautions (i.e. SFMs) should be adopted when working in direct contact with infected patients and high level respiratory protective equipment (minimum of an FFP2/N95 class respirator) should be worn only in the vicinity of infected patients when AGPs are performed [5,6]. As a result, this infection control strategy was adopted in all U.K. NHS organisations [14].

Infectious pathogens may be contained in aerosols which are generally recognised to be <5 µm in aerodynamic diameter, remain suspended for periods of time and travel significant distances. Safety in the presence of infectious aerosols requires respiratory protective equipment (UK standard - FFP3 respirators) to protect exposed HCWs [14]. During human influenza infection, virus emission occurs via coughing and sneezing, which produce a 'respiratory spray' containing particles in a size continuum from <1 to >500 µm [15].

The initial outbreak and subsequent worldwide spread of influenza A (H1N1) 2009 provided an opportunity to perform air sampling to define the viral RNA copy number, and size of aerosols that an AGP (defined by WHO) produces and the relative burden compared to freely respiring patients.

Methods

Objectives

The primary objectives of this study were to:

- 1) Establish if World Health Organization defined 'aerosol generating procedures' produce infectious aerosols.
- 2) If detectable clouds are produced then determine infectious aerosol concentration and particle size.
- 3) To use this information to inform infection control practice.

Participants

Air was sampled around hospitalised patients with suspected or proven lower respiratory tract infection located either in pandemic H1N1 (2009) isolation rooms (single occupancy rooms) or cohort areas (wards in which numerous patients suspected or confirmed as being H1N1 positive were placed away from other patients). Sampling was performed in 5 different hospitals located around England, U.K. This study was performed from October 2009 to January 2011. Peak sampling times corresponded to known periods of heightened H1N1 (2009) activity. Potential recruits were identified in participating units by local principal investigators who informed the sampling team. The sampling team was deployed to units with the highest level of overall activity. Patient inclusion criteria were defined as new chest X-Ray changes (e.g. consolidation, alveolar infiltrates or atelectasis) in the presence of one or more of the following: central temperature ≥38°C (38.5°C in children) or ≤36°C, white blood cell count <4000 cells/mm² or >12,000 cells/mm², positive microbiology or virology from respiratory secretions and mucopurulent secretions from the respiratory tract (Figure 1). During air sampling, investigators recorded any clinical interventions performed, as well as temperature, relative humidity, time and location of air sample, activity levels, patient sex, age, diagnostic specimen type, results and time since admission. Using these data, two consultant physicians (JP & MB), blinded to the air sampling data and the H1N1 status of the patients, independently coded interventions as AGPs if they met 2007 and 2009 WHO definitions (Table 1). Any disagreements were discussed until a consensus was reached. Baseline samples were those taken during interventions not meeting the WHO definitions of an AGP or taken at least 30 minutes after a WHO defined AGP had been completed. All recruits had at least one baseline sampling event, but incidence of

Table 1. In December 2009 the World Health Organization (WHO) updated its advice on AGPs.

2007 WHO Guidance	2009 WHO Guidance
Intubation, and related procedures (e.g. manual ventilation, suction)	Intubation and related procedures, e.g. manual ventilation
Cardiopulmonary resuscitation	Cardiopulmonary resuscitation
Bronchoscopy	Bronchoscopy
Autopsy/surgery	Autopsy procedures
Non-invasive positive pressure ventilation and bilevel positive airway pressure	Respiratory and airway suctioning (including tracheostomy care and open suctioning with invasive ventilation)
High-frequency oscillating ventilation	Collection of lower respiratory tract specimens (e.g. bronchial and tracheal aspirates)
Nebulisation	

N.B. Chest physiotherapy is now not considered an AGP but advice states that a surgical mask should be worn by the patient if tolerated and HCWs should wear PPE as recommended for routine care (i.e. a surgical mask) during the procedure.
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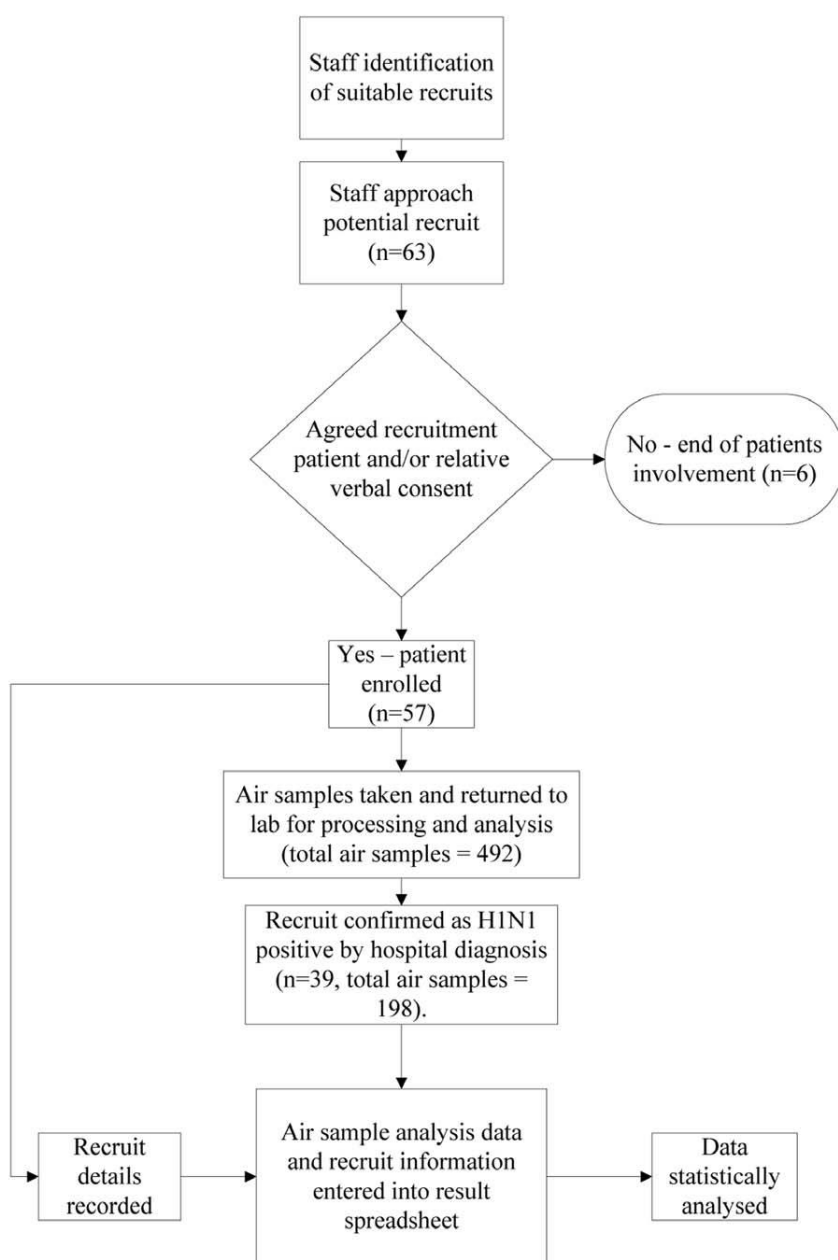


Figure 1. The recruitment and data analysis flowchart.

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WHO defined AGPs was rarer and investigators attempted to capture as many of these as possible.

Description of Procedures or Investigations Undertaken

Glass May 3-stage impingers (produced at HPA, Porton Down), operating at 55 litres per minute and placed at 1 meter height within 1 meter of the patients head, were used to collect air samples for a maximum of 40 minutes [16]. Baseline samples were taken for 10 minutes. Air was collected into 15 mls of sterile, nuclease free, molecular grade, phosphate buffered saline. The May 3-stage impinger fractionates air particles into 3 aerodynamic size ranges, stage 1 collects particles $>7.3 \mu\text{m}$, stage 2 collects particles in the range $4-7.3 \mu\text{m}$ and stage 3 collects particles $0.86-4 \mu\text{m}$. Liquid air samples were transported to the laboratory frozen on dry ice and stored at -20°C until analysis.

The sampling team and all staff/visitors were wearing FFP3 respirators in cohort areas and isolation rooms during the 2009/2010 pandemic. In addition, the sampling team, and a proportion of the staff/visitors were vaccinated against the pandemic strain and the majority of other patients in the intensive care units were on closed ventilator circuits. This means that it is unlikely that the influenza aerosols could have been generated by anyone other than the patient on whom the AGP was being performed. In the case of baseline samples there was often some form of non-AGP classified activity ongoing (e.g. activity associated with chest physiotherapy or respiratory care), and as such these samples do

not represent 'control' samples where no activity was taking place, they merely represent air samples taken when no activity that could be defined as an AGP was taking place.

Sample Processing and Analysis Methodology

On arrival at the laboratory samples were stored at -20°C prior to RNA extraction. Each sample was concentrated into $<500\text{ }\mu\text{l}$ using 30 kD macroseph centrifugal devices (5000 g for 1.5 hours at 4°C). Any viral RNA present within the resulting concentrate was extracted using the Qiagen QIAamp viral RNA spin protocol (Qiagen, U.K.) and eluted into $2\times 30\text{ }\mu\text{l}$ volumes of elution buffer which were subsequently pooled. Samples were frozen at -20°C and defrosted prior to use in the qRT-PCR assay.

A pan-influenza A qRT-PCR assay, based on the pan-influenza segment 7 assay developed by Spackman *et al.* (2002), was used to detect the presence of any influenza A RNA within the samples [17]. The primer, probe concentrations and RNA template volumes were re-optimised from the conditions originally described. The hydrolysis probe was also adapted to use a black hole quencher (BHQ) rather than Carboxytetramethylrhodamine (TAMRA) increasing assay sensitivity. A standard curve was also added to the assay to allow quantification of influenza RNA within the samples. This was prepared using 2009 pandemic nH1N1 A/Cal/04/09 influenza virus. RNA extracted from a live virus preparation was performed using the QIAamp viral RNA mini kit (Qiagen). The full-length influenza segment 7 was amplified by RT-PCR using RT primer Uni12 and PCR primers Bm-M-1 and BM-M-1027 R as described in Hoffman *et al.* (2001) [17]. The amplicon was purified from a 1% (w/v) agarose gel using the QIAquick gel extraction kit (Qiagen), cloned into pCR 2.1 TOPO vector and heat-shocked into *E. Coli* TOP10 cells, as described in the TOPO TA cloning kit (Invitrogen), to construct pCR 2.1 TOPO-CalM. The influenza A/Cal/04/09 segment 7 insert within pCR 2.1 TOPO-CalM was confirmed by sequencing using M13 forward and reverse priming sites that flanked the insert (data not shown). The H1N1 A/Cal/04/09 segment 7 sequence was then amplified from pCR2.1 TOPO-CalM by PCR using primers MCalFwd1 (5'-AGCTAGG-CATGCGCGGCCGAGCAAAAGCAGGTAG-3') and MCal-Rev1 (5'-AGCTAGGCATGCTAATACGACTCACTATAGGGAG-TAGAAACAAGGTAGTTTTT-3') which contained a T7 RNA polymerase promoter sequence (highlighted in italics). A negative sense T7 RNA transcript of the Cal/04/09 M segment sequence was generated from the PCR amplicon, with the amplicon subsequently removed by DNase digestion, using the Megascript T7 kit (Ambion). DNase digestion of the amplicon template was confirmed by agarose gel electrophoresis. The RNA transcript was purified using an RNeasy mini kit (Qiagen) RNA clean-up protocol and the copy number calculated following determination of the RNA transcript concentration with a Nanodrop ND100 spectrophotometer.

All qRT-PCR reactions were performed on 96-well plates using the superscript III platinum one-step quantitative RT-PCR kit (Invitrogen) and run on the Applied Biosystems 7900 real-time PCR system. Each 96-well plate consisted of a standard curve (prepared from a ten-fold dilution series of the nH1N1 A/Cal/04/09 M segment RNA transcript in H_2O) which also acted as the assay positive control, a non-template negative control (molecular grade water) and RNA from processed air samples. All controls and samples were run in duplicate. qRT-PCR reactions consisted of $12.5\text{ }\mu\text{l}$ $2\times$ Buffer, $1.25\text{ }\mu\text{l}$ M+25 oligo (AGA TGA GTC TTC TAA CCG AGG TCG) (300 nM final concentration), $1.25\text{ }\mu\text{l}$ M-

125 oligo (TGC AAA AAC ATC TTC AAG TCT CTG) (300 nM final concentration), $0.5\text{ }\mu\text{l}$ Rox, $0.5\text{ }\mu\text{l}$ Taq/superscript enzyme, $0.25\text{ }\mu\text{l}$ M+65 probe (FAM-TCA GGC CCC CTC AAA GCC GA-BHQ) (250 nM final concentration) and $8.75\text{ }\mu\text{l}$ of either sample RNA, standard curve RNA or negative control (dH_2O) to reach a final volume of $25\text{ }\mu\text{l}$. The Influenza qRT-PCR Cycling Conditions were 50°C for 30 minutes, 95°C for 10 minutes, followed by 50 cycles of 95°C for 15 seconds and 60°C for 60 seconds. The number of virus copies/litre were for each sample was then determined using the standard curve (R^2 values were typically 0.94).

Ethics

The study was approved by Oxfordshire Local Research Ethics Committee (REC reference 09/H0604/119) and the requirement for informed consent was waived. The committee agreed that this study did not constitute intrusive research because it involved only the processing of non-identifiable data. The committee felt that the provisions of the Mental Capacity Act did not apply to this study. The committee welcomed the statements by the researchers that they would always seek the views of patients, parents and/or relatives prior to starting to take air samples and that they would respond to concerns after the sampling had started. The committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the U.K.

Statistical Methods

Statistical analysis was performed with Stata software (version 11.0; Stata Corp., College Station, TX, USA). Only patients confirmed as influenza A H1N1 (2009) RT-PCR positive from respiratory tract samples were considered in the statistical analysis. Univariable logistic regression models were used to examine the relationship between propensity to produce a positive H1N1 aerosol sample and a number of potential risk factors. Wald tests were used to assess risk factor significance. A sample was considered to be positive for aerosolised influenza particles if either or both of May stages 2 and 3 ($0.86\text{--}7.3\text{ }\mu\text{m}$) indicated the presence of H1N1. Copy numbers from stages 2 and 3 were summed to give a total copy number for the sampling occasion. A random effect was included in the logistic models at subject level to account for potential correlation caused by repeated measurements on the same individual. In instances where a positive H1N1 sample was produced, univariable negative binomial regression models, corrected for sample duration, were used to examine the relationship between total copy number per litre per minute and potential risk factors. Only three participants gave more than one positive H1N1 sample and so a random subject-level effect was not used in the negative binomial regressions. Instead a robust standard error was used to adjust for potential correlation in these models.

Finally, the probability of obtaining a positive sample and the viral load obtained from positive samples were modelled to rank the 2007 and 2009 WHO procedure lists and chest physiotherapy and produce a hierarchy of procedures on the basis of potential risk. The classical definition of risk as equal to 'probability times consequence' was used and hence multiplied predictions from the logistic and negative binomial models together in order to obtain a risk measure which gives the expected value of copy number (l/min) associated with each procedure.

Results

A total of 57 patients were studied, however only 39 patients were later confirmed as influenza A H1N1 (2009) RT-PCR positive and were included in the statistical analysis.

Table 2 and 3 show the percentage of total RNA found in each stage of the May impinger (Table 2) and the % of RNA collected in each stage during each procedure (Table 3). These tables show that most of the RNA recovered from the baseline samples has been recovered in the $>7.3\ \mu\text{m}$ size range (53.6% of total RNA and 78.7% of the total RNA recovered from baseline samples). In contrast, the total amount of RNA recovered from all the bronchoscopy samples was only 7.1% (confounded by limited sample size) but 75.1% of this was collected in the stages $<7.3\ \mu\text{m}$. The situation is similar for respiratory and airway suctioning (3.0% total RNA of which 77.6% was in the $<7.3\ \mu\text{m}$ size range). Therefore the results indicate that AGPs as defined by the WHO 2009 definitions tend to produce aerosols of smaller particle sizes than baseline levels.

Figure 1 shows the patient inclusion process but as this paper is interested in the ability of AGPs to generate aerosols rather than respiratory droplets subsequent analysis deals with the results from the second and third stages (particle sizes $0.86\text{--}7.3\ \mu\text{m}$) of the May sampler, however full results can be seen as an online supplement. Tables 4 & 5 show H1N1 patient demographics together with other characteristics of their samples.

There were 99 sampling occasions (windows) producing a total of 198 May stages for analysis in the size ranges $0.86\text{--}7.3\ \mu\text{m}$ (Table 6). Forty-six air stage samples were collected while potential AGPs (according to WHO 2009 definitions – see Table 1) were being performed of which 9 (19.6%) contained viral RNA; in contrast, 152 May stage samples were collected when no WHO 2009 defined AGP was being performed of which 12 (7.9%) contained viral RNA (unadjusted OR = 2.84 (95% CI: 1.11–7.24) adjusted OR = 4.31 (0.83–22.5)).

There were 99 May stages for analysis in the $>7.3\ \mu\text{m}$ size range, 23 air stage samples were collected while potential WHO (2009) AGPs were being performed of which 3 (13.0%) contained viral RNA; 76 May stage samples were collected when no WHO (2009) AGP was being performed of which 9 (11.8%) contained viral RNA. This was not statistically significant (unadjusted OR = 1.06 (0.26–4.29)).

Results from the logistic regressions (Tables 4, 5, 6, 7, 8, 9) indicate that, after adjustment for repeated measurements, none of the variables we examined had a significant influence on the production of an H1N1 positive aerosol ($p < 0.05$) (Table 6). The value of the estimated odds ratio (OR) for the likelihood of producing PCR positive air samples in particle sizes ranges $0.86\text{--}7.3\ \mu\text{m}$ in the presence of a WHO (2009) AGP was 4.31 (0.83–22.5). The categorical variable for WHO (2009) AGP was itself not significant.

Subject-level random effects obtained from the null logistic model indicate that one individual in the study has a significantly higher propensity than average to produce a positive sample, and that others have a raised propensity. This, coupled with the lack of significant relationships given in Tables 4, 5, 6, 7, 8, 9, suggests that propensity to produce a positive sample is more related to unmeasured individual-level attributes than demographic or other measured characteristics. The variation caused by the unmeasured attributes is high as the subject-level random effects have wide confidence intervals. The Variance Partition Coefficient (VPC) for the null logistic model indicates that only 31% of the total variance in the propensity to produce a positive sample is due to differences between individuals, for example in age or hospital location, and hence 69% is due to differences within individuals, for example, stage in infection. Unfortunately we do not have enough data to analyse an individual through time to investigate this further.

Results from the negative binomial regression are also given in Tables 4, 5, 6, 7, 8, 9. Copy number per litre is significantly positively associated with cases aged 50–60 years (incident rate ratio [IRR] 8.85 compared to referent, (95% CI: 4.14–18.9)) and cases from hospital location no. 2 (IRR 6.21(2.49–15.5)). It is significantly negatively associated with days since diagnosis (IRR 0.84 (0.79–0.90)); days since last positive sample (IRR 0.84 (0.78–0.90)); and relative humidity (IRR 0.95 (0.91–0.98)). However, WHO (2009) AGP categorisation itself was found to have no association with copy number, suggesting that some AGPs are associated with high copy numbers and others are associated with low copy numbers, as revealed by the IRR estimates for the various WHO (2009) AGP categories. These range from 0.15 to 5.41 (Table 6) but are, however, inconclusive because of the low numbers in each category. Our analysis of the influences on virus quantity in an aerosol is likely to be subject to confounding because of the low number of positive samples, and possible correlation between risk factors.

When the data are analysed with regard to the WHO (2007) AGP definitions there was a broad agreement with the results detailed above (Table 7). We also included procedures relating to chest physiotherapy in the analysis against AGP (2009) and AGP (2007) (Tables 8 & 9). The results suggest that chest physiotherapy is associated with an increased probability of aerosol production if included in the WHO (2009) AGP model (OR 3.06 (0.28–33.3)), but that aerosol titre is lower than baseline samples (IRR 0.23 (0.06–0.93)). To further establish the relationship between different AGPs the data were modelled to determine a hierarchy of procedures in terms of the potential risk of generating infectious aerosol (Table 10). We found that whilst most AGPs are associated with a higher probability of sampling an H1N1 positive aerosol they are also, with the exception of bronchoscopy, associated with lower copy numbers (1/min) than background samples and this lessens their overall risk (Tables 6, 7, 8, 9). Only bronchoscopy and

Table 2. The percentage of total RNA collected in each stage (size range) of the May impinger compared based on the WHO 2009 AGP definitions.

Procedure	% RNA collected $>7.3\ \mu\text{m}$	% RNA collected $4\text{--}7.3\ \mu\text{m}$	% RNA collected $0.86\text{--}4\ \mu\text{m}$
Baseline	53.6	7.6	6.9
Bronchoscopy	7.1	12.9	8.6
Respiratory & Airway Suction	0.7	0.9	1.4
Intubation	0.0	0.3	0.0

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Table 3. The % of RNA collected from each procedure in each stage of May sampler.

Procedure	Number of sampling occasions (number of patients)	% RNA collected >7.3 μm	% RNA collected 4–7.3 μm	% RNA collected 0.86–4 μm	Median copy no./l (inter-quartile range) for samples with at least one stage with detectable RNA
Baseline	76 (39)	78.7	11.1	10.2	7,913 (2,436–11,613)
Bronchoscopy	3 (3)	24.9	45.2	29.9	148,805 (12,735–284,875)
Respiratory & Airway Suction	14 (11)	22.4	29.7	47.9	1,852 (1,543–2,7521)
Intubation	5 (4)	0.0	100.0	0.0	2,838 (2,838–2,838)

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respiratory/airway suctioning were found to have a risk greater than that encountered in the baseline (background) samples.

Discussion

Evidence regarding the role of AGPs in the transmission of influenza in the hospital setting is limited. [5] The results from Table 2 indicate that smaller particles are preferentially produced during AGP procedures compared to baseline samples. However the total level of RNA recovered is higher during baseline samples, i.e. large particles containing higher quantities of RNA vs smaller particles containing smaller quantities of RNA. Due to the limitations of the sampling method it is impossible to quantify the total number of particles at each particle size – we only have an indication of the quantity of RNA collected in each particle size range. One might speculate (as others have done before) that a dispersed aerosol with a low concentration of influenza containing small particles might potentially be more of a transmission and morbidity risk than a few large particles containing significantly more total influenza. [5,19].

This study detected influenza virus RNA in 14/99 (14.1%) air-sampling windows in particles 0.86–7.3 μm from 10/39 (25.6%) patients in broad agreement with reports from different health care settings [20,21,22,23]. Of particular note is the fact that 19.6% of air specimens taken in the presence of a 2009 defined AGP (AGP 2009) revealed virus RNA infractions 0.86–7.3 μm , compared with only 7.9% in non-AGP (2009) settings (unadjusted OR = 2.84 (95% CI: 1.11–7.24) adjusted OR = 4.31 (0.83–22.5)).

Data were analysed for the propensity of an air-sampling event to produce a positive air sample in the 0.86–7.3 μm aerodynamic size range. None of the variables investigated in this study significantly increased the probability of obtaining a positive air sample for either the 2007 or 2009 analysis. However, there will be variability in the potential for the air sampler to detect positive air samples due to a number of factors including room ventilations patterns, the air particles' initial velocities, temperature, relative humidity, and distance from source [24]. Even with this significant level of uncertainty and the low sample number we estimated an adjusted OR of 4.31 (0.83–22.5) for WHO (2009) AGP vs non WHO (2009) AGP settings ($p = 0.083$). Taken together with an unadjusted OR of 2.84, and in the context of the small study size, these findings suggest a true effect i.e. that AGPs as currently defined by 2009 WHO definitions increase the likelihood of generating infectious aerosols to the extent that this may be relevant in a clinical setting. However, we have almost certainly encountered a Type II statistical error due to small numbers. Further data are therefore required.

Analysis of the specific procedures shows that bronchoscopy is associated with the greatest probability of aerosol production (OR = 43.8(1.06–1809)), but both intubation and related proce-

dures (OR = 2.71 (0.15–49.1)), respiratory/airway suction (OR = 4.11 (0.50–34.0)) and chest physiotherapy (OR = 3.06 (0.28–33.3)) also show increased probability, although none of these results attained statistical significance.

The quantity of viral RNA is known to vary both between patients and within individual patients during the time-course of their illness. Patients early in the course of infection excrete higher titres of virus and thus might generate aerosols containing more viral RNA. [25] In our study only 31% of the total variance in the propensity to produce a positive sample is due to differences between individuals, and 69% is due to differences within individuals. Unfortunately, we did not have ethical committee approval to obtain respiratory tract specimens from patients; thus although we can determine H1N1 diagnostic status from specimens taken by the attending physician (the basis of recruitment into this study), we cannot correlate our air sample findings against patient virus concentrations. Many other studies have also noted high variability in the number of virus particles expelled by subjects infected with respiratory pathogens therefore this work is consistent with previous studies. [22,26,27,28,29].

The influenza RNA loading of a positive air sample is likely to be influenced by the source of the aerosol (i.e. the patient and the location within the patient where the aerosol is produced). In a recent paper by Johnson et al., 2011, it has been suggested that aerosols of different particle sizes can be produced from different areas of the respiratory tract when different activities are performed, such as coughing, breathing and talking [30]. Although not investigated in this study the results suggest that the aerosols detected in our study could have originated from different parts of the respiratory tract, which could account for the wide range of viral titres picked up. If the viral loading differs along the respiratory tract and between individuals, and the different procedures have differing abilities to produce an aerosol, then a wide range of viral titres would be expected. However it is also true that variability in the data can be caused by differences in impinger proximity, orientation, directional air flows, human activity (producing turbulent air conditions) and ventilation levels between sampling sites.

The results indicate (although small sample size prohibits firm conclusions) that performance of a bronchoscopy increases the viral copy number per litre in positive air samples by a factor of 4.37 (CI = 0.60–32.0). Intubation and related procedures and respiratory/airway suctioning show decreased IRRs (0.12 (0.03–0.5) and 0.35 (0.07–1.70), respectively). This is the first evidence to suggest that some AGPs (e.g. bronchoscopy) may confer a greater risk of transmission to HCWs than others.

In order to further understand the risk hierarchy, titre and probability of a positive sample have been used to construct a risk summary stratification table (Table 10). This table has been

Table 4. Location and Environmental conditions of air samples.

Characteristic	H1N1 positive patients (n = 39)			H1N1 positive aerosol samples ^a (n = 14; collected from 10 patients)			A			B		
	n	%	mean (sd)	n	%	Median copy no./l (inter- quartile range)	OR (95% CI)	p value	IRR (95% CI)	p value		
Centre ID												
Location 1	19	49		4 (3)	29	8,888 (4,611–10,738)	referent		referent			
Location 2	10	26		8 (5)	57	7,741 (1,698–62,343)	5.86 (1.10–31.37)		6.21 (2.49–15.5)			
Location 3	6	15		0	0	–	–		–			
Location 4	3	8		2 (2)	14	6,292 (2,838–9,745)	3.70 (0.37–37.55)		0.38 (0.28–0.52)			
Location 5	1	3		0	0	–	–	0.114	–			<0.001
Location												
Cohort area	24	62		11 (9)	79	7,913 (1,852–9,963)	referent		referent			
Isolation	15	38		3 (1)	21	20,614 (1,543–213,659)	0.27 (0.03–2.20)	0.22	5.20 (0.79–34.3)	0.087		
Air sample volume (l)							1.00 (0.999–1.004)	0.137	0.998 (0.998–0.999)	<0.001		
Temperature °C			22.2 (1.42)				1.21 (0.70–2.08)	0.49	1.07 (0.27–4.16)	0.923		
Relative humidity			33.6 (11.12)				0.95 (0.89–1.02)	0.154	0.95 (0.91–0.98)	0.006		

^aSample considered positive if aerosol <7.3 µm indicated the presence of H1N1.

^bn unique patients refers to the number of patients these samples were taken from.

Column A: Results from univariable logistic regression models examining potential risk factors for production of H1N1 positive aerosol. Sample considered positive if aerosol <7.3 µm indicated the presence of H1N1. Estimates adjusted for repeated measurements.

Column B: Results from univariable negative binomial regression models examining potential risk factors for copy number per litre per minute given H1N1 positive aerosol.

A hyphen (–) indicates no positive samples in category. Referent refers to the category of an ordinal or nominal variable against which other categories are compared in the regression model and for which no dummy variable is included in the regression model.

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Table 5. Demographic and patient specific conditions of air samples.

Characteristic	H1N1 positive patients (n = 39)		H1N1 positive aerosol samples ^a (n = 14; collected from 10 patients)		A			B		
	n	%	mean (sd)	n (n unique patients ^b)	%	Median copy no./l (inter- quartile range)	OR (95% CI)	p value	IRR (95% CI)	p value
Sex										
Male	25	64		11 (7)	79	9,745 (1,543–11,613)	referent		referent	
Female	14	36		3 (3)	21	5,518 (2,838–104,072)	0.45 (0.09–2.33)	0.342	1.57 (0.22–11.3)	0.651
Age										
<5	4	10		0	0	–	–		–	
5–50	7	18		4 (3)	29	4,883 (1,262–8,938)	2.62 (0.37–18.8)		0.71 (0.41–1.25)	
50–60	13	33		6 (4)	43	15,180 (5,518–104,072)	2.43 (0.43–13.7)	0.525	8.85 (4.14–18.9)	<0.001
60–70+	15	39		4 (3)	29	6,350 (2,073–10,738)	referent		referent	
ECMO										
No	34	87		10 (8)	71	8,829 (2,838–9,963)	referent		referent	
Yes	5	13		4 (2)	29	11,233 (1,698–117,137)	2.88 (0.44–18.9)	0.269	3.62 (0.83–15.8)	0.087
Repeats per patient			2.5 (1.27)							
Days since diagnosis			7.5 (8.56)							
Days since last positive sample			5.5 (6.32)							
Repeat number			7.5 (8.56)							

^aSample considered positive if aerosol <7.3 µm indicated the presence of H1N1.

^bn unique patients refers to the number of patients these samples were taken from.

Column A: Results from univariable logistic regression models examining potential risk factors for production of H1N1 positive aerosol. Sample considered positive if aerosol <7.3 µm indicated the presence of H1N1. Estimates adjusted for repeated measurements.

Column B: Results from univariable negative binomial regression models examining potential risk factors for copy number per litre per minute given H1N1 positive aerosol.

A hyphen (–) indicates no positive samples in category. Referent refers to the category of an ordinal or nominal variable against which other categories are compared in the regression model and for which no dummy variable is included in the regression model.

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Table 6. Analysis of air samples using the WHO (2009) AGP definitions.

Characteristic	All repeats (n = 99)		H1N1 positive aerosol samples ^a (n = 14; collected from 10 patients)		A				B	
	n	%	n	%	Median copy no./l (inter- quartile range)	OR (95% CI)	p value	IRR (95% CI)	p value	
AGP (2009)										
Baseline (no AGP)	76	77	8 (6)	57	8,888 (3,414–10,788)	referent		referent		
Bronchoscopy	3	3	2 (2)	14	111,702 (9,745–213,659)	36.8 (0.96–1409)		5.41 (0.77–38.0)		
Lower respiratory tract specimen collection	1	1	0	0		–		–		
Intubation & related procedures	5	5	1 (1)	7	2,838 (2,838–2,838)	2.37 (0.13–41.5)		0.15 (0.04–0.58)		
Respiratory/airway suction	14	14	3 (2)	22	1,852 (1,543–20,614)	3.53 (0.45–27.5)	0.231	0.43 (0.09–1.99)		not available
AGP (2009) defined										
No						referent		referent		
Yes						4.31 (0.83–22.5)	0.083	2.04 (0.36–11.62)		0.42

^aSample considered positive if aerosol <7.3 µm indicated the presence of H1N1.

^bn unique patients refers to the number of patients these samples were taken from.

Column A: Results from univariable logistic regression models examining potential risk factors for production of H1N1 positive aerosol. Sample considered positive if aerosol <7.3 µm indicated the presence of H1N1. Estimates adjusted for repeated measurements.

Column B: Results from univariable negative binomial regression models examining potential risk factors for copy number per litre per minute given H1N1 positive aerosol.

A hyphen (–) indicates no positive samples in category. Referent refers to the category of an ordinal or nominal variable against which other categories are compared in the regression model and for which no dummy variable is included in the regression model.

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Table 7. Analysis of air samples using the WHO (2007) AGP definitions.

Characteristic	All repeats (n = 99)			H1N1 positive aerosol samples ^a (n = 14; collected from 10 patients)			B		
	n	%	n (n unique patients ^b)	Median copy no./l (inter-quartile range)	OR (95% CI)	p value	IRR (95% CI)	p value	p value
AGP (2007)									
Baseline (no AGP)	56	57	5 (5)	9,862 (5,518–9,963)	referent		referent		
Bronchoscopy	3	3	2 (2)	111,702 (9,745–213,659)	36.8 (1.04–1302)		3.84 (0.52–28.1)		
High frequency oscillatory ventilation	6	6	0	–	–		–		
Intubation and related procedures	20	20	3 (2)	2,838 (1,543–20,614)	2.11 (0.34–13.2)		0.32 (0.07–1.48)		
Nebulisation	3	3	2 (2)	1,262 (671–1,852)	41.1 (1.20–1404)		0.05 (0.01–0.21)		
Non invasive ventilation	11	11	2 (2)	9,763 (7,913–11,613)	2.66 (0.30–24.0)	0.149	0.33 (0.07–1.60)		<0.001
AGP (2007) defined									
No					referent		referent		
Yes					4.25 (0.84–21.4)	0.079	1.04 (0.17–6.44)		0.964

^aSample considered positive if aerosol <7.3 µm indicated the present of H1N1.

^bn unique patients refers to the number of patients these samples were taken from.

Column A: Results from univariable logistic regression models examining potential risk factors for production of H1N1 positive aerosol. Sample considered positive if aerosol <7.3 µm indicated the presence of H1N1. Estimates adjusted for repeated measurements.

Column B: Results from univariable negative binomial regression models examining potential risk factors for copy number per litre per minute given H1N1 positive aerosol.

A hyphen (–) indicates no positive samples in category. Referent refers to the category of an ordinal or nominal variable against which other categories are compared in the regression model and for which no dummy variable is included in the regression model.

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Table 8. Analysis of the air samples using the WHO (2009) AGP definitions and including chest physiotherapy.

Characteristic	All repeats (n = 99)		H1N1 positive aerosol samples ^a (n = 14; collected from 10 patients)		Median copy no./l (inter-quartile range)		A		B	
	n	%	n	(n unique patients) ^b	n	(n unique patients) ^b	OR (95% CI)	p value	IRR (95% CI)	p value
AGP (2009) with Chest Physiotherapy										
Baseline (no AGP)	66	67	6	(5)	8,888	(5,518–11,613)	referent		referent	
Bronchoscopy	3	3	2	(2)	111,702	(9,745–213,659)	43.8 (1.06–1809)		4.37 (0.60–32.0)	
Lower respiratory tract specimen collection	1	1	0		–		–		–	
Intubation & related procedures	5	5	1	(1)	2,838	(2,838–2,838)	2.71 (0.15–49.1)		0.12 (0.03–0.50)	
Respiratory/airway suction	14	14	3	(2)	1,852	(1,543–20,614)	4.11 (0.50–34.0)		0.35 (0.07–1.70)	
Chest physiotherapy	10	10	2	(1)	5,317	(671–9,963)	3.06 (0.28–33.3)	0.449	0.23 (0.06–0.93)	not available
AGP (2009) defined including chest physiotherapy										
No							referent		referent	
Yes							4.36 (0.91–20.9)	0.065	1.30 (0.20–8.58)	0.787

^aSample considered positive if aerosol <7.3 µm indicated the presence of H1N1.

^bn unique patients refers to the number of patients these samples were taken from.

Column A: Results from univariable logistic regression models examining potential risk factors for production of H1N1 positive aerosol. Sample considered positive if aerosol <7.3 µm indicated the presence of H1N1. Estimates adjusted for repeated measurements.

Column B: Results from univariable negative binomial regression models examining potential risk factors for copy number per litre per minute given H1N1 positive aerosol.

A hyphen (-) indicates no positive samples in category. Referent refers to the category of an ordinal or nominal variable against which other categories are compared in the regression model and for which no dummy variable is included in the regression model.

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Table 9. Analysis of the air samples using the WHO (2007) AGP definitions and including chest physiotherapy.

Characteristic	All repeats (n = 99)		H1N1 positive aerosol samples ^a (n = 14; collected from 10 patients)		Median copy no./l (inter- quartile range)		A		B	
	n	%	n	(n unique patients ^b)			OR (95% CI)	p value	IRR (95% CI)	p value
AGP 2007 with Chest Physiotherapy										
Baseline (no AGP)	48	48	4	(4)	7,690 (3,414–56,967)		referent		referent	
Bronchoscopy	3	3	2	(2)	111,702 (9,745–213,659)		41.88 (1.06–1658)		3.33 (0.43–25.9)	
High frequency oscillatory ventilation	6	6	0				–		–	
Intubation and related procedures	20	20	3	(2)	2,838 (1,543–20,614)		2.32 (0.34–15.68)		0.8 (0.06–1.39)	
Nebulisation	3	3	2	(2)	1,262 (671–1,852)		48.4 (1.22–1918)		0.04 (0.01–0.21)	
Non invasive ventilation	11	11	2	(2)	9,763 (7,913–11,613)		2.92 (0.30–28.3)		0.28 (0.05–1.53)	
Chest physiotherapy	8	8	1	(1)	9,963 (9,963–9,963)		1.94 (0.11–33.5)	0.352	0.33 (0.08–1.45)	not available
AGP 2007 defined including chest physiotherapy										
No							Referent		referent	
Yes							3.91 (0.78–19.6)	0.098	0.85 (0.12–5.75)	0.865

^aSample considered positive if aerosol <7.3 µm indicated the presence of H1N1.

^bn unique patients refers to the number of patients these samples were taken from.

Column A: Results from univariable logistic regression models examining potential risk factors for production of H1N1 positive aerosol. Sample considered positive if aerosol <7.3 µm indicated the presence of H1N1. Estimates adjusted for repeated measurements.

Column B: Results from univariable negative binomial regression models examining potential risk factors for copy number per litre per minute given H1N1 positive aerosol.

A hyphen (–) indicates no positive samples in category. Referent refers to the category of an ordinal or nominal variable against which other categories are compared in the regression model and for which no dummy variable is included in the regression model.

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Table 10. Risk summary stratification table.

AGP definition	Sample size (number of repeats)	Number of H1N1 positive samples	Modelled probability of sampling H1N1 positive aerosol (assumes subject effect = 0) ^a	Modelled copy number (litres/min) ^b	Risk (defined as expected value of copy number, equal to modelled probability * modelled copy number)
Bronchoscopy (2009)	3	2	0.684	9,986	6,829
Bronchoscopy (2007)	3	2	0.659	9,986	6,579
Respiratory/airway suctioning (2009)	14	3	0.169	800	135
Baseline(2007)	48	4	0.044	3,003	132
Baseline (2009)	66	6	0.047	2,285	108
Non invasive ventilation (2007)	11	2	0.119	849	101
Nebulisation (2007)	3	2	0.691	126	87
Chest physiotherapy (2007)	8	1	0.082	996	82
Intubation (2007)	20	3	0.097	833	81
Chest physiotherapy (2009)	10	2	0.131	532	70
Intubation (2009)	5	1	0.118	284	33
Lower respiratory tract specimen (2009)	1	0	0.000	0	0
High frequency oscillatory ventilation 6 (2007)		0	0.000	0	0

^aProbabilities obtained from univariable logistic regression models examining potential risk factors for production of H1N1 positive aerosol. Sample considered positive if aerosol <7.3 µm indicated the presence of H1N1. Estimates adjusted for repeated measurements.

^bEstimates obtained from univariable negative binomial regression models examining potential risk factors for copy number per litre per minute given H1N1 positive aerosol.

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produced simply as a method to summarise the results and modeled numbers are purely an indication of overall risk. However, this table shows that when probability of a positive air sample and the titre of an air sample are used to define risk, only bronchoscopy and the 2009 defined respiratory/airway suctioning carry a greater risk than the baseline samples. Positive baseline samples may be produced from residual aerosols left from previous AGPs, by some other unknown low level AGP, or by other H1N1 positive individuals coughing and sneezing in cohort areas.

The copy number of influenza virus recovered from a positive air sample is strongly influenced by hospital location ($p < 0.001$), age range ($p < 0.001$), day since diagnosis ($p < 0.001$), days since last positive diagnostic sample ($p < 0.001$), air sample volume ($p < 0.001$) and relative humidity ($p = 0.006$).

Hospital location number 2 had significantly higher viral concentrations recovered from positive air samples potentially because this hospital is a tertiary referral centre for respiratory illnesses which provided extracorporeal membrane oxygenation (ECMO) for adults during the H1N1 outbreak. In addition, most bronchoscopies were performed at this location and this hospital contained the patient with a higher than average propensity to produce a positive sample.

Age was shown to have a significant effect with patients aged between 50–60 years having the highest rate of H1N1 aerosol generation in contrast to what would be expected from previous studies [31,32]. This apparent age-related effect could be due to an outlying result; the patient with the significantly higher propensity than average to produce a positive air sample was in this group. A negative association between the copy number recovered and the number of days between diagnosis and sampling was found as would be expected. The significance of the relationship between high relative humidity and lower recovery of viral RNA correlated with previous studies [33].

Limitations

This study has several limitations. Firstly, we did not perform a biological assay to quantify the viability and infectious potential of this viral material. Although the influenza virus is capable of surviving in air in the indoor environment there are no data regarding the stability of pandemic H1N1 (2009) in aerosols. The successful culture of viable viruses from environmental samples is technically difficult and thus relatively insensitive as a bioassay of infectivity [21,22]. However, we believe that the detection of virus RNA in an aerosol within seconds of its generation, favours it being derived from viable viruses.

Secondly, even if an aerosol of the appropriate concentration does reach a health care worker and is inhaled, inhalation does not necessarily equate to infection. Infection depends upon infectious dose, route of inhalation (nose or mouth), tidal volume, breathing rate, timing and underlying susceptibility (immune status) [34]. It also depends upon particle size, for a particle to enter the distal lung it needs to be <5 µm for >10% deposition [35]. As we sampled in a wide range of different hospitals and it was very difficult to establish and get information about ventilation rates and patterns between hospitals and within different areas of the same hospital. In general isolation rooms had higher ventilation rates than ward cohort areas and in some cohort areas the opening of windows was the only form of ventilation evident. Obviously it was impossible to investigate fully all the areas we sampled due to time and logistical constraints in these busy environments. This study, therefore, can only give an indication of the levels of influenza RNA which a health-care worker could be exposed to.

Thirdly, estimating the aerosol infectious dose from previous studies is difficult due to the lack of studies in this area for health and ethical reasons [19,36]. However, Alford *et al.*, (1967) found that the aerosol infectious dose of influenza A2/Bethesda/10/63 was between 0.6–3 TCID₅₀, which equates roughly to 0.6–3 virus particles according to Teunis *et al.*, (2010). [19,37] The potential

exposure of HCW during AGPs can be roughly calculated using the aerosol concentration, breathing rate and exposure time. If we assume a female HCW breathing rate of 15 l/min during an AGP lasting 15 minutes then 225 litres of air will be inhaled during the procedure. [38] The modelled concentration of viral copy numbers found during the bronchoscopy positive air samples was 9,986 copies/litre/minute, suggesting that expected exposure would be 2246850 virus copies. This exposure is significantly greater than the 0.6–3 TCID₅₀ aerosol infectious dose reported by Alford *et al.*, in (1967). The study also shows that significant exposure to H1N1 aerosols (modelled copy number 2,285 copies/litre/minute) occurs in the absence of a recognized AGP in the vicinity. This study and that of Killingley *et al.*, suggest that exposure to aerosols of influenza may regularly occur during epidemics not just in ICUs or hospitals but in many other environments [20].

Fourthly, the May impinger does not collect particles <0.86 µm aerodynamic particle size, several studies have reported finding influenza RNA in air particles <1 µm, thus it is possible that some of the aerosolized RNA was missed [22,23].

Finally, this was a large and complex study involving collaborations between the laboratory, sampling teams and busy clinicians from five hospitals. Due to the limited resources, lack of time and ethical constraints full clinical information on patients was not available. It is likely that the patients will represent a full spectrum of clinical presentations. Some patients would be in the early course of the infection while others had been infected for weeks, therefore, no information on viral load immediately prior to air sampling was available. In addition, there are numerous technical difficulties associated with the recovery of influenza from the air with the potential that many additional positive air samples have been missed due to the reasons previously discussed.

Notwithstanding the constraints imposed by small numbers, our data indicate that some AGPs as defined by WHO in 2009 do

appear to be related to an increased likelihood of viral aerosol generation. The data are particularly clear for bronchoscopy and respiratory/airway suctioning. We conclude that AGPs have the potential to pose a threat of infection transmission to health care workers and that until further data are available, UK and WHO infection control policies for the use of high-filtration face pieces (respectively FFP3 and N95 respirators) during the performance of AGPs remain appropriate and should continue to be practiced according to local guidelines until more data are available.

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Author Contributions

Conceived and designed the experiments: GT AB KAT JP JVT SP PH BD. Performed the experiments: KAT BD HM SM. Analyzed the data: VC KAT JP AB JVT SO PH AB BI GT. Contributed reagents/materials/analysis tools: BD. Wrote the paper: KAT JP AB BD JVT VC SO PH AB BI GT.

References

- McDonald LC, Simor AE, Su IJ, Maloney S, Ofner M, et al. (2004) SARS in healthcare facilities, Toronto and Taiwan. *Emerging Infectious Diseases* 10: 777–781.
- Booth CM, Matukas LM, Tomlinson GA, Rachlis AR, Rose DB, et al. (2003) Clinical features and short-term outcomes of 144 patients with SARS in the greater Toronto area. *JAMA* 289: 2801–2809.
- CDC (2003) Severe acute respiratory syndrome—Taiwan, 2003. *MMWR Morb Mortal Wkly Rep* 52: 461–466.
- Tran K, Cimon K, Severn M, Pessoa-Silva CL, Conly J (2012) Aerosol Generating Procedures and Risk of Transmission of Acute Respiratory Infections to Healthcare Workers: A Systematic Review. *PLoS ONE* 7(4): e35797. doi:10.1371/journal.pone.0035797.
- Davies A, Thomson G, Walker J, Bennett AM (2009) A review of the risks and disease transmission associated with aerosol generating medical procedures. *Journal of Infection Prevention* 10: 122–126.
- Infection prevention and control of epidemic- and pandemic-prone acute respiratory diseases in health care (2007) Available: www.who.int/csr/resources/publications/WHO_CD_EPR_2007_6/en/index.html. Accessed 2012 Jan 4.
- Infection Prevention and control during health care for confirmed, probable or suspected cases of pandemic (H1N1) 2009 virus infection and influenza like illness (2009) Available: <http://www.who.int/csr/resources/publications/swineflu/swineinflinfcont/en/index.html>. Accessed 2012 Jan 4.
- Tellier R (2009) Aerosol transmission of influenza A virus: a review of new studies. *Journal of the Royal Society/Interface* 6 Suppl 6: S783–790.
- Tellier R (2006) Review of aerosol transmission of influenza A virus. *Emerging Infectious Diseases* 12: 1657–1662.
- Brankston G, Gitterman L, Hirji Z, Lemieux C, Gardam M (2007) Transmission of influenza A in human beings. *Lancet Infect Dis* 7: 257–265.
- Interim Guidance on Infection Control measures for 2009 H1N1 Influenza in healthcare Settings, Including Protection of Healthcare Personnel (2009) Available: http://www.cdc.gov/h1n1flu/guidelines_infection_control.htm. Accessed 2011 Jun 24.
- National plan “Influenza Pandemic” Nationale, S.G.D.L.D. (2009) Available: http://www.pandemie-grippale.gouv.fr/IMG/pdf/plan_PG_2009_en.pdf. Accessed 2011 Sep 12.
- Pandemic (H1N1) 2009 Influenza - A summary of guidance for infection control in healthcare settings (2009) Available: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/@ps/documents/digitalasset/dh_110899.pdf. Accessed 2012 Jan 4.
- Pandemic influenza: guidance for infection control in hospitals and primary care settings (2008) Available: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_084178. Accessed 2011 Sep 12.
- Cox CS (1987) *The Aerobiological Pathway of Microorganisms*. Chichester: John Wiley & Sons Ltd.
- May KR (1966) Multistage Liquid Impinger. *Bacteriol Rev* 30: 559–570.
- Spackman E, Senne DA, Myers TJ, Bulaga LL, Garber LP, et al. (2002) Development of a real-time reverse transcriptase PCR assay for type A influenza virus and the avian H5 and H7 hemagglutinin subtypes. *J Clin Microbiol* 40: 3256–3260.
- Hoffmann E, Stech J, Guan Y, Webster RG, Perez DR (2001) Universal primer set for the full-length amplification of all influenza A viruses. *Arch Virol* 146: 2275–2289.
- Alford RH, Kasel JA, Lehigh JR, Knight V (1967) Human responses to experimental infection with influenza A/Equi 2 virus. *Am J Epidemiol* 86: 185–192.
- Killingley B, Greatorex J, Cauchemez S, Enstone JE, Curran M, et al. (2010) Virus shedding and environmental deposition of novel A (H1N1) pandemic influenza virus: interim findings. *Health Technol Assess* 14: 237–354.
- Milton DK, Fabian MP, Angel M, Perez DR, McDevitt J (2010) Influenza Virus Aerosols In Human Exhaled Breath: Particle Size, Culturability, And Effect Of Surgical Masks. *Am J Respir Crit Care Med* 181: A6844–.
- Lindley WG, Blachere FM, Thewlis RE, Vishnu A, Davis KA, et al. (2010) Measurements of airborne influenza virus in aerosol particles from human coughs. *PLoS One* 5: e15100.
- Lindley WG, Blachere FM, Davis KA, Pearce TA, Fisher MA, et al. (2010) Distribution of airborne influenza virus and respiratory syncytial virus in an urgent care medical clinic. *Clin Infect Dis* 50: 693–698.
- Nicas M, Sun G (2006) An integrated model of infection risk in a health-care environment. *Risk Anal* 26: 1085–1096.

25. Carrat F, Vergu E, Ferguson NM, Lemaître M, Cauchemez S, et al. (2008) Time lines of infection and disease in human influenza: a review of volunteer challenge studies. *Am J Epidemiol* 167: 775–785.
26. Edwards DA, Man JC, Brand P, Katstra JP, Sommerer K, et al. (2004) Inhaling to mitigate exhaled bioaerosols. *Proc Natl Acad Sci U S A* 101: 17383–17388.
27. Fabian P, McDevitt JJ, DeHaan WH, Fung RO, Cowling BJ, et al. (2008) Influenza virus in human exhaled breath: an observational study. *PLoS One* 3: e2691.
28. Fabian P, Brain J, Houseman EA, Gern J, Milton DK (2011) Origin of exhaled breath particles from healthy and human rhinovirus-infected subjects. *J Aerosol Med Pulm Drug Deliv* 24: 137–147.
29. Almstrand AC, Bake B, Ljungstrom E, Larsson P, Bredberg A, et al. (2010) Effect of airway opening on production of exhaled particles. *J Appl Physiol* 108: 584–588.
30. Johnson GR, Morawska L, Ristovski ZD, Hargreaves M, Mengersen K, et al. (2011) Modality of human expired aerosol size distributions. *Journal of Aerosol Science* 42: 839–851.
31. To KK, Chan KH, Li IW, Tsang TY, Tse H, et al. (2010) Viral load in patients infected with pandemic H1N1 2009 influenza A virus. *J Med Virol* 82: 1–7.
32. Li IW, Hung IF, To KK, Chan KH, Wong SS, et al. (2010) The natural viral load profile of patients with pandemic 2009 influenza A(H1N1) and the effect of oseltamivir treatment. *Chest* 137: 759–768.
33. Schaffer FL, Soergel ME, Straube DC (1976) Survival of airborne influenza virus: effects of propagating host, relative humidity, and composition of spray fluids. *Arch Virol* 51: 263–273.
34. The Influenza Pandemic Preparedness Team (2011) Routes of Transmission of the Influenza Virus - Scientific Evidence Base Review. Available: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_125332.pdf. Accessed 2013 Jan 16.
35. Soderholm SC (1989) Proposed international conventions for particle size-selective sampling. *Ann Occup Hyg* 33: 301–320.
36. Hall CB, Douglas RG Jr, Geiman JM, Meagher MP (1979) Viral shedding patterns of children with influenza B infection. *J Infect Dis* 140: 610–613.
37. Teunis PF, Brienens N, Kretzschmar ME (2010) High infectivity and pathogenicity of influenza A virus via aerosol and droplet transmission. *Epidemics* 2: 215–222.
38. ISO/TS16976-1: 2007(E) Respiratory protective devices - Human factors - Part 1: Metabolic rates and respiratory flow rates.

Original Article

A quantitative evaluation of aerosol generation during tracheal intubation and extubation

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Summary

The potential aerosolised transmission of severe acute respiratory syndrome coronavirus-2 is of global concern. Airborne precaution personal protective equipment and preventative measures are universally mandated for medical procedures deemed to be aerosol generating. The implementation of these measures is having a huge impact on healthcare provision. There is currently a lack of quantitative evidence on the number and size of airborne particles produced during aerosol-generating procedures to inform risk assessments. To address this evidence gap, we conducted real-time, high-resolution environmental monitoring in ultraclean ventilation operating theatres during tracheal intubation and extubation sequences. Continuous sampling with an optical particle sizer allowed characterisation of aerosol generation within the zone between the patient and anaesthetist. Aerosol monitoring showed a very low background particle count (0.4 particles.l⁻¹) allowing resolution of transient increases in airborne particles associated with airway management. As a positive reference control, we quantitated the aerosol produced in the same setting by a volitional cough (average concentration, 732 (418) particles.l⁻¹, n = 38). Tracheal intubation including facemask ventilation produced very low quantities of aerosolised particles (average concentration, 1.4 (1.4) particles.l⁻¹, n = 14, p < 0.0001 vs. cough). Tracheal extubation, particularly when the patient coughed, produced a detectable aerosol (21 (18) l⁻¹, n = 10) which was 15-fold greater than intubation (p = 0.0004) but 35-fold less than a volitional cough (p < 0.0001). The study does not support the designation of elective tracheal intubation as an aerosol-generating procedure. Extubation generates more detectable aerosol than intubation but falls below the current criterion for designation as a high-risk aerosol-generating procedure. These novel findings from real-time aerosol detection in a routine healthcare setting provide a quantitative methodology for risk assessment that can be extended to other airway management techniques and clinical settings. They also indicate the need for reappraisal of what constitutes an aerosol-generating procedure and the associated precautions for routine anaesthetic airway management.

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Introduction

The severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) and associated coronavirus disease 2019 (COVID-19) pandemic have had an unprecedented impact on global health and the world economy. Drastic interventions to limit transmission have been introduced worldwide, such as lockdowns, physical distancing and the use of personal protective equipment (PPE). Respiratory secretions have a high SARS-CoV-2 viral load and are believed to be the main source for person-to-person transmission [1, Cevik et al., preprint: doi.org/10.1101/2020.07.25.20162107]. Coughing and sneezing atomise respiratory secretions into particles with different aerodynamic properties according to size; particles greater than 20 µm in diameter are conventionally defined as droplets and tend to follow a ballistic trajectory. These droplets can either directly contact and infect a susceptible individual within close proximity or may settle on nearby surfaces (fomites) where viable virus can exist for up to 72 h [2, 3]. This direct droplet and indirect contact transmission are considered the predominant modes of spread of SARS-CoV-2, providing the rationale for physical distancing and hand hygiene as primary measures to reduce the incidence of COVID-19.

The extent to which SARS-CoV-2 is transmitted by the airborne route is a controversial topic [3–6]. Aerosolised particles (typically considered to be < 20 µm in diameter and particularly those of < 5 µm) may transmit infection by deposition on respiratory epithelium and can potentially transit the full extent of the respiratory tract. It is also feared that these small particles may remain airborne for long periods and may be carried far from the site of origin by air currents. The risks from aerosols and optimum methods of preventing transmission are under active debate [7–10]. To minimise airborne transmission of SARS-CoV-2 to healthcare workers, specific patient care activities have been designated as aerosol-generating procedures. Tracheal intubation and extubation, manual ventilation via facemask and respiratory tract suctioning are all designated as aerosol-generating procedures [11–13]. Many organisations, including the World Health Organization and the public health bodies of the UK, have recommended that those undertaking these aerosol-generating procedures wear airborne precaution PPE consisting of a fitted face-piece (FFP3 or NR95), a long sleeved, fluid-resistant gown, gloves and eye protection [1, 13].

The quantitative evidence base for these guidelines is weak and the relative magnitude of risk for each aerosol-generating procedure is unknown [3, 11]. The evidence for this designation is largely based on retrospective cohort

and case-controlled studies of transmission during the severe acute respiratory syndrome (SARS) pandemic in 2003 [12, 14]. A systematic review of these studies concluded that tracheal intubation was associated with a significant increase in risk of disease transmission but categorised the quality of available evidence as “very low quality based on GRADE” and identified that “a significant research gap exists in the epidemiology of the risk of transmission of acute respiratory infections from patients undergoing aerosol generating procedures to healthcare workers, and clinical studies should be carefully planned to address specific questions around the risks of transmission in these settings” [12]. An attempt to provide such evidence employed aerosol sampling traps placed in the vicinity of patients with H1N1 influenza during periods of hospital care, including some with aerosol-generating procedures, but this large study did not clearly demonstrate an increased risk above background of detecting virus RNA in the air [15]. There is still no quantitative evidence of increased aerosol generation from the designated aerosol-generating procedures, which likely relates to the challenge of obtaining such measurements in routine healthcare settings.

When considering the risk of transmission of SARS-CoV-2, it is helpful to reflect on the definition of an aerosol-generating procedure that has been expressly stated as “aerosol generating procedures are considered to have a greater likelihood of producing aerosols compared to coughing.” [16]. There is a comparatively large quantitative evidence base around aerosolised particle generation by coughing from laboratory-based investigations with sizes ranging from visible droplets to submicron particles [17–20]. Given the uncertain balance of potential risks and benefits associated with the protective strategies put in place to limit viral transmission, it is important to quantitatively assess the degree to which individual aerosol-generating procedures generate aerosolised particles. In this study, we have quantitated airborne particle emission in real-time during tracheal intubation and extubation, using particle analysis instruments in a working operating theatre environment and compared this with volitional coughs as a reference.

Methods

A prospective environmental monitoring study was conducted to quantitate the airborne particle size distribution and particle number concentration produced by aerosol-generating procedures in four operating theatres in a UK hospital (North Bristol NHS Trust). Institutional Review

Board approval for the study was given by the Faculty of Life Science and Science Research Ethics Committee at the University of Bristol. As this was an observational study, the anaesthetic and theatre team undertook their normal practice during airway management. The researchers were not involved in the delivery of anaesthetic care.

Observations were made within operating theatres with an ultraclean, laminar flow ventilation system (EXFLOW 32; Howorth Air Technology, Farnworth, UK) with high efficiency particulate air (HEPA) filtration. This ventilation system has a canopy 'clean zone' where surgical procedures are performed; the air circulation velocity is 0.2 m.s^{-1} at 1 m above the floor below the canopy and produces 500–650 air changes per hour. All aerosol recordings were performed under the canopy. Air temperature in theatres was set to 20°C and humidity between 40 and 60%.

A lightweight, portable Optical Particle Sizer (TSI Incorporated, model 3330, Shoreview, NM, USA) was used which samples air at 1 l.min^{-1} and detects particles by laser optical scattering. The optical particle sizer reports the particle number concentration and size distribution within the diameter range 300 nm to $10 \mu\text{m}$ with a time resolution of 1 s. It is widely used for aerosol studies both within laboratories and clean rooms to use in more demanding applications in the outside environment. It is calibrated by the manufacturer using polystyrene latex spheres and its performance conforms to the ISO standard 21501-4:2018. A sampling funnel was 3D printed (RAISE3D Pro2 Printer, 3DGBIRE, Chorley, UK) with a maximum diameter of 150 mm, cone height of 90 mm with a 10-mm exit port. A conductive silicone sampling tube of 2 m length and internal diameter 4.8 mm (3001788, TSI) connected the sampling funnel to the optical particle sizer. This had an internal volume of 145 ml giving a transit lag between the funnel and the particle sizer (with a flow of 1 l.min^{-1}) of 8.7 s which was taken into account in the time registration of measurements.

In an initial set of pilot studies in the ultraclean theatre environment, it was possible to reliably detect a volitional cough from a subject lying supine (JB) at a sampling distance of 0.5 m from the mouth to the funnel. Sampling at 0.5 m approximates the distance from the face of the airway management practitioner to the patient's mouth during the intubation sequence. For recordings during intubation and extubation, the sampling funnel was, therefore, positioned at a distance of 0.5 m facing the patient's mouth and close to the anaesthetist (Fig. 1). For several extubations, we repositioned the funnel to lie above and behind the patient's head, again at 0.5 m and facing the patient's



Figure 1 Simulation of aerosol measurement approach within operating theatre environment. The sampling funnel was positioned 0.5 m above the source of aerosol in the airway management zone allowing a sampling stream of air (1 l.min^{-1}) to be routed to the optical particle sizer.

airway. The funnel was handheld to ensure it could be quickly removed from the airway management zone in case of clinical need (this was not needed in the course of the study). All healthcare workers, and members of the investigating team, wore airborne precaution PPE during aerosol-generating procedure measurements.

Tracheal intubation and extubation consist of a series of discrete events and procedures which we designated as sequences. For tracheal intubation measurements, anaesthetic induction followed a conventional sequence with pre-oxygenation, intravenous induction by administration of anaesthetic and neuromuscular blocking drugs, manual ventilation of the lungs via a facemask, direct laryngoscopy and intubation of the trachea followed by inflation of the tracheal tube cuff which was the reference end point of the intubation sequence. Standard anaesthetic monitoring was used including waveform capnography. This whole intubation sequence typically lasted 3–4 min with continuous aerosol monitoring throughout. The 5-min period before inflation of the tracheal tube cuff was analysed.

For recordings during tracheal extubation, the level of anaesthesia was lightened, spontaneous breathing allowed

to recommence, the oropharynx was suctioned before the tracheal tube cuff was deflated, and the trachea was then extubated according to the anaesthetist's normal practice. After extubation and confirmation of airway patency, the patient received oxygen via an anaesthetic facemask and then a Hudson™ mask. The reference point for the start of extubation was tracheal tube cuff deflation (releasing the seal on the airway). Continuous monitoring with the optical particle sizer was conducted throughout and a period of 3 min before and up to 2 min after cuff deflation was analysed.

Airway management events including cuff inflation, deflation and coughs were recorded contemporaneously by the researcher using a time stamp application (Emerald Timestamp, Emerald Sequoia LLC, <https://emeraldsequoia.com/ts/index.html>). Data were exported from the TSI optical particle sizer, processed in the TSI Aerosol Instrument Manager software, and analysed in Origin Pro (Originlab, Northampton, MA, USA) and Prism v8 (Graphpad, San Diego, CA, USA). Comparisons were made between aerosol-generating events with unpaired t-tests with the significance level set at $p < 0.05$.

Results

Environmental aerosol monitoring was conducted over a 3-week period during operating lists for orthopaedic trauma and neurosurgical emergencies. Recordings were made of 19 intubations and 14 extubations. The conduct of anaesthesia was left at the discretion of the anaesthetist, who ranged in experience from junior trainee to senior consultant. Control environmental monitoring recordings showed the ultraclean, laminar flow ventilation and air filtration system produced a very low background of aerosol particles averaging 0.4 l^{-1} when the theatre was empty, and 3.4 l^{-1} when the theatre was in use but no aerosol-generating procedures were in progress. Thirty-eight volitional coughs were sampled at 0.5-m distance. These coughs showed a characteristic profile with a rapid and transient spike of expectorated particles (Fig. 2a). Peak aerosol concentration occurred 2 s after the cough was registered and averaged $1310 (905) \text{ particles.l}^{-1}$. The spike in aerosol particle count decayed back to baseline with a time constant of approximately 2.7 s. Each cough contained an average of 134 (77) detected airborne particles (over the 12 s window). The large majority of the particles were $< 1 \mu\text{m}$ diameter (Fig. 2d). Although we conducted our monitoring under the ultraclean ventilation canopy, the temporary suspension of the laminar flow system (0.2 m.s^{-1}) did not alter the number of particles detected

per cough: 164 (80) with ventilation on vs. 153 (82) with ventilation off ($p = 0.77$, $n = 9$ per group).

All tracheal intubation sequences included manual facemask ventilation and three also required repeated attempts at laryngoscopy/intubation. The mean (SD) number of particles detected in a 5-min period during anaesthetic induction and intubation was 7 (6) ($n = 14$), compared with a background in the empty theatre of approximately two particles per 5-min period (Fig. 2b). The average concentration of particles recorded during the intubation period ($1.4 (1.4) \text{ l}^{-1}$, $n = 14$) was 500-fold lower than the mean (SD) concentration recorded during volitional coughs ($732 (418) \text{ particles.l}^{-1}$, $n = 38$, $p < 0.0001$). Similarly, the maximum concentration recorded during intubation averaged across events ($77 (49) \text{ particles.l}^{-1}$, $n = 14$) was 22-fold lower than that seen with volitional coughs ($1688 (872)$, $n = 38$, $p < 0.0001$). An equivalent series of aerosol measurements during tracheal intubation with laminar flow ventilation suspended produced a similar particle count to that seen in the presence of flow (6 (2) particles with flow off, $n = 5$, $p = 0.65$ vs. flow on).

Extubation produced a mean (SD) concentration of aerosolised particles of $21 (18) \text{ l}^{-1}$ ($n = 10$, Fig. 2c) which was 35-fold lower than that seen during a volitional cough ($p < 0.0001$) but 15-fold greater than that seen during intubation ($p = 0.0004$). The maximum concentration recorded during extubation averaged across events ($432 (209) \text{ particles.l}^{-1}$, $n = 10$) was lower than that seen with volitional coughs ($1688 (872)$, $n = 38$, $p < 0.0001$). The average total number of particles detected during the period of extubation was 100 (85). This is similar to that detected during a single volitional cough, although sampling during extubation summed particles produced over 5 min and each cough over 12 s. During four of the ten extubations, the patient coughed at least once (typically after tube removal) (Fig. 2c). These extubation coughs produced aerosolised particles of a similar size distribution to the reference coughs (Fig. 2d) but were always smaller in magnitude than the average volitional cough and, on average, produced only a quarter of the number of particles: 33 (10) (from a total of five coughs during four extubations, Fig. 2e). Because the usual position for the anaesthetist during extubation is to stand above and behind the patient, who is typically semi-recumbent, a further set of aerosol recordings were made with the particle collector located in that position (0.5 m away and still facing towards the patient). Aerosol monitoring from that position during extubation (three with cough events) greatly decreased the concentration of detected airborne particles to close to background levels seen in an active theatre ($3.7 (5.9) \text{ l}^{-1}$).

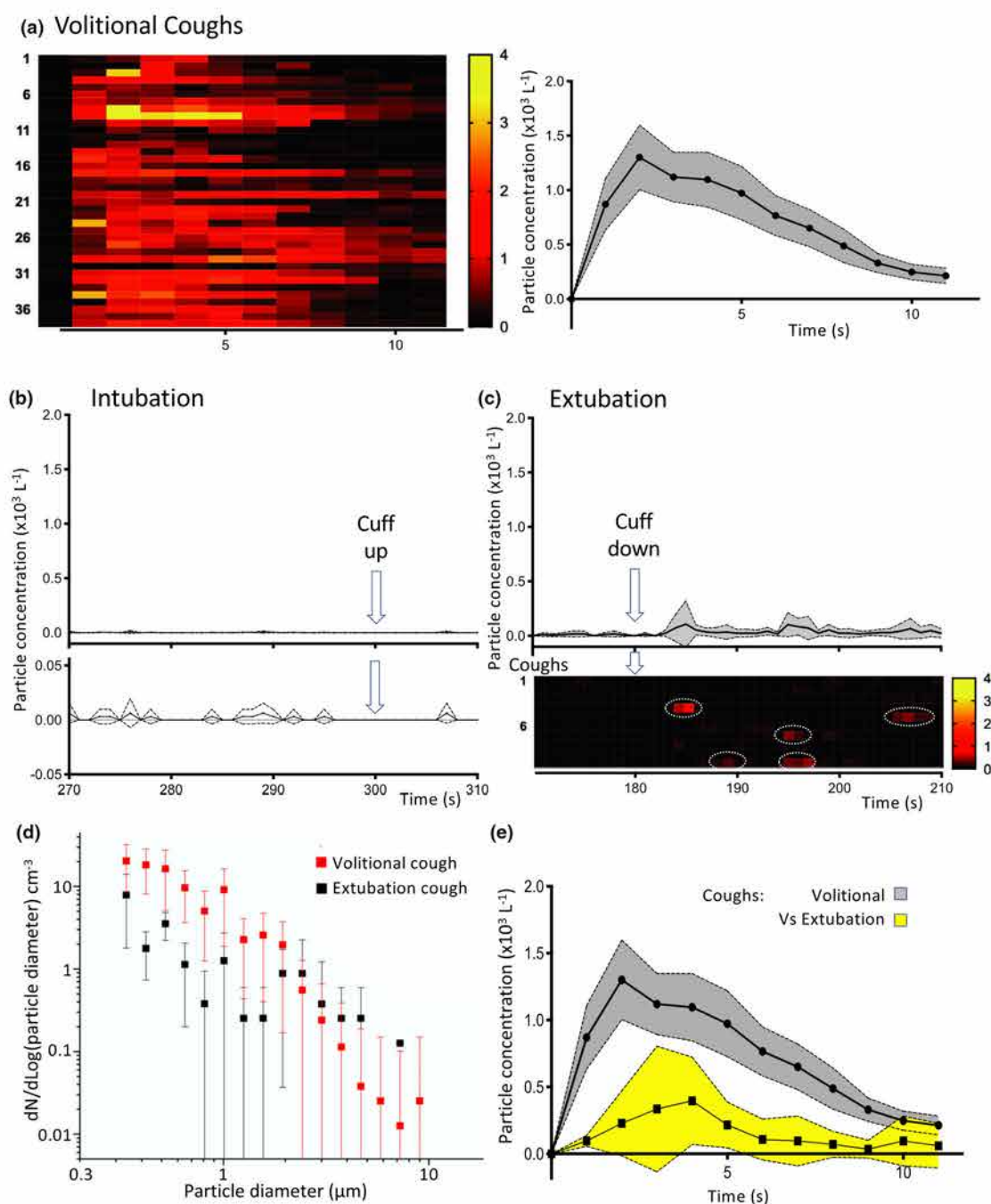


Figure 2 Aerosol measurements during intubation and extubation in operating theatre environment. (a) Temporal profile of aerosol generation from volitional coughs. Individual recordings ($n = 38$) represented on heat map showing the total number particle concentration over time. Average time course plotted (mean with 95%CI) showing a peak after 2 s and a rapid decay back to baseline. (b) Profile of the total number concentration of aerosol detected during the critical phase of intubation (arrow at 300 s marks completion of intubation with cuff up). When plotted on the same scale as the cough (b) then this looks essentially flat and when shown on a ten-fold expanded scale below it can be seen that it is not significantly different to baseline as the confidence intervals always span zero (mean $\pm$ 95%CI). (c) Extubation recordings from each patient ($n = 10$) plotted as the average and individually as rows on heat map of number concentration of particles (lower, on same scale as b). This showed sporadic aerosol events (red, ringed) after cuff deflation set on a low baseline level of particles. The average concentration of aerosol shown above was low overall (mean $\pm$ 95%CI). (d) The extubation cough events ($n = 5$) had a similar aerosol particle size distribution to volitional coughs with a predominance of diameters < 1 μm (mean $\pm$ SD). (e) The extubation coughs were of a smaller magnitude than the volitional coughs (particle number concentration profile shown overlaid, mean $\pm$ 95%CI).

Discussion

We conducted aerosol sampling in an ultraclean operating theatre environment during routine clinical practice enabling quantitative measurement of aerosols produced by tracheal intubation and extubation. Using the quantity and concentration of aerosolised particles generated by volitional coughs as a reference, we have shown that both intubation and extubation sequences produce less aerosol than voluntary coughing. For the sequence of tracheal intubation, in particular, the concentration of aerosol generated is several orders of magnitude less than a single cough and is only very modestly above background levels of circulating particles in an ultraclean theatre. These findings demonstrate that the process of tracheal intubation is associated with a very low risk of aerosol generation.

Standard anaesthetic induction and intubation sequences are designed to obtund airway reflexes and the use of a neuromuscular blocking drug ensures that the anaesthetised patient can neither breathe nor cough. Of note, we detected no increases in aerosolised particles above the patient's face during anaesthesia, facemask ventilation, airway suction and, on occasion, several repeated attempts at intubation. This reflects typical clinical practice by anaesthetists with a range of experience, providing further reassurance regarding the low level of aerosol generation.

A more nuanced picture is seen during the tracheal extubation sequence where aerosol concentration was greater than that seen with intubation but substantially less than a single cough. The total number of expectorated airborne particles (over a 5-min period) was similar to a single volitional cough. Indeed, a cough event was noted clinically in 50% of extubations and this was frequently detected as an aerosol spike. These extubation coughs produced a similar particle size distribution but there were fewer airborne particles than with volitional coughs (approximately 25%). Extubation cough aerosol was also transient and only detectable for approximately 5 s. Therefore, it would appear that aerosol generation during extubation with a cough is quantitatively different from extubation without a cough. Although a cough at extubation may be interpreted as a positive sign signalling the return of protective airway reflexes, it is likely to increase the risk of aerosolised particle generation. Therefore, mitigation strategies should be considered to reduce the risk of coughing and exposure to aerosols. As sampling showed much reduced particle numbers behind the patient's head compared with above their airway, clinician exposure could be reduced by the simple expedient of standing behind the

patient's head (as is conventional) and, thus, out of the direct stream of any potential cough plume. Coughing on extubation could also be minimised by modifying the anaesthetic technique in higher risk patients [21].

The combination of monitoring within an ultraclean ventilation theatre and the use of a highly sensitive optical particle sampler has afforded sufficient resolution to quantitate aerosol generation in real time during anaesthetic delivery. To put this in context, it is worth noting that we are unaware of any previous recording of aerosol generated even by coughing in a routine healthcare environment as this normally requires highly specialised and controlled laboratory conditions [17–20]. The ultraclean laminar flow ventilation system theatre had a very low level of airborne particles (0.4 l^{-1}); in comparison the baseline aerosolised particle concentration in a nearby non-laminar theatre was more than 3 orders of magnitude higher ($15 \times 10^3 \text{ l}^{-1}$), which would have precluded detection of aerosols generated either by tracheal intubation or extubation (and perhaps even a cough). To assess the impact of the laminar flow on our observations, we undertook measurements with the ultraclean theatre ventilation on and off both for coughing and for tracheal intubation and these did not differ. This demonstrates that the low aerosol particle counts were not secondary to immediate aerosol clearance by high laminar ventilation flows. Although we did not assess the impact of ventilation flow on the aerosol generated during extubation (because of the pragmatic issue of turning off the ventilation while the case is in theatre and the perceived need to disperse any accumulated aerosol) we have no reason to believe, based on the cough and intubation measurements, that the presence of laminar flow has materially influenced these extubation measurements.

There are a number of limitations to the study and these include a relatively small number of observations, the use of pragmatic design without control over the specific anaesthetic administered or the grade of practitioner and sampling aerosol from a limited arc encompassed by the funnel. The reference coughs were from a single subject (one of the investigators), but data from another study (Brown et al., unpublished data) indicate that they were not outliers when compared with other healthy subjects. Additionally, we have made no measurements from subjects known to have COVID-19 or other intercurrent respiratory comorbidity, which would be an important area for investigation, although challenging to conduct. The measurements were taken during anaesthesia for patients receiving urgent orthopaedic and neurosurgical interventions

and may not be generalisable to intubations in a critical care/emergency setting that may be conducted in extremis.

Importantly, it should be acknowledged that we are unable to make any conclusion about the risk of actual SARS-CoV-2 transmission as aerosol generation is still only a presumed risk-factor and particle number concentration is a plausible but unproven surrogate measure of that infection risk. We have presented our data as mean particle concentration during the event, maximum concentration recorded during the epoch and total numbers of detected airborne particles and note that there is no available evidence to indicate which measure will prove to be the best surrogate measure of infection risk [3]. Other dimensions that are likely to be important are the size distribution of the aerosolised particles (which influences their airborne transport and ability to be carried into the respiratory tract), the total volume of expectorate (which can be derived if assumptions about sphericity and composition are made) and the concentration of live virions within the particles (not measured here). Each measure has limitations, but we consider that the average concentration over time gives the best estimate of the relative exposure smoothed over the at-risk period during which particles may be inhaled or deposited on mucous membranes. We note that the peak concentration is likely to overestimate the risk; for example, a single particle detected in a 1-s time bin during an intubation sequence (5-min period of recording) would correspond to a maximum of 60 particles. l^{-1} (with 1 $\text{l}\cdot\text{min}^{-1}$ air flow through the particle detector). However, this is probably better represented as the average concentration of 0.2 particles. l^{-1} when assessing the relative risk over time, reflecting the fact that no particles are detected for 299 of the 300 s recording period. Notwithstanding these considerations, we believe that our aerosol measurements constitute a valuable quantitative dataset and we note that the methodology could be applied to other anaesthetic airway management techniques and designated aerosol-generating procedures to extend the relative risk ranking.

Our results for the risk of aerosol generation associated with tracheal intubation are at odds with previous retrospective evidence that was used to designate intubation in an aerosol-generating procedure [12, 14]. These studies found an association between acquiring SARS and being in the room during intubation but without any measure of aerosol generation. It is difficult to directly compare these two sources of evidence: in our study, all patients received a controlled anaesthetic induction that included a neuromuscular blocking drug. Conversely, during the SARS epidemic patients were unwell, may have been coughing during the intubation sequence and it is

likely that viral secretion was at peak levels at the point of initiating intensive care management (which is not the case for COVID-19 Cevik et al., preprint: doi.org/10.1101/2020.07.25.20162107). It is equally plausible that other mechanisms of transmission, such as direct exposure to respiratory secretions or fomites or association between those who undertook tracheal intubation and performance of other high-risk activities, could have contributed to the spread of SARS.

By the definition noted earlier, aerosol-generating procedures are considered to have a greater likelihood of producing aerosols compared with coughing [16]. Our study indicates that the process of elective tracheal intubation produces a barely recordable increase in aerosol and, consequently, should not be designated as an aerosol-generating procedure. When a patient coughs during tracheal extubation, a measurable particle plume is produced but the aerosol is still smaller than a single volitional cough. These relative risks of aerosol generation need to be balanced against the knowledge that the use of airborne precaution PPE has substantial impact on clinical practice. Additionally, methods introduced to mitigate the risks posed by bio-aerosols have reduced operating theatre turnover, decreased hospital productivity and increased waiting times for elective and cancer surgery. A further important consideration relates to the cost and limited supply of PPE which has to be targeted to appropriate healthcare settings on the basis of risk. These results, therefore, should help inform future airborne prevention PPE guidelines by providing evidence on the relative risk of aerosol generation associated with tracheal intubation and extubation.

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References

1. Cook TM. Personal protective equipment during the coronavirus disease (COVID) 2019 pandemic – a narrative review. *Anaesthesia* 2020; **75**: 920–7.
2. van Doremalen N, Bushmaker T, Morris DH, et al. Aerosol and surface stability of SARS-CoV-2 as compared with SARS-CoV-1. *New England Journal of Medicine* 2020; **382**: 1564–7.
3. Wilson NM, Norton A, Young FP, Collins DW. Airborne transmission of severe acute respiratory syndrome coronavirus-2 to healthcare workers: a narrative review. *Anaesthesia* 2020; **75**: 1086–95.
4. Miller SL, Nazaroff WW, Jimenez JL, et al. Transmission of SARS-CoV-2 by inhalation of respiratory aerosol in the Skagit Valley

- Chorale superspreading event. *Indoor Air* 2020. Epub 26 September. doi.org/10.1111/ina.12751
5. Morawska L, Milton DK. It is time to address airborne transmission of COVID-19. *Clinical Infectious Diseases* 2020. Epub 7 July. <https://doi.org/10.1093/cid/ciaa939>.
 6. Schutzer-Weissmann J, Magee DJ, Farquhar-Smith P. Severe acute respiratory syndrome coronavirus 2 infection risk during elective peri-operative care: a narrative review. *Anaesthesia* 2020. Epub 11 July. <https://doi.org/10.1111/anae.15221>.
 7. Asadi S, Bouvier N, Wexler AS, Ristenpart WD. The coronavirus pandemic and aerosols: does COVID-19 transmit via expiratory particles? *Aerosol Science and Technology* 2020. Epub 3 April. <https://doi.org/10.1080/02786826.2020.1749229>
 8. Jayaweera M, Perera H, Gunawardana B, Manatunge J. Transmission of COVID-19 virus by droplets and aerosols: a critical review on the unresolved dichotomy. *Environmental Research* 2020. Epub 13 June. <https://doi.org/10.1016/j.envres.2020.109819>.
 9. Liu Y, Ning Z, Chen Y, et al. Aerodynamic analysis of SARS-CoV-2 in two Wuhan hospitals. *Nature* 2020; **582**: 557–60.
 10. Zhang R, Li Y, Zhang AL, Wang Y, Molina MJ. Identifying airborne transmission as the dominant route for the spread of COVID-19. *Proceedings of the National Academy of Sciences of the United States of America* 2020; **117**: 14857–63.
 11. NHS National Services Scotland and Health Protection Scotland. Aerosol Generating Procedures (AGPs). 2020. <http://www.nipcm.hps.scot.nhs.uk/web-resources-container/transmission-based-precautions-literature-review-aerosol-generating-procedures> (accessed 08/09/2020).
 12. Tran K, Cimon K, Severn M, Pessoa-Silva CL, Conly J. Aerosol generating procedures and risk of transmission of acute respiratory infections to healthcare workers: a systematic review. *PLoS One* 2012; **7**: e35797.
 13. Public Health England. COVID-19: personal protective equipment use for aerosol generating procedures. 2020. <https://www.gov.uk/government/publications/covid-19-personal-protective-equipment-use-for-aerosol-generating-procedures> (accessed 08/09/2020).
 14. Davies A, Thomson G, Walker J, Bennett A. A review of the risks and disease transmission associated with aerosol generating medical procedures. *Journal of Infection Prevention* 2009; **10**: 122–6.
 15. Thompson KA, Pappachan JV, Bennett AM, et al. Influenza aerosols in UK hospitals during the H1N1 (2009) pandemic – the risk of aerosol generation during medical procedures. *PLoS One* 2013; **8**: e56278.
 16. Public Health England. Infection control precautions to minimise transmission of acute respiratory tract infections in healthcare settings. 2016. <https://www.gov.uk/government/publications/respiratory-tract-infections-infection-control> (accessed 08/09/2020).
 17. Stelzer-Braid S, Oliver BG, Blazey AJ, et al. Exhalation of respiratory viruses by breathing, coughing, and talking. *Journal of Medical Virology* 2009; **81**: 1674–9.
 18. Yang S, Lee GW, Chen CM, Wu CC, Yu KP. The size and concentration of droplets generated by coughing in human subjects. *Journal of Aerosol Medicine* 2007; **20**: 484–94.
 19. Johnson GR, Morawska L, Ristovski ZD, et al. Modality of human expired aerosol size distributions. *Journal of Aerosol Science* 2011; **42**: 839–51.
 20. Zayas G, Chiang MC, Wong E, et al. Cough aerosol in healthy participants: fundamental knowledge to optimize droplet-spread infectious respiratory disease management. *BMC Pulmonary Medicine* 2012; **12**: 11.
 21. Tung A, Fergusson NA, Ng N, Hu V, Dormuth C, Griesdale DEG. Medications to reduce emergence coughing after general anaesthesia with tracheal intubation: a systematic review and network meta-analysis. *British Journal of Anaesthesia* 2020; **124**: 480–495. <https://doi.org/10.1016/j.bja.2019.12.041>.



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How can airborne transmission of COVID-19 indoors be minimised?



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ABSTRACT

During the rapid rise in COVID-19 illnesses and deaths globally, and notwithstanding recommended precautions, questions are voiced about routes of transmission for this pandemic disease. Inhaling small airborne droplets is probable as a third route of infection, in addition to more widely recognized transmission via larger respiratory droplets and direct contact with infected people or contaminated surfaces. While uncertainties remain regarding the relative contributions of the different transmission pathways, we argue that existing evidence is sufficiently strong to warrant engineering controls targeting airborne transmission as part of an overall strategy to limit infection risk indoors. Appropriate building engineering controls include sufficient and effective ventilation, possibly enhanced by particle filtration and air disinfection, avoiding air recirculation and avoiding overcrowding. Often, such measures can be easily implemented and without much cost, but if only they are recognised as significant in contributing to infection control goals. We believe that the use of engineering controls in public buildings, including hospitals, shops, offices, schools, kindergartens, libraries, restaurants, cruise ships, elevators, conference rooms or public transport, in parallel with effective application of other controls (including isolation and quarantine, social distancing and hand hygiene), would be an additional important measure globally to reduce the likelihood of transmission and thereby protect healthcare workers, patients and the general public.

1. Recognising the potential for the airborne transmission of SARS-CoV-2

The significance of viral transmission via small airborne micro-droplets (also commonly referred to as ‘aerosols’) has been intensely discussed in the context of the SARS-CoV-2/COVID-19 (severe acute respiratory syndrome coronavirus-2/coronavirus disease 2019) pandemic (Lewis, 2020; Morawska and Cao, 2020). This is one of three commonly accepted modes of viral transmission, the other two being via larger respiratory droplets (which fall close to where they are expired), and direct contact with contaminated surfaces (fomites). Especially with the ongoing global shortage of personal protective equipment (mainly surgical masks and N95/FFP2/FFP3 respirators) (WHO, 2020c), additional methods to reduce the risk of SARS-CoV-2 transmission indoors need to be considered. The need is acute in particular in hospitals and other healthcare facilities managing COVID-19 patients.

While evidence for airborne transmission of COVID-19 is currently incomplete, several hospital-based studies have performed air-sampling for SARS-CoV-2, including one published paper (Ong et al., 2020), one early-release paper (Guo et al., 2020) and 5 papers still in pre-print at the time of writing (Chia et al., 2020; Ding et al., 2020; Jiang et al., 2019; Liu et al., 2020; Santarpia et al., 2020). Four of these studies found several positive samples for SARS-CoV-2 genome (RNA) in air using polymerase chain reaction (PCR) testing (Chia et al., 2020; Jiang et al., 2019; Liu et al., 2020; Santarpia et al., 2020), two found very small numbers of positive samples (Ding et al., 2020), and only one (Ong et al., 2020) found no positive air samples. This evidence at least demonstrates a *potential* risk for airborne transmission of SARS-CoV-2.

In addition, amongst these studies, three also reported some quantitative viral RNA data. The Singaporean study found positive air samples in 2 of the 3 patient infection isolation rooms, with samples in

the 1–4 μm and $> 4 \mu\text{m}$ size ranges containing a range of viral loads (1.8–3.4 viral RNA copies per L of air) (Chia et al., 2020). The study from Nebraska, USA found that 63% of the air samples were positive with a mean viral load of 2.9 copies/L, including in patient rooms and the hallway air (Santarpia et al., 2020). In one case, they sampled close to the patient (mean: 4.1 copies/L) and at $> 1.8 \text{ m}$ (mean: 2.5 copies/L), suggesting some dilution with distance. The highest viral loads were found in personal samplers worn by the sampling team when in the presence of a patient receiving oxygen via nasal cannula (mean: 19 and 48 copies/L), indicating that this treatment may promote the spread of airborne virus. A study in Wuhan, China (Liu et al., 2020) provides quantitative data for their small number of positive air samples, with 0.02 RNA copies/L in a toilet area and 0.02–0.04 copies/L in a room used to remove PPE. More than half the viral RNA in these samples was associated with aerosols $< 2.5 \mu\text{m}$. This study also measured deposition through passive aerosol sampling, reporting deposition rates of 31 and 113 RNA copies/ m^2 per h at samplers located approximately 2 m and 3 m from the patients, respectively (Liu et al., 2020).

Whilst this evidence may be deemed to be incomplete at present, more will arise as the COVID-19 pandemic continues. In contrast, the end-stage pathway to infection of the droplet and contact transmission routes has always been assumed to be via self-inoculation into mucous membranes (of the eyes, nose and mouth). Surprisingly, no direct confirmatory evidence of this phenomenon has been reported, e.g. where there have been: (i) follow-up of fomite or droplet-contaminated fingers of a host, self-inoculated to the mucous membranes to cause infection, through the related disease incubation period, to the development of disease, and (ii) followed by diagnostic sampling, detection, sequencing and phylogenetic analysis of that pathogen genome to then match the sample pathogen sequence back to that in the original fomite or droplet. It is scientifically incongruous that the level of evidence

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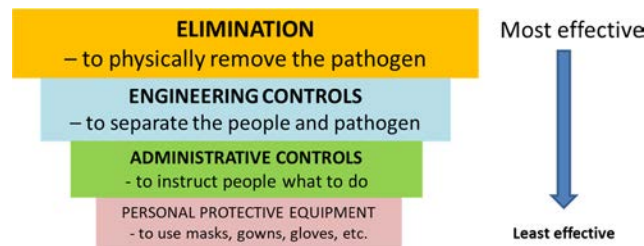


Fig. 1. Traditional infection control pyramid adapted from the US Centers for Disease Control (CDC, 2015).

required to demonstrate airborne transmission is so much higher than for these other transmission modes (Morawska et al., 2020).

The infectious agents of several other diseases (tuberculosis, measles, chickenpox) are recognised to be transmissible via the airborne route, either by the short-range (face-to-face, conversational exposure) or by longer-range aerosols (Department of Health, 2015; Tellier et al., 2019). Measles and varicella zoster (the virus causing chickenpox) can also be efficiently transmitted through direct contact during their acute phase of infection (e.g. by kissing). During a close contact situation, all transmission routes can be potentially responsible for infection.

For other respiratory viruses, including SARS-CoV, MERS-CoV (Middle-East Respiratory Syndrome coronavirus), respiratory syncytial virus (RSV – a common cause of bronchiolitis in infants) and influenza, both short-range and longer-range airborne transmission are possible, but the predominance of longer range transmission route in various exposure scenarios is difficult to quantify (Booth et al., 2013; Kim et al., 2016; Kulkarni et al., 2016; Li et al., 2007; Tellier et al., 2019), and may at times be opportunistic (Roy and Milton, 2004).

A recent mechanistic modelling study showed that short-range airborne transmission dominates exposure during close contact (Chen et al., 2020). Other studies investigating the transport of human-expired microdroplets and airflow patterns between people also provide substantive support for this transmission route (Ai et al., 2019; Li et al., 2007; Liu et al., 2017). Therefore, in light of this body of evidence for these other respiratory viruses; we believe that SARS-CoV-2 should not be treated any differently – with at least the potential for airborne transmission indoors.

Yet despite this, international health organisations, like the WHO (World Health Organization) (WHO, 2020b), continue to place insufficient emphasis on protection from small, virus laden, airborne droplets. Other organisations that deal with building environmental control systems, such as REHVA (the Federation of European Heating, Ventilation and Air Conditioning Associations) and ASHRAE (the American Society of Heating, Ventilating, and Air-Conditioning Engineers), have acknowledged the potential airborne hazard indoors and recommended ventilation control measures accordingly (ASHRAE, 2020a; REHVA, 2020).

Infection control specialists also often inquire about the relative contribution of airborne transmission compared to the other transmission modes ('contact' and 'droplet'). Multiple studies provide strong evidence for indoor airborne transmission of viruses, particularly in crowded, poorly ventilated environments (Coleman et al., 2018; Distasio et al., 1990; Knibbs et al., 2012; Li et al., 2005; Moser et al., 1979; Nishiura et al., 2020). However, it is generally difficult to quantitatively compare and conclude which transmission route is the most significant in a given situation. Infection may occur via all routes to different degrees depending on the specific exposure circumstances. Effective infection control necessitates protection against all potentially important exposure pathways.

Here, in the face of such uncertainty, we argue that the benefits of an effective ventilation system, possibly enhanced by particle filtration and air disinfection, for contributing to an overall reduction in the indoor airborne infection risk, are obvious (Eames et al., 2009).

2. Engineering controls to reduce the potential airborne transmission of SARS-CoV-2

To maximise protection of the population against the airborne spread of SARS-CoV-2 and any other airborne virus-containing small microdroplets, several recommendations are necessary as presented below. These focus on indoor environments, because this is where most transmission occurs (Nishiura et al., 2020). Further, the measures mostly apply to public buildings. In residential houses and apartments, normal practices (e.g. segregating infected individuals, opening windows and doors, and using portable air-cleaning devices when practical) to ensure healthy indoor air, should stay in place at any moment.

Ventilation airborne protection measures which already exist can be easily enhanced at a relatively low cost to reduce the number of infections and consequently to save lives. The options discussed below should always be implemented in combination with other existing measures (like hand-washing and use of PPE) to reduce infection via other important routes of transmission, as none of them can be completely excluded in any exposure event. The remainder of this article will only cover recommendations for 'engineering level' controls, as described in the traditional infection control hierarchy (Fig. 1) to reduce the environmental risks for airborne transmission.

2.1. Ventilation should be recognised as a means to reduce airborne transmission

Ventilation is the process of providing outdoor air to a space or building by natural or mechanical means (ISO, 2017). It controls how quickly room air is removed and replaced over a period of time. In some cases, it is necessary to remove pollution from outdoor air before bringing it into a building, by using adequate filtration systems. Ventilation plays a critical role in removing exhaled virus-laden air, thus lowering the overall concentration and therefore any subsequent dose inhaled by the occupants.

Appropriate distribution of ventilation (e.g. placement of supply and exhaust vents) ensures that adequate dilution is achieved where and when needed, avoiding the build-up of viral contamination (Melikov, 2011, 2016; Thatiparti et al., 2016, 2017). The central guiding principle is to replace contaminated air with clean air, but sometimes local barriers to this process may occur, e.g. where partitions are used or curtains drawn for privacy or medical procedures. If these barriers are in use, secondary or auxiliary measures may be needed to achieve requisite ventilation effectiveness.

Good ventilation practices are already in place in many hospital settings, as part of everyday and emergency measures to protect against droplet and contact transmission (Phiri, 2014). Good ventilation also protects the occupants against airborne transmission. The capacity to increase ventilation rates when needed (such as during the COVID-19 pandemic) may differ, and may be somewhat limited by their original design specifications and implementation.

Note that many hospitals are naturally ventilated in ward areas, including in some rooms used for critical care. However, if the airflow passage is obstructed (e.g. by closing windows and doors), airborne pathogen concentration can sharply rise leading to an increased risk of

airborne transmission and infection (Gilkeson et al., 2013). Natural ventilation concepts apply to healthcare facilities in both developed and resource-limited countries in favourable climatic conditions. The design, operation and maintenance of naturally ventilated facilities is not straightforward, and comprehensive guidance is available (WHO, 2009). For instance WHO in March, (WHO, 2020a) specifies that in a COVID-19 infective ward at least 160 L/s/patient have to be provided if natural ventilation is used.

We have recently seen the creation of very large emergency hospital wards, within exhibition centres for example, which house hundreds or even thousands of patients (MSN, 2020). Although these facilities will have mechanical ventilation that is adequate for normal exhibition or conference use, it is not clear if sufficient ventilation will be available for patient management and infection control purposes when they are adapted for such purposes, as during the COVID-19 pandemic.

The situation can be worse in public buildings and other shared spaces, such as shops, offices, schools, kindergartens, libraries, restaurants, cruise ships, elevators, conference rooms or public transport, where ventilation systems can range from purpose-designed mechanical systems to simply relying on open doors and windows. In most of these environments, ventilation rates are significantly lower than in hospitals for various reasons, including limiting airflows for energy and cost savings.

Hence, in such environments, with lower ventilation rates intended primarily to control indoor air quality (which may also include some hospital emergency, acute admissions, general ward and clinic areas) (Booth et al., 2013; Jo et al., 2019; Kulkarni et al., 2016; Rule et al., 2018; Sornboot et al., 2019), the likelihood of infected persons sharing air with susceptible occupants is high, posing an infection risk contributing to the spread of the infectious disease.

Various studies have been performed on the survival of airborne pathogens (Brown et al., 2015; Kim et al., 2016; Kormuth et al., 2018; Kulkarni et al., 2016; Marr et al., 2019; Pyankov et al., 2018; Tang 2009). The SARS-CoV-2 virus has been shown to be stable in airborne particles with a half-life of more than one hour (van Doremalen et al., 2020), so it can potentially be inhaled by susceptible individuals causing infection and further spreading of the disease.

As 'stay-at-home' lockdown measures are gradually relaxed, much of the population may return to spending increasing amounts of time in inadequately ventilated workplaces, offices, schools and other public buildings, where they may be exposed to a risk of acquiring viral infections by inhalation.

2.2. Ventilation rates should be increased by system modifications.

In a mechanically ventilated building, ventilation air is typically provided by a heating, ventilating and air conditioning (HVAC) system. Sometimes, ventilation air is provided by dedicated fans or outdoor air units.

HVAC system control strategies can usually be modified to increase ventilation to a certain extent in the occupied zones, with relatively little additional cost, to reduce the risks of airborne transmission between occupants. However, this is not via a simple 'flip of a switch', as HVAC systems are complex and usually designed for individual buildings within standard specific operating parameters. Many requirements need to be considered apart from the ventilation rate, including control of temperature, relative humidity, air flow distribution and direction.

Such systems can be specifically customised as needed by HVAC engineers, e.g. to reduce the risks of airborne transmission. Indeed, the ventilation guidance of ASHRAE (The American Society of Heating, Refrigerating, and Air-conditioning Engineers), REHVA, SHASE (The Society of Heating, Air-Conditioning and Sanitary Engineers of Japan) have all just been updated to address the spread of COVID-19 (ASHRAE, 2020b; REHVA, 2020; SHASE, 2020). Another example is the modification of a hospital ward ventilation system to create a negative pressure isolation ward (Miller et al., 2017).

If ventilation is provided using windows openings (aeration) or other means (fixed openings, e.g., natural ventilation), an estimation of the possible outdoor flow rate can be made using CEN Standard, EN 16798-7:2017 (CEN, 2017), or other available references as (AIVC, 1996; CIBSE, 2005). The outdoor air flow rate that is achieved is strongly dependent on the specific local conditions (opening sizes, relative positions, climatic and weather conditions, etc.) and should be estimated case by case; it can easily range from 2 up to 50 ACH or more.

For naturally ventilated public buildings, particularly in cold climates, other challenges will arise, but these can also be addressed in order to reduce the risk of airborne infection transmission. It may be necessary to provide additional heating in some buildings to maintain thermal comfort, particularly where the occupants are vulnerable.

2.3. Avoid air recirculation

The recirculation of air is a measure for saving energy, but care must be taken, as it can transport airborne contaminants (including infectious viruses) from one space and distribute them to other spaces connected to the same system, potentially increasing the risk of airborne infection in areas that otherwise would not have been contaminated. This concern has been noted previously in regard to the possible recirculation of biological agents during terrorist attacks that have investigated the effectiveness of eliminating recirculation (e.g. providing 100% outside air to spaces and exhausting all of it) as a countermeasure following an indoor release of the agent (Persily et al., 2007). A study modelling the risk of airborne influenza transmission in passenger cars provided also a case against air recirculation in such situations (Knibbs et al., 2012).

Particulate filters and disinfection equipment in recirculated air streams can reduce this risk, but they need to be purposely designed to control risk of airborne infection and need regular service to maintain their effectiveness. Many systems are designed for filters that are intended to remove larger particles that may affect the functioning of equipment and that are not effective at removing small, sub micrometre or micrometre size particles associated with adverse health effects. Filter ratings by test methods, such as ASHRAE Standard 52.2 (ASHRAE, 2017) that give an indication of performance as a function of particle size should be utilized in choosing appropriate filters.

Following the above considerations, during an epidemic, including the current COVID-19 pandemic, air should not be recirculated as far as practically possible, to avoid the dissemination of virus-laden particles throughout the indoor environment. For central air handling units at a building level or serving multiple zones, recirculation should be avoided, and the system operated on 100% outdoor air (OA) if possible. Disabling recirculation can be achieved by closing the recirculation dampers and opening outdoor air dampers. In systems where it is not possible, one should try to maximize the OA-level and apply filtering or ultraviolet germicidal irradiation to remove or deactivate potential viral contamination from the recirculated air. In many health care settings, air recirculation is, in most cases not allowed at all, though though recirculation is commonly used in non-hospital settings for improving energy efficiency. At a room (decentral) level, secondary air circulation systems may be installed. One needs to assure that any of such systems also provides ventilation with outdoor air (e.g., induction units). If this is the case, such a system should not be switched off. Other systems, which do not have this feature (e.g., split air-conditioning units) should if possible be turned off, to avoid potential transfer of virus through air flows between people. When such a system is needed for cooling then additional ventilation with outdoor air should be secured by regular/periodic ventilation through, e.g., window opening.

2.4. Air cleaning and disinfection devices may be beneficial

In environments where it is difficult to improve ventilation, the addition of local air cleaning or disinfection devices, such as germicidal

ultraviolet (GUV, or UVGI - ultraviolet germicidal irradiation) may offer benefits. Under laboratory conditions GUV has been shown to be effective against a suite of microorganisms including coronaviruses (Walker and Ko, 2007), vaccinia (McDevitt et al., 2007) and *Mycobacteria* (Xu et al., 2003), and even influenza (McDevitt et al., 2012; McLean 1961). Several studies show that inactivation decreases with increased humidity for both bacterial (Xu et al., 2005) and viral aerosols (McDevitt et al., 2012). Darnell et al. (2004) showed that SARS-CoV-1 could be inactivated by UV-C, while Bedell et al. (2016) showed a UV-C decontamination device could inactivate MERS-CoV at 1.22 m, with almost a 6 log reduction in 5 min. There is no data yet for SARS-CoV-2, but the data for other coronaviruses suggest it is highly likely that it is susceptible to UV-C.

One application that grew dramatically during the multi-drug resistant tuberculosis outbreaks of the 1980s (Young and Wormser, 1994), is the 'upper-room' system in which lamps are placed in the upper part of the room, either on the walls or mounted on the ceiling, directing the UV light into the upper zone with louvers and limiting UV exposure in the occupied space (Xu et al., 2005, 2003). Upper-room GUV is a good technology to consider in crowded, poorly ventilated environments where aerosol transmission could occur and where the ability to increase ventilation is limited. Long ago, McLean (1961) presented data showing interruption of influenza transmission in a hospital setting. It has been estimated that upper-room GUV may reduce infection risk by an amount equivalent to doubling the ventilation rate (Noakes et al., 2015). Escombe et al. (2009) showed 77% reduction in human to guinea pig transmission in a hospital setting, while chamber based studies show the effectiveness of GUV against a number of bacterial aerosols (Xu et al., 2005, 2003; Yang et al., 2012). These concur with modelling studies (Gilkeson and Noakes, 2013; Noakes et al., 2004; Sung and Kato, 2010; Yang et al., 2012) showing that the effectiveness depends on the placement of the lamps relative to the ventilation flow and that addition of a ceiling fan enhances GUV effectiveness (Xu et al., 2013; Zhu et al., 2014).

Factors that must be considered when evaluating the ability of upper-room GUV to kill or inactivate airborne microorganisms include the sensitivity of the microorganisms to GUV and the dose received by a microorganism or population of microorganisms. GUV dose is the ultraviolet (UV) irradiance multiplied by the time of exposure and is usually expressed as $\mu\text{W}\cdot\text{s}/\text{cm}^2$. Well-designed upper-room GUV may be effective in killing or inactivating most airborne droplet nuclei containing mycobacteria if designed to provide an average UV fluence rate in the upper room in the range of $30 \mu\text{W}/\text{cm}^2$ to $50 \mu\text{W}/\text{cm}^2$, provided the other elements stipulated in these guidelines are met. In addition, the fixtures should be installed to provide as uniform a UVGI distribution in the upper room as possible (CDC/NIOSH 2009). A zonal infection risk model (Noakes et al., 2015) suggests that an upper-room GUV with a plane average irradiance of $0.2 \text{ W}/\text{m}^2$ at the UV fixtures could be comparable to increasing the ventilation rate from 3 to 6 ACH.

Portable consumer air cleaning devices may be beneficial in smaller rooms, although it should be recognised that such devices must be appropriately sized for the space (Miller-Leiden et al., 1996). There is wide variation in performance of air cleaners depending on air cleaner design and size of room in which it is used (Shaughnessy and Sextro, 2006). A useful metric for determining performance is the clean air delivery rate, which is equivalent to the volumetric flow rate of

particle-free air produced by the air cleaner (Foard, 1999). Kujundzic et al. (2006) reported air cleaners were similarly effective against removing both airborne bacterial and fungal spores from the air at clean air delivery rates of between 26 and $980 \text{ m}^3/\text{h}$ corresponding to effective cleaning of between 5 and 189 m^3 room volumes respectively.

GUV 'in-duct' application within air-conditioning systems and ventilation ducts may also be a practical approach for disinfecting contaminated extracts or in cases where it is not possible to stop recirculation of ventilation flows (Kujundzic et al., 2007). However, these systems are of little benefit against person-to-person transmission when installed in the supply air of once-through systems that do not recirculate air within the space or building. The US Centers for Disease Control has approved both upper-room and in-duct systems for use in controlling tuberculosis transmission as an adjunct to HEPA filtration (CDC/NIOSH, 2009).

2.5. Minimise the number of people within the same indoor environment in an epidemic

This measure is self-explanatory in the context of the need to lower the concentration of airborne virus-carrying particles, and reduce the number of people who can be exposed at any time. There is no one specific value for a number of people who could share the same space during pandemics, and this measure should be considered in conjunction with the engineering measures discussed above, and particularly in relation to the ventilation parameters of the space. Although the physical distance required to avoid transmission through direct contact dictates the requirements for the floor area per person, the rate of ventilation provided and the efficiency of ventilation are the parameters that control the concentration of virus-laden microdroplets in the air exhaled by the occupants, and will guide decisions on safe occupancy numbers. In a school or a supermarket, for example, if the number of infected students or shoppers is low, and the ventilation rate is high, the risk of airborne transmission can be low. Similarly, during an epidemic, reducing the number of people using public or private transport *at the same time*, e.g. in subway train systems or busses, is part of effective social distancing (Knibbs et al., 2012; Stopera and Stopera, 2020).

3. Conclusions

Until effective pharmacological treatments or vaccines are available to reduce the effective reproductive number to less than 1.0 and stop the ongoing COVID-19 pandemic, enhanced ventilation may be a key element in limiting the spread of the SARS-CoV-2 virus. These are the key ventilation-associated recommendations (see Fig. 2):

- (1) To remind and highlight to building managers and hospital administrators and infection control teams that engineering controls are effective to control and reduce the risks of airborne infection – and SARS-CoV-2 has the potential and is likely to be causing some infections by this route.
- (2) To increase the existing ventilation rates (outdoor air change rate) and enhance ventilation effectiveness - using existing systems.
- (3) To eliminate any air-recirculation within the ventilation system so as to just supply fresh (outdoor) air.

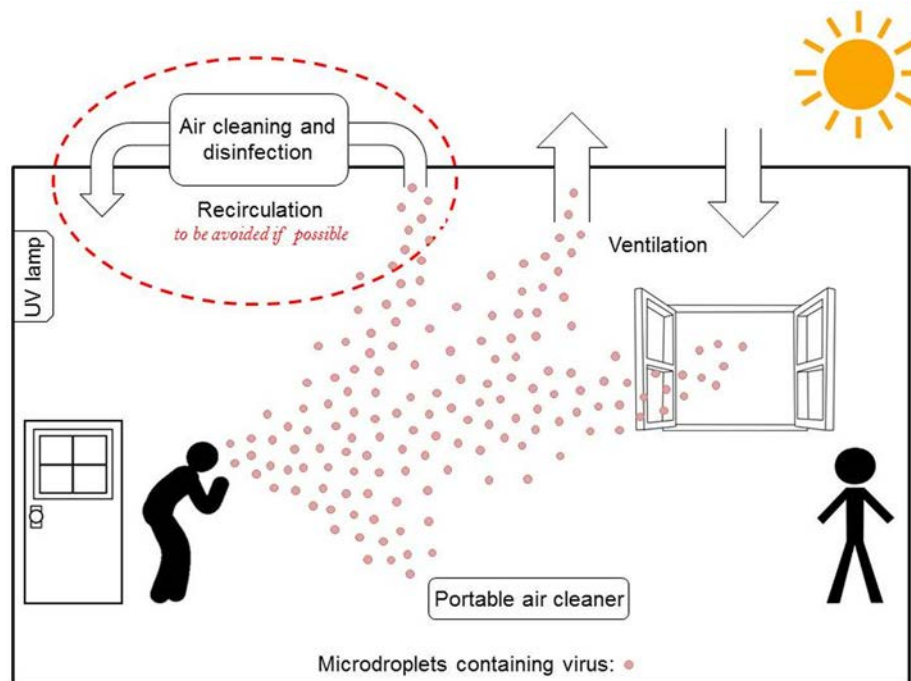


Fig. 2. Engineering level controls to reduce the environmental risks for airborne transmission.

- (4) To supplement existing ventilation with portable air cleaners (with mechanical filtration systems to capture the airborne microdroplets), where there are areas of known air stagnation (which are not well-ventilated with the existing system), or isolate high patient exhaled airborne viral loads (e.g. on COVID-19 cohort patient bays or wards). Adequate replacement of the filters in the air cleaners and their maintenance is crucial.
- (5) To avoid over-crowding, e.g. pupils sitting at every other desk in school classrooms, or customers at every other table in restaurants, or every other seat in public transport, cinemas, etc.

If implemented correctly, these recommended building-related measures will lower the overall environmental concentrations of airborne pathogens and thus will reduce the spread of infection by the airborne route. Together with other guidance on minimising the risk of contact and droplet transmission (through hand-washing, cleaning of hand-touch sites, and the appropriate use of PPE), these ventilation-related interventions will reduce the airborne infection rates not just for SARS-CoV-2 in the current COVID-19 pandemic, but also for other airborne infectious agents.

While much of the focus has been on case finding, isolation and quarantine, social distancing and hand hygiene, we emphasise that a parallel reduction in airborne transmission using such engineering controls in hospitals and other public buildings will further protect healthcare workers, patients and the general public.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

References

- Ai, Z., Hashimoto, K., Melikov, A.K., 2019. Airborne transmission between room occupants during short-term events: Measurement and evaluation. *Indoor Air* 29, 563–576.
- AIVC, 1996. A Guide to Energy Efficient Ventilation. Air Infiltration and Ventilation Centre, Brussels.
- ASHRAE, 2017. ASHRAE Standard 52.2-2017 Method of testing general ventilation air-cleaning devices for removal efficiency by particle size.
- ASHRAE, 2020a. COVID-19 (CORONAVIRUS) PREPAREDNESS RESOURCES. American Society of Heating, Ventilating, and Air-Conditioning Engineers.
- ASHRAE, 2020b. Position Document on Airborne Infectious Diseases, Approved by the Board of Directors, January 19, 2014. Reaffirmed by the Technology Council, February 5, 2020. Atlanta, Georgia.
- Bedell, K., Buchaklian, A.H., Perlman, S., 2016. Efficacy of an automated multiple emitter whole-room ultraviolet-C disinfection system against coronaviruses MHV and MERS-CoV. *Infect. Control Hosp. Epidemiol.* 37, 598–599.
- Booth, C.M., Clayton, M., Crook, B., Gawn, J., 2013. Effectiveness of surgical masks against influenza bioaerosols. *J. Hosp. Infect.* 84, 22–26.
- Brown, J., Tang, J., Pankhurst, L., Klein, N., Gant, V., Lai, K., et al., 2015. Influenza virus survival in aerosols and estimates of viable virus loss resulting from aerosolization and air-sampling. *J. Hosp. Infect.* 91, 278–281.
- CDC, 2015. Hierarchy of Controls. Centers for Disease Control and Prevention.
- CDC/NIOSH, 2009. Environmental Control for Tuberculosis: Basic Upper-Room Ultraviolet Germicidal Irradiation Guidelines for Healthcare Settings. Publication No. 2009–105. Department of Health and Human Services, Centers for Disease Control and Prevention & National Institute for Occupational Safety and Health.
- CEN, 2017. Energy performance of buildings – Ventilation for buildings. CEN Standard EN 16798–7: 2017. Part 7: Calculation methods for the determination of air flow rates in buildings including infiltration. European Committee for Standardization, Bruxelles.
- Chen, W., Zhang, N., Wei, J., Yen, H.-L., 2020. Short-range airborne route dominates exposure of respiratory infection during close contact. *Build. Environ.* 176, 106859.
- Chia, P.Y., Coleman, K.K., Tan, Y.K., Ong, S.W.X., Gum, M., Lau, S.K., et al., 2020. Detection of Air and Surface Contamination by Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) in Hospital Rooms of Infected Patients. *medRxiv*.
- CIBSE, 2005. CIBSE Guideline AM10: Natural Ventilation in Non-domestic Buildings. Chartered Institution of Building Services Engineers, London.
- Coleman, K.K., Nguyen, T.T., Yadana, S., Hansen-Estruch, C., Lindsley, W.G., Gray, G.C., 2018. Bioaerosol sampling for respiratory viruses in singapore's mass rapid transit

- network. *Sci. Rep.* 8, 1–7.
- Darnell, M.E., Subbarao, K., Feinstone, S.M., Taylor, D.R., 2004. Inactivation of the coronavirus that induces severe acute respiratory syndrome SARS-CoV. *J. Virol. Methods* 121, 85–91.
- Department of Health, 2015. U.G. Guidance, Green Book Chapter 4: Varicella; Notifiable in Scotland and Northern Ireland (<https://www.gov.uk/government/publications/varicella-the-green-book-chapter-34>) (accessed 23 April 2020). Department of Health, UK Government.
- Ding, Z., Qian, H., Xu, B., Huang, Y., Miao, T., Yen, H.-L., et al., 2020. Toilets dominate environmental detection of SARS-CoV-2 virus in a hospital. *medRxiv*.
- Distasio, A.J., Trump, D.H., 1990. The investigation of a tuberculosis outbreak in the closed environment of a US Navy ship, 1987. *Mil. Med.* 155, 347–351.
- Eames, I., Tang, J., Li, Y., Wilson, P., 2009. Airborne transmission of disease in hospitals. *J. R. Soc. Interface* 6, S697–S702.
- Escombe, A.R., Moore, D.A., Gilman, R.H., Navincopa, M., Ticona, E., Mitchell, B., et al., 2009. Upper-room ultraviolet light and negative air ionization to prevent tuberculosis transmission. *PLoS Med.* 6.
- Foarde, K.K., 1999. Methodology to perform clean air delivery rate type determinations with microbiological aerosols. *Aerosol Sci. Technol.* 30, 235–245.
- Gilkeson, C., Camargo-Valero, M., Pickin, L., Noakes, C., 2013. Measurement of ventilation and airborne infection risk in large naturally ventilated hospital wards. *Build. Environ.* 65, 35–48.
- Gilkeson, C.A., Noakes, C., 2013. Application of CFD simulation to predicting upper-room UVGI effectiveness. *Photochem. Photobiol.* 89, 799–810.
- Guo, Z.-D., Wang, Z.-Y., Zhang, S.-F., Li, X., Li, L., Li, C., et al., 2020. Aerosol and surface distribution of severe acute respiratory syndrome coronavirus 2 in hospital wards, Wuhan, China, 2020. *Emerg. Infect. Dis.* 26.
- ISO, B. 17772-1: 2017. Energy performance of buildings. Indoor environmental quality. Indoor environmental input parameters for the design and assessment of energy performance of buildings.
- Jiang, Y., Wang, H., Chen, Y., He, J., Chen, L., Liu, Y., et al. Clinical Data on Hospital Environmental Hygiene Monitoring and Medical Staff Protection during the Coronavirus Disease 2019 Outbreak. *medRxiv* 2020.
- Jo, S., Hong, J., Lee, S.-E., Ki, M., Choi, B.Y., Sung, M., 2019. Airflow analysis of Pyeongtaek St Mary's Hospital during hospitalization of the first Middle East respiratory syndrome patient in Korea. *R. Soc. Open Sci.* 6, 181164.
- Kim, S.-H., Chang, S.Y., Sung, M., Park, J.H., Bin Kim, H., Lee, H., et al., 2016. Extensive viable Middle East respiratory syndrome (MERS) coronavirus contamination in air and surrounding environment in MERS isolation wards. *Rev. Infect. Dis.* 63, 363–369.
- Knibbs, L.D., Morawska, L., Bell, S.C., 2012. The risk of airborne influenza transmission in passenger cars. *Epidemiol. Infect.* 140, 474–478.
- Kormuth, K.A., Lin, K., Prussin, A.J., Vejerano, E.P., Tiwari, A.J., Cox, S.S., et al., 2018. Influenza virus infectivity is retained in aerosols and droplets independent of relative humidity. *J. Infect. Dis.* 218, 739–747.
- Kujundzic, E., Hernandez, M., Miller, S.L., 2007. Ultraviolet germicidal irradiation inactivation of airborne fungal spores and bacteria in upper-room air and HVAC in-duct configurations. *J. Environ. Eng. Sci.* 6, 1–9.
- Kujundzic, E., Matalak, F., Howard, C.J., Hernandez, M., Miller, S.L., 2006. UV air cleaners and upper-room air ultraviolet germicidal irradiation for controlling airborne bacteria and fungal spores. *J. Occup. Environ. Hygiene* 3, 536–546.
- Kulkarni, H., Smith, C.M., Lee, D.D.H., Hirst, R.A., Easton, A.J., O'Callaghan, C., 2016. Evidence of respiratory syncytial virus spread by aerosol. Time to revisit infection control strategies? *Am. J. Respir. Crit. Care Med.* 194, 308–316.
- Lewis, D., 2020. Is the coronavirus airborne? Experts can't agree. *Nature News*.
- Li, Y., Huang, X., Yu, I., Wong, T., Qian, H., 2005. Role of air distribution in SARS transmission during the largest nosocomial outbreak in Hong Kong. *Indoor Air* 15, 83–95.
- Li, Y., Leung, G.M., Tang, J., Yang, X., Chao, C., Lin, J.Z., et al., 2007. Role of ventilation in airborne transmission of infectious agents in the built environment-a multi-disciplinary systematic review. *Indoor Air* 17, 2–18.
- Liu, L., Li, Y., Nielsen, P.V., Wei, J., Jensen, R.L., 2017. Short-range airborne transmission of expiratory droplets between two people. *Indoor Air* 27, 452–462.
- Liu, Y., Ning, Z., Chen, Y., Guo, M., Liu, Y., Gali, N.K., et al., 2020. Aerodynamic Characterizing of Airborne Concentration of SARS-CoV-2 Aerosol in Wuhan Hospitals during COVID-19 Outbreak. *bioRxiv*.
- Marr, L.C., Tang, J.W., Van Mullekom, J., Lakdawala, S.S., 2019. Mechanistic insights into the effect of humidity on airborne influenza virus survival, transmission and incidence. *J. R. Soc. Interface* 16, 20180298.
- McDevitt, J.J., Lai, K.M., Rudnick, S.N., Houseman, E.A., First, M.W., Milton, D.K., 2007. Characterization of UVC light sensitivity of vaccinia virus. *Appl. Environ. Microbiol.* 73, 5760–5766.
- McDevitt, J.J., Rudnick, S.N., Radonovich, L.J., 2012. Aerosol susceptibility of influenza virus to UV-C light. *Appl. Environ. Microbiol.* 78, 1666–1669.
- McLean, R., 1961. The mechanism of spread of Asian influenza: general discussion. *Am. Rev. Respir. Dis.* 83, 36–38.
- Melikov, A.K., 2011. Advanced air distribution. *ASHRAE J.* 53, 73–77.
- Melikov, A.K., 2016. Advanced air distribution: improving health and comfort while reducing energy use. *Indoor Air* 26, 112–124.
- Miller-Leiden, S., Lohascio, C., Nazaroff, W., Macher, J., 1996. Effectiveness of in-room air filtration and dilution ventilation for tuberculosis infection control. *J. Air Waste Manag. Assoc.* 46, 869–882.
- Miller, S.L., Clements, N., Elliott, S.A., Subhash, S.S., Eagan, A., Radonovich, L.J., 2017. Implementing a negative-pressure isolation ward for a surge in airborne infectious patients. *Am. J. Infect. Control* 45, 652–659.
- Morawska, L., Cao, J., 2020. Airborne transmission of SARS-CoV-2: the world should face the reality. *Environ. Int.* 105730.
- Moser, M.R., Bender, T.R., Margolis, H.S., Noble, G.R., Kendal, A.P., Ritter, D.G., 1979. An outbreak of influenza aboard a commercial airliner. *Am. J. Epidemiol.* 110, 1–6.
- MSN, 2020. Look inside Singapore's exhibition hall turned hospital (Photos).
- Nishiura, H., Oshitani, H., Kobayashi, T., Saito, T., Sunagawa, T., Matsui, T., et al., 2020. Closed environments facilitate secondary transmission of coronavirus disease 2019 (COVID-19). *medRxiv*.
- Noakes, C., Beggs, C., Sleight, P., 2004. Modelling the performance of upper room ultraviolet germicidal irradiation devices in ventilated rooms: comparison of analytical and CFD methods. *Indoor Built Environ.* 13, 477–488.
- Noakes, C.J., Khan, M.A.I., Gilkeson, C.A., 2015. Modeling infection risk and energy use of upper-room ultraviolet germicidal irradiation systems in multi-room environments. *Sci. Technol. Built Environ.* 21, 99–111.
- Ong, S.W.X., Tan, Y.K., Chia, P.Y., Lee, T.H., Ng, O.T., Wong, M.S.Y., et al., 2020. Air, surface environmental, and personal protective equipment contamination by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) from a symptomatic patient. *JAMA*.
- Persily, A., Chapman, R.E., Emmerich, S.J., Dols, W.S., Davis, H., Lavappa, P., et al. Building retrofits for increased protection against airborne chemical and biological releases. National Institute of Standards and Technology, Gaithersburg, MD 2007.
- Phiri, M., 2014. Health Building Note 00-01 General design Guidance for Healthcare Buildings. UK Government.
- Pyankov, O.V., Bodnev, S.A., Pyankova, O.G., Agranovski, I.E., 2018. Survival of aerosolized coronavirus in the ambient air. *J. Aerosol Sci.* 115, 158–163.
- REHVA, 2020. COVID-19 Guidance.
- Roy, C.J., Milton, D.K., 2004. Airborne transmission of communicable infection-the elusive pathway. *N. Engl. J. Med.* 350, 1710.
- Rule, A.M., Apau, O., Ahrenholz, S.H., Brueck, S.E., Lindsley, W.G., de Perio, M.A., et al., 2018. Healthcare personnel exposure in an emergency department during influenza season. *PLoS ONE* 13.
- Santarpia, J.L., Rivera, D.N., Herrera, V., Morwitzer, M.J., Creager, H., Santarpia, G.W., et al., 2020. Transmission potential of SARS-CoV-2 in viral shedding observed at the University of Nebraska Medical Center. *medRxiv*.
- SHASE, 2020. Role of ventilation in the control of the COVID-19 infection: Emergency presidential discourse. The Society of Heating, Air-Conditioning and Sanitary Engineers of Japan (SHASE).
- Shaughnessy, R., Sextro, R., 2006. What is an effective portable air cleaning device? A review. *J. Occup. Environ. Hygiene* 3, 169–181.
- Sornboot, J., Aekplakorn, W., Ramasoota, P., Bualert, S., Tumwasorn, S., Jiamjarasrangsri, W., 2019. Detection of airborne Mycobacterium tuberculosis complex in high-risk areas of health care facilities in Thailand. *Int. J. Tuberc. Lung Dis.* 23, 465–473.
- Stopera, M., Stopera, D., 2020. 19 Pictures Of The Most Dangerous Places In New York City Right Now.
- Sung, M., Kato, S., 2010. Method to evaluate UV dose of upper-room UVGI system using the concept of ventilation efficiency. *Build. Environ.* 45, 1626–1631.
- Tang, J.W., 2009. The effect of environmental parameters on the survival of airborne infectious agents. *J. R. Soc. Interface* 6, S737–S746.
- Tellier, R., Li, Y., Cowling, B.J., Tang, J.W., 2019. Recognition of aerosol transmission of infectious agents: a commentary. *BMC Infect. Dis.* 19, 101.
- Thatiparti, D.S., Ghia, U., Mead, K.R., 2016. Assessing effectiveness of ceiling-ventilated mock airborne infection isolation room in preventing hospital-acquired influenza transmission to health care workers. *ASHRAE Trans.* 122, 35.
- Thatiparti, D.S., Ghia, U., Mead, K.R., 2017. Computational fluid dynamics study on the influence of an alternate ventilation configuration on the possible flow path of infectious cough aerosols in a mock airborne infection isolation room. *Sci. Technol. Built Environ.* 23, 355–366.
- van Doremalen, N., Bushmaker, T., Morris, D.H., Holbrook, M.G., Gamble, A., Williams, B.N., et al., 2020. Aerosol and surface stability of SARS-CoV-2 as compared with SARS-CoV-1. *N. Engl. J. Med.*
- Walker, C.M., Ko, G., 2007. Effect of ultraviolet germicidal irradiation on viral aerosols. *Environ. Sci. Technol.* 41, 5460–5465.
- WHO, 2009. Natural ventilation for infection control in health-care settings (https://www.who.int/water_sanitation_health/publications/natural_ventilation/en/) (accessed 14 April 2020). In: Chartier Y., Pessoa-Silva C., Li Y., Seto W.-H. (Eds.), World Health Organization.
- WHO, 2020a. Infection Prevention and Control During Health Care When COVID-19 is Suspected. Interim Guidance. World Health Organization, 19 March 2020.
- WHO, 2020b. Scientific Brief: Modes of Transmission of Virus Causing COVID-19: Implications for IPC Precaution Recommendations. World Health Organisation.
- WHO, 2020c. Shortage of Personal Protective Equipment Endangering Health Workers Worldwide. World Health Organisation, Geneva, Switzerland.

- Xu, P., Fisher, N., Miller, S.L., 2013. Using computational fluid dynamics modeling to evaluate the design of hospital ultraviolet germicidal irradiation systems for inactivating airborne mycobacteria. *Photochem. Photobiol.* 89, 792–798.
- Xu, P., Kujundzic, E., Peccia, J., Schafer, M.P., Moss, G., Hernandez, M., et al., 2005. Impact of environmental factors on efficacy of upper-room air ultraviolet germicidal irradiation for inactivating airborne mycobacteria. *Environ. Sci. Technol.* 39, 9656–9664.
- Xu, P., Peccia, J., Fabian, P., Martyny, J.W., Fennelly, K.P., Hernandez, M., et al., 2003. Efficacy of ultraviolet germicidal irradiation of upper-room air in inactivating airborne bacterial spores and mycobacteria in full-scale studies. *Atmos. Environ.* 37, 405–419.
- Yang, Y., Chan, W.Y., Wu, C., Kong, R., Lai, A., 2012. Minimizing the exposure of airborne pathogens by upper-room ultraviolet germicidal irradiation: an experimental and numerical study. *J. R. Soc. Interface* 9, 3184–3195.
- Young, L., Wormser, G., 1994. The resurgence of tuberculosis. *Scand. J. Infect. Dis. Suppl.* 93, 9–19.
- Zhu, S., Srebric, J., Rudnick, S.N., Vincent, R.L., Nardell, E.A., 2014. Numerical modeling of indoor environment with a ceiling fan and an upper-room ultraviolet germicidal irradiation system. *Build. Environ.* 72, 116–124.

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The control by ventilation of airborne bacterial transfer between hospital patients, and its assessment by means of a particle tracer

II. Ventilation in subdivided isolation units

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SUMMARY

Values are deduced for the efficiency of isolation against airborne particulates, e.g. micro-organisms, of a variety of ventilation systems. The calculated values show reasonable correspondence with the limited experimental data available. Much better control and indication of the air flow is necessary if high degrees of isolation are required.

INTRODUCTION

In an isolation unit ventilation may serve any or all of three purposes, to maintain a comfortable environment, to remove smells, to reduce the possibilities of airborne transport of micro-organisms from one patient to another. The criteria for the first two purposes are well known and not difficult to meet. The third, however, is less clear. Epidemiological evidence as to the relevance of airborne infection is generally lacking so that a precise specification cannot be given. It seems likely, however, that if any clinical benefit is to be obtained it will only be gained by reducing the extent of airborne transport by several orders of magnitude. There are very few data on the physical effectiveness of different ventilation systems, but some deductions can be made from a theoretical analysis and these then compared with the scanty material available.

As a simplified model we may consider a number of rooms opening off a communications area (Fig. 1).

EXCHANGE OF AIR BETWEEN ROOMS

In calculating the transport of particles from the air exchange between the parts of a system, it is convenient to assume that turbulent air mixing within each room is sufficient to produce a substantially uniform concentration of particles within it. This is a satisfactory approximation so long as the spaces involved are not too large or unusually shaped.

In assessing the performance of any system it is more realistic to compare it with the situation in which all the patients are housed in one room having the same

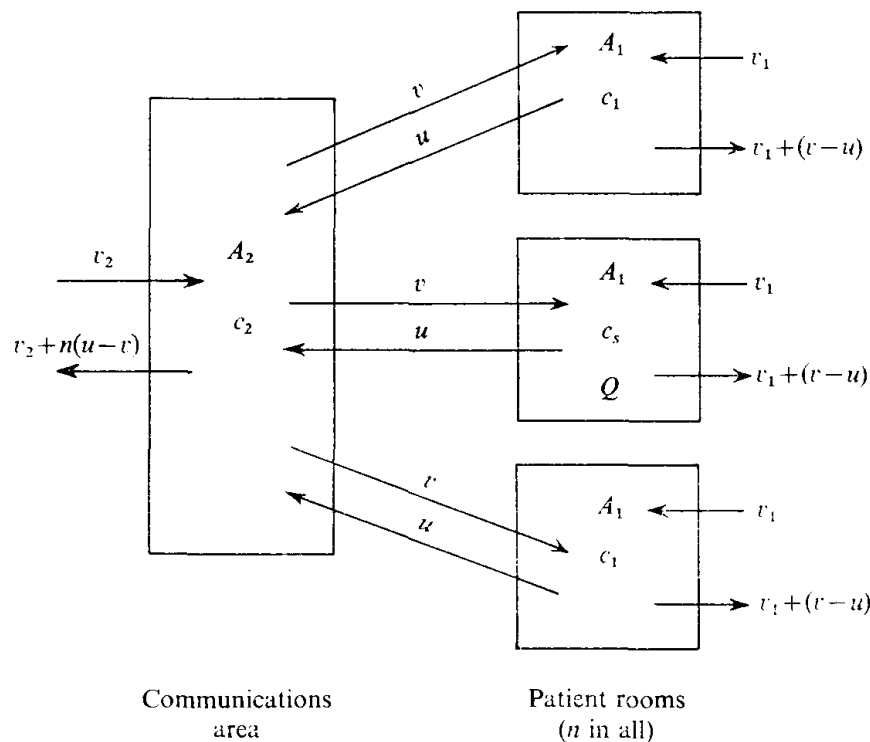


Fig. 1. Schematic diagram of the system analysed. The arrows show the directions of the air movements between the n patient rooms and the communications area together with the air supply and consequent exhaust. The symbols u and v , with suffixes as appropriate, indicate the volumetric rates of air movement, for example in m^3/hr . Symbols c_1 , c_2 denote the equilibrium particle concentrations arising from a source, Q particles per unit time (e.g. per hr.), in one patient room where the equilibrium concentration is c_s . A_1 and A_2 are the floor areas (more properly the aggregate areas of the horizontal surfaces on which particle sedimentation takes place) of the rooms.

total ventilation and floor area than just to compare the particle concentration in a room housing a source with that in the other patient rooms. The ratio of these concentrations, α in equation (5) below, which is all that is available for measurement by observations made within the system itself, gives an unduly favourable estimate of the efficiency of the isolation since the particle concentration in the source room is increased when the source is contained in a small room.

If, then, there is a source generating Q units of particle contamination/hr. in one of the rooms of the system shown in Fig. 1 the following equations will define the equilibrium state, neglecting the effect of particle settling

$$c_s (v_1 + v - u) + c_s u = v c_2 + Q, \quad (1)$$

$$c_1 (v_1 + v - u) + c_1 u = v c_2, \quad (2)$$

$$c_2 (v_2 + n (u - v)) + c_2 n v = u c_s + c_1 (n - 1) u, \quad (3)$$

where the symbols have the meaning shown in Fig. 1.

In addition if the system were replaced by a single space with a floor area and ventilation supply equal to the sum of those of the individual rooms and the communications area then the equilibrium state would be defined by

$$c_m (v_2 + n v_1) = Q. \quad (4)$$

This value of the particle concentration, c_m , is the value to which c_s , c_1 and c_2 all tend as u and v both become very large but $v \sim u$ remains small.

From equations (1)–(4) it is easy to deduce that

$$c_s/c_1 = \alpha = 1 + (v_1 v_2 + v_2 v + nuv_1)/uv, \quad (5)$$

$$c_m/c_1 = \beta = (v + v_1) (v_1 v_2 + v_2 v + nuv_1)/uv (v_2 + nv_1). \quad (6)$$

If both u and v are small relative to v_1 and v_2 then

$$\alpha = c_s/c_1 \simeq v_1 v_2/uv, \quad (5A)$$

$$\beta = c_m/c_1 \simeq v_1 v_1 v_2/uv (v_2 + nv_1), \quad (6A)$$

and

$$\alpha/\beta = c_s/c_m = n + v_2/v_1. \quad (7)$$

In addition

$$c_s/c_2 = \alpha' = 1 + (v_1 v_2 + v_2 v + \overline{n-1} uv_1)/u (v_1 + v), \quad (8)$$

$$c_2/c_1 = \alpha'' = 1 + v_1/v, \quad (9)$$

or if both u and v are small as before

$$\alpha' = c_s/c_2 \simeq v_2/u, \quad (8A)$$

$$\alpha'' = c_2/c_1 \simeq v_1/v. \quad (9A)$$

In all the above equations u and v , the volumes of air passing between the individual rooms and the communications area, include air movements due to imbalance in the air supplied to or extracted from the rooms, air exchange across the doorways or other openings as a result of thermal differences and air exchanged across doorways when the doors are opened and shut and when people pass through them.

The effects of particle size

In addition to the effects of ventilation, the particles carrying the micro-organisms will be settling under the influence of gravity. The effect of this on the dispersal and air-concentration of the particles is equivalent, under conditions of complete turbulent air mixing within the individual rooms, to adding to the clean air input into any room a quantity As , where A is the floor area of the room concerned and s is the effective settling velocity of the particles. For bacteria-carrying particles the value of s is usually close to 0.3 m./min. (Noble, Lidwell & Kingston, 1963).

Transport through airlocks

In order to apply the results of the preceding section to systems which include airlocks, with doors to both the patient room and the communications area, it is necessary to obtain some estimate of the effective transfer of air through them when a person enters or leaves the room, i.e. of the rate of direct transfer of air from the room to the corridor, or in the reverse direction, that would transfer the same amount of airborne contamination as that effected by passage through the airlock. These estimates can then be introduced into equations 5–9 as the appropri-

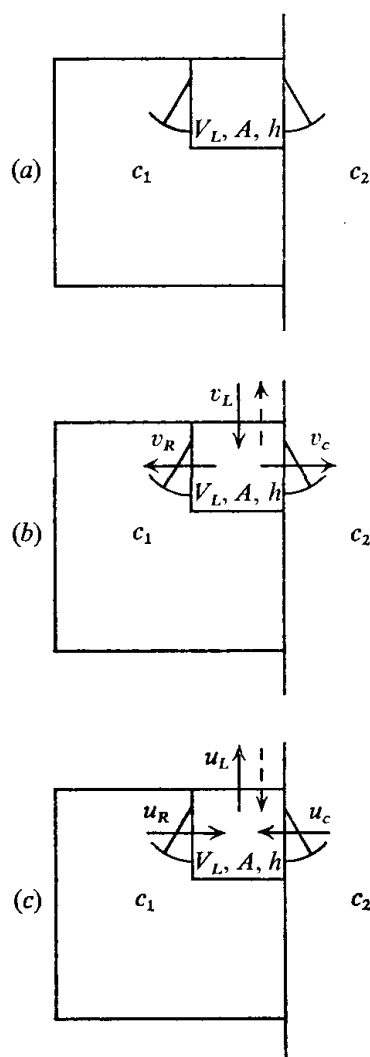


Fig. 2. Airlocks. Symbols c_1 , c_s and c_2 , as in Fig. 1, denote the equilibrium particle concentrations in the n patient rooms and in the communications area. V_L is the volume of an airlock, A its floor area and h its internal ceiling height. (a) Unventilated airlock. (b) Input ventilation at v_L of which v_R passes into the patient room and v_c into the communications area. (c) Extract ventilation at u_L of which u_R is drawn from the patient room and u_c from the communication area.

ate values of u and v . Three situations are illustrated in Fig. 2: (a) an unventilated lock; (b) a lock with clean air input; (c) a lock with extract.

The direction of air flow around the door edges with a balanced ventilation system and an unventilated lock are indeterminate. If there is no flow in either direction when the doors are shut then $u = v = mw^2/V_L$, when there are both m entries into the room and m exits from the room through the airlock in unit time, w is the volume of air exchanged across a door opening each time a door is opened and shut and V_L is the cubic volume of the lock. Loss by sedimentation within the lock is small, a dwell time of about 6 min. would be necessary to halve the concentration of particles within the lock even if it were no more than 2.5 m. high, given the assumed settling velocity of 0.3 m./min. A consequence of this slow die-away, however, is that particles already introduced into the lock may be transferred by a subsequent passage through. For an assumed rate of five passages/

hr. in each direction, one in either direction every 6 min., this will approximately treble the particle transfer,

$$u = v = mw^2/V_L (1 + \frac{1}{2} + \frac{1}{4} + \dots + \frac{1}{2} + \frac{1}{4} + \dots) = 3mw^2/V_L.*$$

In practice there will almost certainly be a flow in one direction or the other, due to residual imbalance in the ventilating system so that either u or v will be many times larger than this figure.

For locks with clean air input greater than any extract, the air in the lock will be clean in the absence of any passage through. Even with an input of 200 m.³/hr. into a lock of volume 10 m.³, 80 % of any contamination introduced on entering the lock will remain after a dwell time of 0.01 hr.; but this is of no significance, since any contamination introduced by opening doors will be distributed to the two sides of the airlock in proportion to the air flows. The effect of this is identical in whichever direction a person passes through the lock, so that $u = 2mwv_C/v_L$ and $v = 2mwv_R/v_L$. If there is no extract and $v_C = v_R = \frac{1}{2}v_L$ then $u = v = mw$. Loss by settling during the time taken to flush the contamination out of the lock will however reduce the effective particle transfer. The proportion so lost by settling is given by $60sA/(60sA + v_L)$. If the air input is 100 m.³/hr., the settling area within the lock is 4 m.² and s is taken as 0.3 m./min. then the proportion so lost = $72/(72 + 100) = 0.42$. If $v_C = v_R = \frac{1}{2}v_L$ then as far as the transport of particles through the airlock is concerned effectively $u = v = (1 - 0.42)mw = 0.58mw$. The net air input to the lock must be regarded as additional ventilation air to the system, divided according to the proportionate air flows in the two directions (i.e. v_R is to be included in v_1 and nv_C in v_2). Any contamination produced by activities within the airlock, e.g. putting on or taking off protective clothing etc., will be carried both into the room and into the communications area in proportion to the air flows, subject to losses from sedimentation similar to those described above.

The air within an airlock with extract in excess of any input is always contaminated from both sides in proportion to the relative input flows from both sides. Dwell time in the lock is therefore again irrelevant, since it is not entry into the lock that introduces the airborne particles. On entering or leaving the lock, particles are transferred across the door concerned, hence $u = 2mwu_R/u_L$ and $v = 2mwu_C/u_L$. If there is no input and $u_R = u_C = \frac{1}{2}u_L$ then $u = v = mw$. The continuous loss by sedimentation within the airlock will reduce this to a similar extent to that given above for the positive input situation substituting u_L for v_L . Contamination produced by activities within the lock itself will be transferred in the direction of subsequent passage. With little effect from any dwell time of less than 2–3 min., the fraction will approximate to w/V_L , usually substantially less than the amount transferred from a positively ventilated lock.

Further reduction in the transfer through an airlock can be obtained by a high

* This assumes that w/V_L is sufficiently small for the reduction in concentration of particles left in the airlock each time a volume w is lost on opening a door to be negligible. If w/V_L is as large as 1/10 when the other conditions are as assumed above then the values of u and v will be reduced to approximately $2.2mw^2/V_L$.

rate of near balanced ventilation to the lock, or recirculation through a filter within it. The advantage gained will depend upon the recirculation rate, the time during which recirculation is applied, if not continuous, and the type of airlock involved.

For a lock with positive supply v_L in addition to recirculation at a volumetric rate R , applied on entry to the lock, transfer on passage in the forward direction is reduced to approximately $mw(w/V_L + v_R/(R + v_L))$ for rapid passage through and to $mwv_R/(R + v_L)$ if the dwell time is sufficiently long. Return through the lock will also transfer $mwv_R/(R + v_L)$ in the same direction irrespective of dwell time, i.e. $v = mw(w/V_L + 2v_R/(R + v_L))$ for rapid passage, dropping to $2mwv_R/(R + v_L)$ with sufficient dwell time. Transfer in the reverse direction, u , will be determined by replacing v_R by v_C in the above formula. As an example, if recirculation at 2000 m.³/hr. is applied to a lock of volume 10 m.³ with $v_C = v_R = 50$ then the transfer on rapid passage is $mw(0.1w + 100/2100) = mw(0.1w + 0.048)$. With this rate of ventilation the effects of sedimentation are negligible and the residual concentration in the lock is reduced to about 12 % after a dwell of 0.01 hr. Transfer on passage is then reduced to $mw(0.012w + 0.048)$ which is insignificantly different from that resulting from indefinitely long dwell time, i.e. $0.048mw$, since w is likely to be of the order of 1 m.³ (see below). The effects of recirculation applied continuously are identical with those obtained with operation only on entering the lock.

If there is extract from the lock, continuous recirculation will reduce transfer to $u = 2mwu_R/(R + u_L)$ and $v = 2mwu_C/(R + u_L)$ irrespective of dwell time. If the recirculation is switched on only on entry into the lock, the recirculation will have no effect on transfer by rapid passage, and the transfer rate can be no more than halved even with prolonged dwell time.

By the use of directed downward flow ventilation in the airlock nearly 100 % clearance could be obtained in a single air pass. At a velocity of 0.5 m./sec. this would take little more than 5 sec. If, however, the floor area of the airlock were 5 m.² the air supply rate would then need to be some 9000 m.³/hr. or 150 m.³/min.

Calculated transfer values

The relationships discussed above may be applied to an infinite variety of possible systems. For illustrative purposes the results obtained for a series of variations on a single layout, using plausible values for the various parameters, have been set out in Table 1. The assumptions of complete and uniform mixing within each space and of uniform regular entries and exits to the several rooms are manifestly approximations so that the precise numerical values must be treated with reserve.

In addition to selecting values for the physical dimensions of the system and for the rates of ventilation, it has also been necessary to assume values for m , the number of passages in each direction between a room and the communications area and for w , the volume of air exchanged between the two sides of a door when it is opened and closed in quick succession.

One study of a two-bed isolation room (Lidwell & Towers, 1970) has shown an

Table 1. *Calculated reductions in exposure to airborne particle transfer*

Condition	u	v	α	β
A. Balanced supply (no airlocks)	1000	1000	11 (6)	2 (1.7)
	500	500	28 (11)	4 (2)
	200	200	80 (34)	7.5 (4)
	100	100	230 (90)	19 (9)
	50	50	800 (270)	60 (21)
B. Directional flow (no airlocks)	500	10	0.9×10^3	65
	200	10	1.4×10^3	100
	60	10	3.3×10^3	220
	10	500	0.6×10^3	73
	10	200	1.0×10^3	100
	10	60	2.9×10^3	220
C. Airlocks				
Unventilated:				
(a) balanced	[1.5	1.5	6.7×10^5	4.7×10^4]
(b) with directional	{ 50	1.5	2.0×10^4	1.4×10^3
air flow	{ 1.5	50	2.0×10^4	1.4×10^3
(All with allowance for sedimentation in the airlock)				
Ventilated:				
input or extract	5	5	6.0×10^4	4.2×10^3
with allowance for sedimentation	2.9	2.9	1.8×10^5	1.3×10^4
D. Airlocks with recirculation				
Input ventilation				
(a) rapid passage	0.75	0.75	2.7×10^6	1.9×10^5
(b) 0.01 hr. dwell	0.24	0.24	2.6×10^7	1.8×10^6
Extract ventilation				
(a) rapid passage	2.9	2.9	1.8×10^5	1.3×10^4
(b) 0.01 hr. dwell	1.5	1.5	6.7×10^5	4.7×10^4
Directed ('laminar') flow	$\rightarrow 0$	$\rightarrow 0$	$\rightarrow \infty$	$\rightarrow \infty$

The table shows values of the ratio, α , of particle concentration in the source room to that in other patient rooms, and the ratio, β , of the concentration if all the rooms were combined into one space with uniform mixing throughout to the concentration in non-source patient room for the particular system, i.e. the larger the figure the better the isolation. u and v , the air flows from each room into the communications area and in the reverse direction are given in m.³/hr.

The following values have been used in the evaluation of α and β , particle settling velocity 0.3 m./min. Ten patient rooms each with floor area 15 m.² and air input at 300 m.³/hr. (this corresponds to a ventilation rate of 6/hr. for a room height of 3 m.). Settling in these rooms is then equivalent to an additional clean air supply of $0.3 \times 60 \times 15 = 270$ m.³/hr., hence $v_1 = 300 + 270$ and has been taken as 600 m.³/hr. The communications area covers 80 m.² with an air input of 1200 m.³/hr. (this corresponds to a ventilation rate of 5/hr. for a ceiling height of 3 m.). Settling in this area is equivalent to an additional clean air supply of $0.3 \times 60 \times 80 = 1440$ m.³/hr., hence $v_2 = 1200 + 1440$ and has been taken as 2500 m.³/hr. Entries and exits to and from each room have each been taken as 5/hr. ($m = 5$) and 1 m.³ of air has been assumed to be exchanged across the door opening each time a door is opened and shut. The volume of an airlock has been taken as 10 m.³ with a floor area of 4 m.² and with 100 m.³/hr. input or extract when appropriate. When the airlock is ventilated the air has been considered as delivered to or taken from both sides of the lock in equal amounts. Recirculation has been taken as 2000 m.³/hr. and assumed to come into operation only on entering the locks. The figures in parentheses in group A relate to conditions of negligible ventilation supply to the system. The values for the unventilated airlock have been enclosed in square brackets since this condition is practically unrealizable unless sealed doors are used.

average of 360 openings of the room door, entries or exits, per 24 hr. or 15/hr. ($m = 7.5$). Observations on single rooms in a burns unit (Hambræus & Sanderson, 1972) gave a figure of about half this for a burned patient and rather more for an amputee. It would therefore seem reasonable to take a value of 10 exits or entries/hr., i.e. $m = 5$, for the number of passages/hr. in each direction.

There do not appear to be any published data available on the exchange of air through a doorway on opening and closing the door. Since the volume swept out by a hinged door of conventional size is of the order of 1 m^3 this figure has been taken as an approximation for the purposes of calculation.

Unpublished experiments carried out recently by the Building Services Research Unit of Glasgow University (W. Whyte & B. Shaw, personal communication) indicate values of 0.5 m^3 for the air transfer on opening a swing door of conventional dimensions. The figure is substantially less for a sliding door, but the large gaps around such doors may lead to significant air exchange across the closed door unless there is sufficient directed air supplied to swamp reverse convectional air flow.

In general hospitals in Britain the doors of patient rooms without airlocks are commonly found to be left open for considerable periods of time (Baird, 1969; N. Foord & O. M. Lidwell, to be published). There have been several published studies of air exchange through open doors or similar apertures as a consequence of small temperature difference (Wolf, Harris & Hall, 1961; Brown, Wilson & Solvason, 1963; Kethley, 1966; Ma, 1965). Unfortunately the numerical values given by the different authors are not in agreement. They range from 40 to $1100 \text{ m}^3/\text{hr.}$ for a temperature difference of 1°C. across a $2 \text{ m.} \times 1 \text{ m.}$ doorway, with as much as $350 \text{ m}^3/\text{hr.}$ for only 0.1°C. temperature difference in one instance. Since the air flow, theoretically, is proportional to the square root of the temperature difference quite high air flows may result from very small differences and values of between 100 and $500 \text{ m}^3/\text{hr.}$ seem not unlikely in practice.

DISCUSSION

With balanced or natural ventilation systems (group A, Table 1) values of α might be expected to lie between 10 and about 250. The actual advantage of subdivision compared with the exposure expected if all the patients were in a single room, given by the value of β , is, as explained earlier, much less, a reduction of between 2- and 20-fold in exposure to airborne particles. Comparison with the limited experimental results available, given in Table 2, shows a reasonable correspondence with the calculated figures. The degree of isolation obtained was, as would be expected, markedly less and the probable extent of air exchange between the parts of the ward much greater in the first situation referred to in Table 2. In this hospital the ward was partitioned but the patient areas opened directly off the communications corridor, being separated from it by no more than a low wall less than 1 m. high.

The introduction of a substantial directional flow to swamp the convectional exchange (group B, Table 1) raises the value of α to around 10^3 and β to about 100

Table 2. *The exposure to airborne particle transfer observed in some hospital situations*

Ref.	System	Conditions	Tracer	v_1	v_2	u or v	α
A. Natural and balanced							
1	Partitioned ward	Natural ventilation	<i>Staph. aureus</i>	—	—	(1400)	5
2	Divided ward	Natural ventilation	<i>Staph. aureus</i>	—	—	(600)	10
3	Divided ward	Natural ventilation	<i>Staph. aureus</i>	—	—	(200)	40
4	Divided ward	Natural ventilation	<i>Staph. aureus</i>	—	—	(400)	18
5	Divided ward	Part mechanical ventilation	Nitrous oxide	50–200	4000	100–170	70–80
5	Divided ward	Air conditioned	Nitrous oxide	700	4000	300	80
B. Directional flows							
6	Isolation unit	Positive rooms	<i>Staph. aureus</i>	350	1500	20	500
7	Divided ward	Positive rooms	<i>Staph. aureus</i>	800	2500	*	14
7	Divided ward	Positive rooms	Freon gas	800	2500	50	100
7	Divided ward	Positive rooms	Pot. iodide particle	800	2500	50	400
C. Airlocks							
8	Isolation unit	Extract airlocks	Pot. iodide particle	200	1100	2.9	3.4×10^5
8	Isolation unit	Extract airlocks	Pot. iodide particle	200	1100	17	9.6×10^3

The table shows the observed values of α , the ratio of the particles concentration in the source room to that in other patient rooms. The values of v_1 , the ventilation supply to a patient room and v_2 , that to the communication area, both given in m.³/hr., are usually only rough estimates based on limited information. Values of u or v , also in m.³/hr., have been deduced from the above using equation 5. For the balanced and natural ventilation system u and v are assumed equal. For references 6 and 7 u has been taken as 200 and 400 m.³/hr. respectively and the values given in the 7th column are those calculated for v . Where the tracer is particulate v_1 and v_2 have been doubled to allow for sedimentation (this is true if $s = 0.3$ m./min., $h = 3$ m. and ventilation is at 6 changes/hr.) before applying the formula. No estimates of v_1 or v_2 can usefully be made for the first four situations listed. The values of u and v given in parentheses are deduced from those given in Table 1 for the no ventilation condition.

The two values of u , v and α for reference 8 refer to 10 and 60 entries/exits per hr. respectively ($m = 5$ and $m = 30$).

* The discrepancy between the value of α in this row and that for the same system with a similar-sized tracer particle in the row below, suggests that the micro-organisms reached the non-source rooms by other routes than air transfer.

References. 1, Lidwell *et al.* (1971); 2, Lidwell *et al.* (1966); 3, Williams (1967); 4, Edmunds (1970); 5, Baird (1969); 6, Williams & Harding (1969); 7, Foord & Lidwell (to be published); 8, Hambræus & Sanderson (1972).

(this assumes the figure of 10 entries or exits to or from the room in each hour transferring 1 m.³ of air with each door opening). The observed ratios (group B, Table 2) are not quite as high as this and correspond to transfer against the direction of air flow of 20–50 m.³/hr., 2–5 times the assumed figure. This would suggest that the directional flows were inadequate to prevent reverse flow. The insertion of an airlock between the room and the corridor, group C, further increases the ratio α to between 10^4 and 10^5 , on the same assumptions of the frequency of door opening and the extent of air transfer associated with this. The calculated

performance for a ventilated airlock is independent of any delay or dwell on passing through the lock. Extract from the lock has the advantage of reducing dispersal of any airborne contamination generated within it. The one set of figures available in Table 2 show quite close agreement with the theoretical calculations and are presented in greater detail in the next paper (Hambraeus & Sanderson, 1972).

By using high volume recirculation in an airlock it should be possible to increase the value of α to very high values indeed but these could be realized in practice only if transfer of particles by other means than free air, for example on clothes or in the respiratory system, was kept to similarly low levels.

The clinical significance of these calculations and observations is quite uncertain since in no situation have we precise knowledge of the risk of infection by the airborne route as a function of exposure. It is, however, desirable that whenever studies are made of the clinical value of an isolation system measurements of the airborne particle transfer within it should be made under working conditions and that, if a high level of air isolation is considered desirable, the design should be such as to produce this. In order that any system may function effectively the actual air volumes and balances must be stable and correspond to those called for by the design. This is not generally the case, and most systems that I have examined have been both variable and divergent from their design intentions, for example the isolation unit referred to in reference 8 (Table 2) was designed for an input of 200 m.³/hr. to each of the patient rooms with an extract of 100 m.³/hr. from the airlock, supplied as to 50 m.³/hr. from the room and 50 m.³/hr. from the corridor. The value of α given in the table was obtained as between rooms where these flows were, at least approximately, maintained. However, out of 27 observations of the air flow around the doors into the air locks made on six separate days the *direction* of flow was reversed around one or other door on no fewer than 11 occasions. Hambraeus & Sanderson (1972) report similar observations. It must always be difficult to maintain the balance between flows as small as the above and if it is to be achieved some stabilizing factor, for example a relatively high-pressure drop across a filter or control orifice, must be included in the system. In addition, visual or other indicators of the flow directions are called for to ensure maintenance of the design conditions.

REFERENCES

- BAIRD, G. (1969). Air change and air transfer in a hospital ward unit. *Building Science* **3**, 113.
- BROWN, W. G., WILSON, A. G. & SOLVASON, K. R. (1963). Heat and moisture flow through openings by convection. *National Research Council of Canada Division of Building Research. Research paper No. 200*. Ottawa, Canada.
- EDMUNDS, P. N. (1970). Staphylococcal infection in sub-divided general surgical wards. *Journal of Hygiene* **68**, 531.
- HAMBRAEUS, A. & SANDERSON, H. F. (1972). Studies with an airborne particle tracer in an isolation ward for burned patients. *Journal of Hygiene* **70**, 299.
- KETHLEY, W. (1966). Internal report of the Engineering Experiment Station Georgia Institute of Technology, Atlanta, Georgia, U.S.A.
- LIDWELL, O. M., POLAKOFF, S., JEVONS, M. P., PARKER, M. T., SHOOTER, R. A., FRENCH, V. I. & DUNKERLEY, D. R. (1966). Staphylococcal infections in thoracic surgery: experience in a divided ward. *Journal of Hygiene* **64**, 321.

Ventilation in subdivided units

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- LIDWELL, O. M., DAVIES, J., PAYNE, R. W., NEWMAN, P. & WILLIAMS, R. E. O. (1971). Nasal acquisition of *Staphylococcus aureus* in partly divided wards. *Journal of Hygiene* **69**, 113.
- LIDWELL, O. M. & TOWERS, A. G. (1970). Uni-directional flow ventilation in patient isolation. In *Aerobiology Proceedings of the Third International Symposium*, p. 109. Ed. I. H. Silver. London: Academic Press.
- MA, W. Y. L. (1965). Air conditioning design for hospital operating rooms (appendix). *Journal of the Institute of Heating and Ventilating Engineers* **33**, Sept.
- NOBLE, W. C., LIDWELL, O. M. & KINGSTON, D. (1963). The size-distribution of particles carrying micro-organisms. *Journal of Hygiene* **61**, 385.
- WILLIAMS, R. E. O. (1967). Airborne staphylococci in the surgical ward. *Journal of Hygiene* **65**, 207.
- WILLIAMS, R. E. O. & HARDING, L. (1969). Studies of the effectiveness of an isolation ward. *Journal of Hygiene* **67**, 649.
- WOLF, H. W., HARRIS, M. M. & HALL, L. B. (1961). Open operating room doors and *Staphylococcus aureus*. *Hospitals (Journal of the American Hospital Association)*, 16 March.

arrive tired and wish to sign on with minimum fuss. To avoid queues at the registration booths, all queries should be referred to the secretariat. Any delegate who is unable to produce a congress registration card should be escorted personally to the secretariat, where the problem should be resolved. The common cause of a problem is usually a lost card (in which case a duplicate may be issued), or perhaps registration fees have been paid late, in which case no card would have been issued. It is not unusual for delegates from Eastern Europe to prefer to pay on arrival.

Queries may also arise over tickets for the various social events and here you reap the benefit of being able to produce, from the

same plastic envelope as the record card, the delegate's original ticket application form.

A cashier is essential in the registration area to handle registrations, including day registrations and ticket payments. Life is much simpler if only *one* person handles cash and if they have proper facilities.

Throughout the conference, and especially during peak registration times, members of the local organising committee should be constantly on hand to deal with contingencies and also to introduce themselves to any delegate who looks lost. The impression this gives, and justifiably so, of looking after your delegates, greatly helps the success of the entire project.

Hospital Topics

Isolating patients in hospital to control infection*

Part III—Design and construction of isolation accommodation

K D BAGSHAWE, R BLOWERS, O M LIDWELL

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Good isolation practice is easier in a well-designed building. Easy, direct, and short-distance access to patients, supplies, and facilities lightens the nursing load, thereby giving more time for the proper observance of isolation procedures. There is, however, a potential conflict between the advantages of compact planning and the increased possibilities that this affords for transfer of micro-organisms between patients, by contact and airborne routes. Segregation of patients from each other and separation of clean from potentially contaminated materials is of first importance in creating an effective isolation complex. Reconciling these factors in a practical way is the problem of isolation-unit designs.

Remoteness

It is common experience that infection with particular strains of micro-organisms may be widespread in one ward of a hospital but spread only slowly, if at all, to other ward units. Several factors might be implicated. There will be different nursing and probably domestic staff for each ward, although auxiliary and,

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to some extent, medical staff may be in common. The wards are usually physically separated from each other by stair-wells and corridors or may be in separate buildings; this will reduce considerably the possibilities of airborne transfer. There will also be a time interval for any contact transfer between the separate units, and during this time micro-organisms might die or be lost from clothing.

These factors that reduce the transfer of microbes between ordinary wards are still more relevant for an isolation unit that is physically separate from the rest of the hospital. For example, hand-washing and clothing changes are more likely to be performed; regulations for restricted access are more likely to be observed. The use of "tacky" mats at the entrance is probably of little bacteriological importance but will improve the general cleanliness within the unit, which may encourage high standards in other respects.

The open ward

If a patient is to be isolated in an open ward the isolation area should be defined as generously as possible and demarcated by washable screens. Selection of the area should take account of ward traffic, location of wash-bowls and toilets, etc. Tables or trolleys for supplies from the central sterile supplies department (CSSD) should be available and a generous supply of bags provided for disposing of contaminated articles. Good lighting is necessary. Clear notices with instructions to exclude cleaners, etc., are important.

VENTILATION OF OPEN WARDS

Good ventilation is a traditional requirement. It does not seem likely, however, that mechanical ventilation of large wards can have any substantial value in controlling hospital cross-infection; the possible reduction of airborne contamination by this means is slight. It is possible to design the ventilation of a

subdivided ward so as to reduce substantially airborne-particle transfer between rooms, by a system in which all the sections are supplied with excess air while the corridor acts as a common air drain, or alternatively all the sections have excess extract and air is supplied from the corridor supply.^{1 2}

The airflows needed and the degree of effectiveness will depend on whether or not doors are kept closed and on temperature differences and wind pressures acting on the building. It is not usually practicable to keep doors closed except in a specifically designated isolation unit. If doors are often open the excess air volumes required to maintain unidirectional flows over the whole door aperture are about 0.3-0.4 m³/second (500-700 ft³/min)³ with temperature differences as low as 0.5°C (1°F). In a fully air-conditioned building, however, where the temperatures are uniform, as little as 0.1-0.2 m³/second (200-300 ft³/min) may be enough.² Although airborne-particle transfer may be a hundredfold less than in an unventilated unit, it is very doubtful whether any clinical benefit results. With normal nursing the opportunities for transfer of micro-organisms by direct or indirect contact and from resuspended airborne material derived from contaminated clothing are great.⁴

AIRCURTAIN BEDS

Attempts have been made to provide a clean environment for a patient still remaining in a general ward. Air drawn from the ward is passed through high-efficiency filters and discharged over the patient, either vertically downwards from an overhead canopy or horizontally from a panel behind the bedhead. Without impermeable side curtains the effectiveness of the air jets in containing the clean air and preventing ingress of contaminated air is limited.⁵ This reduction is probably not worth while. If side curtains were provided the result would be equivalent to a single room with a high level of ventilation, which could be designed to be either positive or negative with respect to the general ward area. If effective barrier-nursing procedures were then used good isolation should be possible.

Single rooms: ventilation and airlocks

Airborne transfer of infective material between the rooms of a ward or isolation unit may occur in various ways (see part I). For controlling these methods of transfer, several methods of ventilating rooms can be considered.

SIMPLE DIRECTIONAL VENTILATION AND SINGLE DOOR TO CORRIDOR

Fig 1 shows two types of simple directional ventilation in a room with a single door into a corridor. In (a) the air is extracted from the room and made up from the corridor. No special conditioning plant is required, and the room is suitable for isolating infective patients. In (b) air is brought into the room and discharged into the corridor. Air-conditioning equipment is

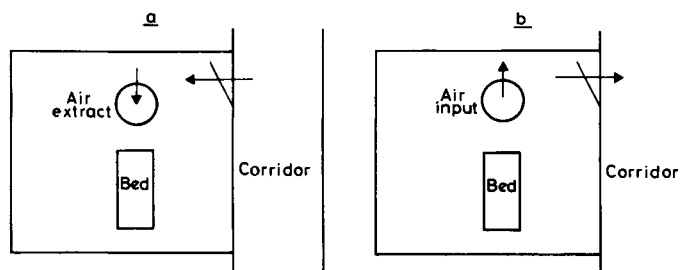


FIG 1—Simple ventilation arrangements for isolation room: (a) extract from room; air enters from the corridor through doorway or gaps around door; (b) input to room; air passes into corridor through doorway or gaps around door.

needed unless a recirculating system taking air from the corridor through a filter is used.⁶ This system is suitable for isolating susceptible patients.

These systems need only simple engineering and there are no problems of balancing airflows, so that malfunction and reversed air flows are unlikely to occur. In practice single doors are often left open, which encourages unnecessary entry to the room and increases air exchange with the passage. At least 0.1-0.2 m³/second (200-300 ft³/min) is needed to prevent air exchange across an open doorway; if there is a temperature difference of no more than 1°C (2°F) between the room and the corridor this figure will be more than doubled.³

If all the rooms in a unit are ventilated in the same way (a) and (b) give similar degrees of protection from airborne contamination between rooms. The effective improvement over an open situation is about a hundredfold⁷; (a) keeps the corridor free from contamination from patient sources in the isolation rooms but exposes the patients to airborne material from the corridor; (b) uses the corridor as a kind of air sewer but protects patients in the rooms from the corridor.

It is usually unnecessary to provide grilles or other apertures for the airflow; gaps round doors and other structural cracks generally leave enough room for air to escape.

If the doors to the patients' rooms are kept closed the efficiency of the system can be greatly increased. By using close-fitting doors, eliminating other leaks into the corridor, and providing alternative input or discharge ports that do not communicate with the corridor, the airflow from or to the corridor—which ever corresponds to the design direction—can be reduced to less than 0.03 m³/second (50 ft³/min). The resulting improvement in air isolation between rooms may be tenfold or more. Reverse flow will occur only when the doors are opened.⁷

DIRECTIONAL VENTILATION WITH LOBBY AND HATCHES

Adding a lobby or airlock improves the air isolation, possibly by a factor of 10 compared with the simple arrangements of fig 1.⁷ Either direction of airflow may be used with the same advantage of engineering simplicity and reliability. The lobby and hatches do, however, facilitate better control of contact transfer (see fig 2). Doors will more often be kept closed, with a

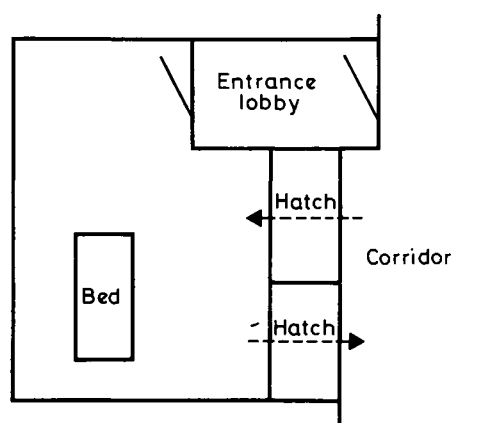


FIG 2—Addition of unventilated entrance lobby and pass-through hatches to room layout; broken arrows indicate movement of materials. Room ventilation may be as indicated in fig 1 (a) or (b).

reduction of entries and exits. Because only one door to the lobby is open at a time it is necessary only to maintain the desired direction of airflow around the doors and through other gaps. This may be done with quite small air volumes even if there are appreciable temperature differences between the room and the corridor; 0.05-0.1 m³/second (100-200 ft³/min) is probably adequate.

A two-bed dismountable isolation unit has been designed by the Atomic Energy Research Establishment (AERE) for the Department of Health and Social Security.⁸ This incorporates several interesting design features. It seems unlikely that isolation rooms will, in fact, often be dismantled and moved and erected elsewhere in a hospital; the equipment needs to be considered primarily as a convenient and possibly cheap way of providing additional isolation facilities.

TWO-WAY ISOLATION WITH A VENTILATED AIRLOCK

With a ventilated airlock it is possible to isolate a room in both directions simultaneously and to obtain a high degree of protection against airborne room-to-room transfer (fig 3). For example, the degree of protection may be about 10 000 times that found in an open situation, and considerable isolation may be maintained between room and corridor.^{7 9 10} There is no difference in this respect between input to or extract from the airlock but the extract arrangement reduces transfer into the room of any contamination generated in the airlock itself and is therefore preferable.

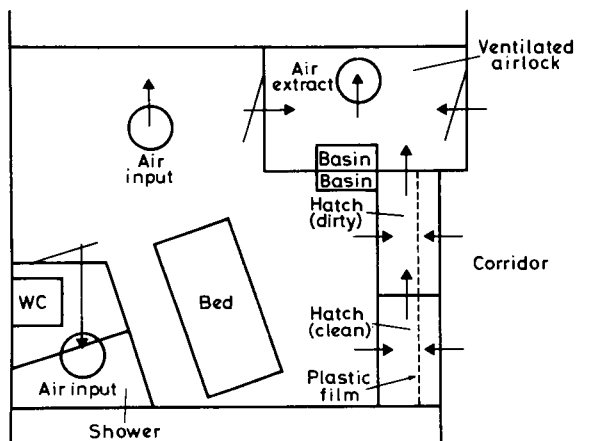


FIG 3—Isolation room with extract-ventilated airlock, toilet, and pass-through hatches. Arrows indicate directions of airflow.

When there is a room supply of air of 0.1–0.15 m³/second (200–300 ft³/min) about half may be extracted from the room (including extract from the toilet). If 0.1–0.15 m³/second (200–300 ft³/min) is extracted from the airlock about half this will be drawn from the room and an equal volume from the corridor. To maintain the isolation across pass-through hatches part of the airflow—perhaps one-third of the total—should be directed through these.

This system demands a more elaborate ventilation system than other arrangements; in particular the input and extract air volumes must be maintained in the appropriate relation; the maximum tolerance in the designed volumes will be about $\pm 25\%$. Actual installations are usually unsatisfactory in this respect.^{10 11}

UNIDIRECTIONAL (LAMINAR) AIRFLOW

The need for dust-free environments for industry has led to the development of high-efficiency air filters which are used to provide particle- and microbe-free air as a directed non-turbulent flow which sweeps out the working space. This arrangement has been applied to the care of highly susceptible patients.^{12 13} Because it is relatively easy to reduce airborne contamination to a level at which contact and autogenous infection become predominant even with the best precautions against these, some of the technical requirements for ventilating patient

rooms may be considerably less rigorous than for industrial work. The linear air velocity needed to reduce turbulence sufficiently for unidirectional horizontal flow to be established appears to be no more than 0.15–0.25 m/second (30–50 ft/min),¹⁴ and even 0.1 m/second (20 ft/min) may suffice in a downflow room.¹⁵ A filtration efficiency of 90% to the US standard DOP test or BSI sodium-flame test (using particles of 0.1–0.2 μ m in diameter) is probably adequate to reach limiting air sterility in the room. Noise control is, however, a major concern and ratings of no more than NC 35–40¹⁶ are required. (This scale takes account of noise concentrated at particular parts of the frequency range.) It has been claimed that this form of ventilation actually reduces autogenous infection,¹⁷ which suggests that this is sometimes airborne.

It is possible to use this form of ventilation to isolate several patients in one room without partitions (fig 4).¹⁵ This may be

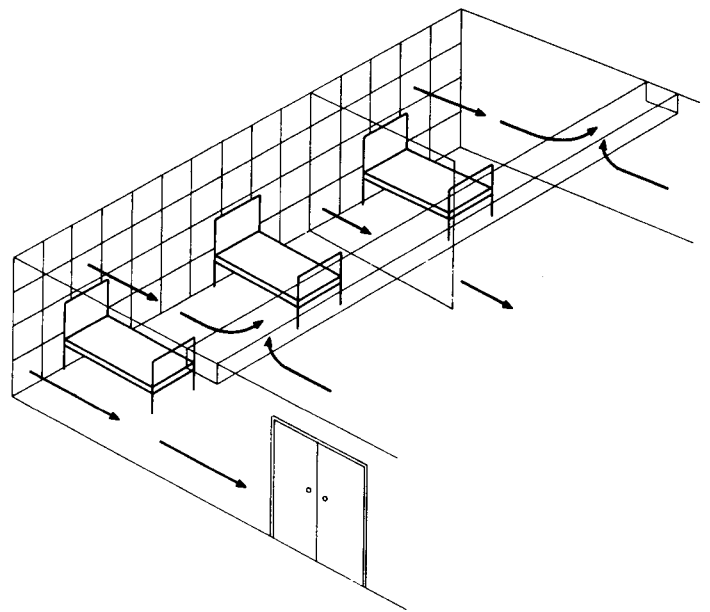


FIG 4—Open-ended multibed unit ventilated by a unidirectional airflow. Air enters through the filter bank behind bedheads and is extracted through slot in roof. Only about 10% of airflow passes into downstream end of the room beyond roof slot. Screens or curtains may be positioned between beds.

advantageous for patients who need much nursing and supervision and for those with claustrophobia in single rooms. Those who come into direct contact with the patients must obviously practise non-contact techniques—for example, with regard to clothing, hand preparation, etc—but others who enter the room for activities not needing patient contact need observe only minimal precautions if they remain downstream or to the side of the patients.

With this form of ventilation about 90% of the air is recirculated with the addition of enough fresh air to control smells, carbon dioxide, and other gases. Full air-conditioning is required to control heat gain from the fans. The cost is considerable but convenience and comfort are high and the level of isolation that can be attained is limited only by the measures used to reduce contact transfer. The ease of access itself makes considerable demands on aseptic discipline.

Plastic isolators and ultraviolet light

“Wrapping” the patient in a sterile bag to isolate him from the outside environment is another possibility. The “bag” is held on a frame to give the patient space; is ventilated with a filtered air supply, which may be unidirectional; and is provided with ports for introducing and removing materials, and with

glove ports or invaginations for nursing procedures.¹⁸ Some designs also incorporate enough space around the bed for the patient to sit, stand, or even walk a few paces. Toilet accommodation can also be provided. Such systems seem to approach the ultimate in isolation, but carry inherent difficulties in management.¹⁹

Ultraviolet light has been used as part of isolation systems, especially as a barrier at room doors. There are some difficulties associated with its effect on skin and eyes; the need to screen the lamps from direct vision, unless protective clothing is worn, reduces their effect considerably. Calculations do not suggest that sufficient intensity can conveniently be used to provide an effective barrier to airborne micro-organisms carried on air currents through an open doorway. But irradiation of airlocks may somewhat reduce airborne bacterial transfer through them.²⁰ Whole-room effects, obtained by irradiation of the air above 2 metres (7 ft), do not exceed those obtained by dilution ventilation and are probably not large enough to be useful. The bactericidal effect of ultraviolet irradiation is less at high relative humidities.²¹

Doors and communications

Doors in isolation units introduce some difficulties. Swing doors need space in which to operate, which may be particularly difficult to find in airlocks, and cause considerable air disturbance. Sliding doors may overcome both these disadvantages, but they are mechanically less satisfactory and need more effort to operate. The grooves in the floor or the hollow spaces into which some doors slide may collect dirt and be difficult to clean.

The need to operate a door handle is inconvenient when something is being carried and provides a possible route for bacteriological transfer via the handle. Mechanically operated doors are becoming more widespread and more reliable. Operation may be by foot pressure or photoelectric; hand press-buttons defeat one object of mechanical operation. The AERE isolation unit⁸ incorporates simple mechanically operated sliding doors.

Restricted access from outside the unit needs to be accompanied by means of communication from the entrance to some point within, preferably by two-way telephone, if there is no receptionist or secretary at the entrance. In a unit of any size a means of locating and communicating with nurses from some central point avoids much wasted time. This may be combined with the patient-call system or integrated with a centralised hospital communications system, such as the Cass system.²²

Many isolation rooms, especially when provided with entrance airlocks and toilet facilities, are effectively cut off from direct communication with the access corridor. This is often disliked by the patients and introduces unnecessary difficulties in nursing. For some patients the sense of abandonment leads to appreciable psychological problems.⁷ This aspect of design has usually been ignored by medical staff and architects alike. The design layout in fig 3 allows good direct vision for patient and nurses and if a speaking panel or window of unperforated plastic (as in the AERE design⁸) is used, direct speech is also possible. The provision of separate pass-through hatches for clean and dirty supplies in the area below the inner window allows separate circulation of these two classes of materials and eliminates the need for many entries into the isolation room itself.

Some units have been designed so that visitors can see and speak to the patient without entering the unit. Providing a special corridor for this purpose is expensive. Visitors are usually less of a bacteriological hazard than the hospital staff, and if they take the same precautions with regard to clothing, etc, as the nursing staff they may generally be allowed to enter the patient's room. When this is undesirable, as for the extremely susceptible or highly infectious patient, the use of plastic speaking panels may provide adequate communication

similar to that afforded by a visitors' corridor. It will be more acceptable if the layout can be arranged to provide some privacy.

Materials and finishes

Smooth, clean, impervious surfaces without lodgement for dust are obviously desirable. In the extreme their effect can be acoustically and visually repelling. In most places perforated acoustic ceiling materials are bacteriologically unobjectionable. Washable vinyl-faced or vinyl-sheet wall coverings are satisfactory. Noise and the risks of falls are reduced by soft-backed vinyl flooring.

Easy cleaning is important because the appearance of cleanliness is valuable, and minimal maintenance is especially important when some cleaning has to be done by the nursing staff. For strict isolation the fewer patient-staff contacts the better.

Engineering

The requirements for wash basins are discussed below. Avoidance of any risk of bacteriological contamination of the water supplies, as in holding tanks,²³ is clearly more important than usual for highly susceptible patients.

Water closets should be siphonic to reduce aerosol dispersal during flushing^{24 25}; for extreme forms of protective isolation exhaust ventilation of the pan may be useful.²⁶

The cost of ventilation plant is high, but a high proportion of installations rarely or never function in accordance with the design specification. It is therefore important that an adequate testing programme should be completed before the work is accepted and that this forms part of the contract.¹⁰ Account should be taken in the testing programme of the possible effects of varied weather, especially winds. Good regular maintenance is equally important. This is more likely to achieve its object if there are visual indications, preferably in the isolation unit itself, that critical airflows are within the design limits and that the directions of airflow are correct.

Control of relative humidity (humidification) is likely to be needed for some patients, such as those with exposed burns and those who have undergone chest operations. It will be needed more often if temperatures are kept above 22°C (72°F), which may be advantageous in that it reduces the amount of bedding needed.

Filtration of outside air will rarely need to be better than that recommended for the surgical operating room²⁷—that is, to 5 µm—unless there are problems of dust staining. Recirculation or the need for unusually high degrees of bacteriological cleanliness may call for filtration to 90% against 0.1–0.2 µm particles as indicated by the DOP or sodium-flame tests. Contamination of ducts is slight under normal conditions and re-dispersal rare.²⁸ There has been vigorous advocacy of terminal filters. These undoubtedly eliminate any small risk there might be from the ducts and may be taken down and cleaned or replaced after an especially infectious patient, but in most circumstances the extra cost does not seem to be justified. In any case the diffusers should be easily cleanable because air turbulence often leads to substantial dust deposits on them from the air of the room.

Isolation rooms should be designed so that, so far as possible, engineering maintenance can be done by staff working outside the rooms.

VALUE OF SUBDIVISION AND VENTILATION

Building design and, in particular, ventilation and air-movement control are primarily relevant when the infecting agent is transmitted by airborne material. In general, the potential for transmission by contact is much greater than by

the airborne route but varies according to the nature of infection and the nursing regimen.

There is almost no information to indicate how large a reduction in airborne exposure should be aimed at in any given circumstance. There is, however, reason to think that reductions of less than a factor of 10 are not valuable. Whenever the population exposed to risk varies substantially in susceptibility the number infected will vary less than any variation in exposure.²⁹ Observations on nasal acquisition of *Staphylococcus aureus* suggest that this effect may be large. The risk of nasal acquisition of this organism appeared to vary less than the change in the inhaled dose and no more than one-half to one-fifth power of the inhaled dose.³⁰

References

- ¹ Smylie, H G, *et al*, *British Medical Journal*, 1971, **1**, 67.
- ² Foord, N, and Lidwell, O M, *Journal of Hygiene*, 1975, **75**, 15.
- ³ Shaw, B H, and Whyte, W, *The Building Services Engineer*, 1974, **42**, 210.
- ⁴ Lidwell, O M, *et al*, *Journal of Hygiene*, 1975, **75**, 445.
- ⁵ Lowbury, E J L, *et al*, *Journal of Hygiene*, 1971, **69**, 529.
- ⁶ Williams, R E O, and Harding, L, *Journal of Hygiene*, 1969, **67**, 649.
- ⁷ Lidwell, O M, *Hospital Update*, 1977, **3**, 261.
- ⁸ *Nursing Times*, 1971, **67**, 1893.
- ⁹ Lidwell, O M, *Journal of Hygiene*, 1972, **70**, 287.
- ¹⁰ Abel, E, in *Airborne Transmission and Airborne Infection*, ed J F Ph Hers and K C Winkler, p 519. Utrecht, Oosthoek, 1973.
- ¹¹ Hambræus, A, and Sanderson, H F, *Journal of Hygiene*, 1972, **70**, 299.
- ¹² Bodey, G P, Freireich, E J, and Frei, E, *Cancer*, 1969, **24**, 972.
- ¹³ Levine, A S, *et al*, *New Zealand Journal of Medicine*, 1973, **288**, 477.
- ¹⁴ Lidwell, O M, and Towers, A G, *Journal of Hygiene*, 1969, **67**, 95.
- ¹⁵ Lidwell, O M, and Towers, A G, *Lancet*, 1972, **1**, 347.
- ¹⁶ National Physical Laboratory, *The Control of Noise*. London, HMSO, 1962.
- ¹⁷ Burke, J F, in *Proceedings of International Conference on Nosocomial Infection*, ed P S Brachman and T C Eickhoff, p 216. Chicago, American Hospital Association, 1971.
- ¹⁸ Levenson, S M, *et al*, in *Research in Burns*, ed A B Wallace and A W Wilkinson, p 563. Edinburgh, Livingstone, 1966.
- ¹⁹ Levitan, A A, *et al*, *Journal of the American Medical Association*, 1968, **203**, 105.
- ²⁰ Ayliffe, G A J, *et al*, *Journal of Hygiene*, 1971, **69**, 511.
- ²¹ van den Ende, M, Bourdillon, R B, and Lidwell, O M, in *Studies in Air Hygiene*, Medical Research Council Special Report Series No 262, p 176. London, HMSO, 1948.
- ²² Galley, J, *Health and Social Services Journal*, 1977, **87**, 968.
- ²³ Bassett, D C J, Stokes, K J, and Thomas, W R G, *Lancet*, 1970, **1**, 1188.
- ²⁴ Newsom, S W B, *Lancet*, 1972, **2**, 700.
- ²⁵ Bound, W H, and Atkinson, R I, *Lancet*, 1966, **1**, 1369.
- ²⁶ Darlow, H M, and Bale, W R, *Lancet*, 1959, **1**, 1196.
- ²⁷ Report, *Ventilation in Operation Suites*. London, Medical Research Council and Department of Health and Social Security, 1973.
- ²⁸ Whyte, W, *Journal of Hygiene*, 1968, **66**, 567.
- ²⁹ Lidwell, O M, in *Infection in Hospitals*, ed R E O Williams and R A Shooter, p 49. Oxford, Blackwell, 1963.
- ³⁰ Lidwell, O M, *et al*, *Journal of Hygiene*, 1975, **75**, 445.

MATERIA NON MEDICA

"Turn down the sound, you're disturbing the elephants"

We woke at dawn in a train trundling slowly through the African bush to the sight of wildebeest, gazelle, and giraffes browsing unconcernedly at the side of the track. This was not the end of an exotic holiday or the last lap of a long safari. We were, in fact, returning from the annual meeting of the Kenya Association of Radiologists.

Once a year we hold an out-of-town meeting, both to let the non-Nairobi members take part and to enable us to have a scientific and social get-together in pleasant surroundings. This year's meeting was held in a coast hotel near Mombasa, where the off-season temperature was kept to a cool 29°C by the brisk south-east monsoon. Our small group managed to produce a scientific session of a reasonable standard with interest added by a variety of unusual cases from leukaemic kidneys to calcified splenic cysts. It would, however, be surprising to a British radiologist to be shown films of Paget's disease, asbestosis, and diverticulitis as examples of rare conditions.

Business over, we relaxed with a swim in the Indian Ocean followed by a dinner-dance held under the stars and gently blowing palm trees.

Last year's meeting was in the no less exciting setting of Tsavo National Park. From the lodge bar, between papers, we were able to view a variety of game at the water-hole against the magnificent backdrop of the snow-capped Kilimanjaro, while inquisitive ground squirrels searched for crumbs around our feet and tropical birds added their brightly coloured plumages to the scene.

Such exotic settings for meetings are, however, not without their disadvantages, or, as we were told by the lodge manager at our evening film, "Turn down the sound, you're disturbing the elephants!" JOHN F CALDER (radiologist, Nairobi).

Seeds of time

Hearing that the garden of a well-known medical institution in London had lost all its foxgloves, I said I would be happy to supply some more seed. Returning home, I thought how much more appropriate it would be if I got the seed from William Withering's former country seat, a short walk away. Edgbaston Hall is hidden behind the Old Church where he is buried, an imposing, Georgian, red-brick mansion overlooking extensive parklands. Now the site of a peaceful golf-course and a 50-acre lake inhabited by geese, duck, and grebes, the estate seems far removed from those lawless days in 1791 when the Birmingham mob, infuriated by dissenters celebrating the French Revolution, burnt down Joseph Priestley's home and threatened to do the same to his friend Withering's. The surrounding

woodland has recently been taken over by the University as a small nature reserve, and we had joined an extra-mural class to study its ecology, so it was not difficult to collect the seed, and it was duly dispatched.

Earlier this summer we stood in Gloucestershire fields on a beautiful evening admiring the remains of a Roman village being excavated near Kingscote. On a heap of rubble to one side a group of magnificent poppies tinged blood red by the dying sun reminded us of flowers we had seen in the Mediterranean. "Oh yes," said the custodian proudly, "those are Roman poppies." Driving back we laughed at the woman's naiveté; after all, seeds were carried across fields by the wind or scattered by birds. And then I suddenly remembered my Withering foxgloves: I too was guilty of romanticising, but could cold reason prove either of us wrong?—ALEX PATON (physician, Birmingham).

The vision splendid

If, as I do, you travel a good deal by air you get used to sunsets. The plane, flying into them, prolongs the picture almost interminably and often only with a persistent gold or red rim. Flying away from the sun leads to a rapid depressing suffocation of day, guaranteed to make me reach for my novel and my martini. But to fly across a sunset can be an emotional experience without equal. I've done it often enough—helicoptering into doubtfully secure fire bases, homing from the Australian outback, and merely commuting from city to city in various continents.

Nevertheless, only occasionally does one in Banjo Peterson's words see "the vision splendid." It was my good fortune to catch such a moment flying from Aberdeen recently. Somebody celestial had daubed a streak of smoky red horizontally across the upper azure sky. Below this, from an altitude of 29 000 ft, what another poet called "the upshot beam" was tinging the underbelly of cloud with a pink that in some subtle way interacted rather than clashed with the upper heaven. As ever, the beam was due to fade both as the sun marched westward and the aircraft descended, but not before a last lingering flash of salmon-coloured cotton wool wiped the western horizon clear of detail.

Out of curiosity I looked to my fellow passengers. Only one on the west side of the aircraft was sharing my experience. Most obvious were a quartet of well-organised television executives, whose casual clothes, good suntans, and repeated bar orders exuded the confidence of their self-created, if artificial, environment. They played cards and the beauties of their immediate surroundings were as if they had never been. As the lofty shade advanced, their loud voices established a pseudo-reality and I returned to scribbling a grant application—HUGH DUDLEY (professor of surgery, London).

Guidance on ventilation revised and updated

Speaking in the 'System Governance' stream on the first day of last October's IHEEM Healthcare Estates 2021 conference, consulting engineer, Malcolm Thomas, the main author of the 2021 version of HTM 03-01, *Specialist Ventilation for Healthcare Premises*, published last June, explained the background to, and aims behind, the HTM's revision, and highlighted some of the major changes that those responsible for ventilation plant in hospitals and other healthcare facilities need to be aware of. *HEJ* editor, Jonathan Baillie, reports.

Malcolm Thomas was the lead author for both editions (published in 2007 and last year) of HTM 03-01, and also of the ventilation-related HTM 2025 that preceded them. Also the lead author of the engineering section of several HBNs, he has worked in the healthcare sector for over 40 years – both within and outside the NHS. He is President of the Specialised Ventilation for Healthcare Society, and a visiting lecturer at the University of Leeds. Welcoming attendees to his presentation, he explained that as the lead author of HTM 03-01 (2021), he would explain some of the main thinking behind it, and set out the reasons for a number of key changes in the 'rewritten version'. He began: "As some background to where the HTMs and other guidance on ventilation originated, back in 1972 Dr Owen Lidwell led a Joint Working Party on ventilation and operating suites, and this was the foundation of all the guidance that has emerged since. Many people have asked me," he continued, "why we bother with material that is 'so old'? The reason is that when this work was done, it was very evident what worked well in practice, and what didn't, in a way that's no longer nearly so clear. When you have significant infection rates in operating theatres, it's quite easy to see whether – if you change the colour of the paintwork – it makes any difference. Conversely, with very small infection rates – which fortunately we have now – it's very difficult to know whether changing the surgeons' gowns, the air change rate, or the colour of the walls, or putting carpet in, makes any significant difference. We're talking about low percentage changes. We're in a situation now where people think changes will improve things, but they don't actually know, and it's hard to prove what is a good or a bad thing. Back when Owen



Malcolm Thomas, the main author of the HTM 03-01 (2021), *Specialist Ventilation for Healthcare Premises*, published last June.

Lidwell did this work, it was relatively easy, there were step-changes, and he was able to conduct a number of trials."

Comparative trials

Malcolm Thomas explained that in one, Owen Lidwell and his team took a particular acute hospital, and identified two operating theatres as theatres 'A' and 'B', with had two surgical teams – also named 'A' and 'B', staffing them. He elaborated: "They picked out patients at random, drawing lots to decide which theatre they were operated in. They could thus see which team and which patients fared better under certain circumstances, and thus demonstrate changes in the

outcomes in infection rate terms." From this work, and drawing on theatres with low infection rates and good patient outcomes, Owen Lidwell and his team were able to determine the optimal airflow and temperature, and consider elements such as the impact of different gowning procedures. This in turn enabled them to draw some conclusions.

"The conclusions they drew have stood the test of time," said Malcolm Thomas. Following Owen Lidwell's work, the Department of Health and Social Security – as it was then – set up a working group, and codified the ventilation of operating departments in a document called DV4, specifying what was required for the theatre, and what worked and what didn't, 'taking Lidwell's work forward'.

Request to update guidance

"When I came on board," Malcolm Thomas explained, "I was asked to update DV4, but soon after I'd finished doing this, I was told it was now going to be an HTM, and HTM 2025 was duly published in 1994. Some years later I was asked if I could I take that forward again, and HTM 03-01, *Specialised ventilation healthcare*, was published in 2007. It was delayed by SARS, and avian flu, just as the Coronavirus outbreak delayed the publication of the current version of HTM 03-01. So, all of these iterations are based on some good solid work many years ago. I've been working in this area for some time, and it's very evident that these earlier learnings have stood the test of time. Where we have encountered problems, it's generally been clear that the guidance wasn't followed."

Historical reasons for not following guidance

Among the historical reasons for failure to follow established guidance, the speaker explained, had been changing procedures in both operating suites, and other 'spaces' in healthcare facilities, while on occasions people 'had not perhaps been as careful as they should have been' –

We're in a situation now where people think changes will improve things, but they don't actually know, and it's hard to prove what is a good or a bad thing

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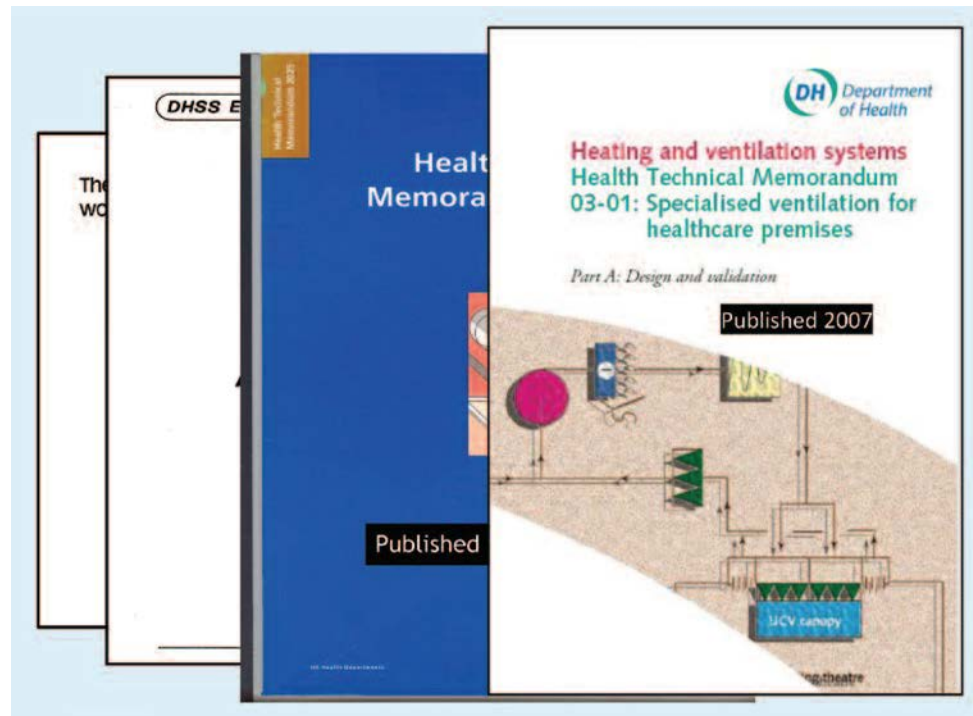
leading to 'something going wrong with the ventilation'. Malcolm Thomas said: "Put the people right, and – if I can put it like that – we'll get the ventilation right. There's a good pedigree, a good history, and we can have some confidence in past learnings and guidance. It isn't just people's opinion; it's what works." 'Backing this up, he added, was 'a fair amount of ongoing research by Department of Health, the NHS, and private companies', with the findings taken on board when HTMs were revised and updated. He said: "So, in these guidance documents we try to avoid just featuring people's opinion of what works and what doesn't, and instead coming down to some facts. History appears to show that this is a correct way of doing it."

Do we need the HTM guidance?

'Back in 2017/18', he explained, when it was decided to look at revising HTM 03-01, one of the questions asked had been: 'Do we need it?' He explained: "We have, in fact, been trying to reduce the amount of guidance issued, because at one point there were something like 400 different pieces of guidance, and it's almost impossible to keep that sort of volume of guidance up to date." Over the years there had thus been some 'pruning', together with a 'focus on what is different about ventilation in healthcare'. The speaker said: "What matters to us is, for example, whether CIBSE guidance on ventilation is adequate. If so, that's great, but if not, do we need to do more than CIBSE is suggesting, or perhaps less in some cases? Things that CIBSE would allow may not be what we want to do. They may not be appropriate in a hospital or other healthcare setting. So," he said, "having decided we did indeed need HTM 03-01, we questioned whether it needed updating, and, having determined that it did, began looking at how." This resulted in a 'scoping exercise' which ran for over a year with wide-ranging consultation, to look at what was in the documents, whether the HTM could just be given 'a dust down' and a little updating, or whether indeed some fundamental changes were needed. He said: "That led to the move to produce a new document, in two parts, with part A on design and installation for those putting in something new, and Part B about how you manage an existing healthcare ventilation system."

A 'complete re-write' required

He continued: "It was decided that Part A needed to be completely rewritten, it having become clear from the scoping exercise that in existing form it assumed that designers knew what the healthcare industry needed." "Interestingly," he added, "back when I authored the HTM for the first time, I was told: 'Well, you



The latest iteration of HTM 03-01 – on which Malcolm Thomas primarily focused – followed several previous guidance documents on healthcare ventilation.

can't put that sort of thing in, Malcolm. People who do these things already know what they're doing.' On the contrary though, it became very evident – and particularly with the PFI process – that a lot of people designing hospitals and hospital systems in fact had no idea what their customer wanted."

Historical context

Here Malcolm Thomas showed slides of Owen Lidwell's report, followed by DV4, then HTM 2025, and then HTM 03-01, both in 2007 form and in the latest iteration. Referring to HTM 03-01 (2021), he said: "It was decided that we should produce the latest HTM 03-01 in two parts – it was clear that Part A needed to have more of an explanation, not just of what we wanted, but why – so that people understood the importance of things. We thus changed the title, the Concept, the Design, Specification, Installation, and Acceptance Testing – the whole process. We tended in the PFI days to say: 'Give us a new hospital, and give me the key when it's finished', and clearly that wasn't a good idea. While we have some very good hospitals, constructed and built and working well, some were much less successful than they should have been. Part A of the 2021 HTM 03-01 thus refers both to all new installations, and to refurbishments and changes in use of existing installations. I would stress that it's not retrospective; you don't have to rip everything out and re-start. However, if you're in the middle of the project, and you find that the new HTM would suit you better, then providing everybody else agrees, and

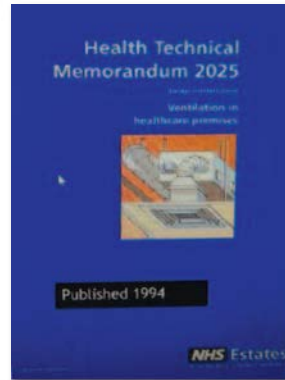
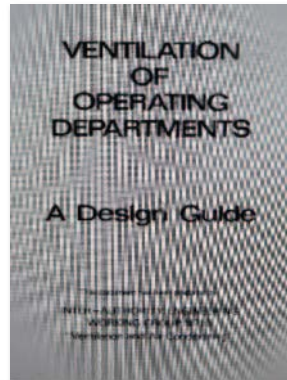
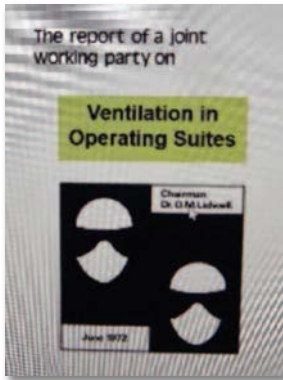
you've addressed any cost implications, there's no reason why you can't move over to the new standard." This, Malcolm Thomas said, applied even where a project team was working to guidance set out in the 'old' HTM."

Part B of the new HTM

He continued: "Part B is about the management, operation, maintenance, and routine testing, of existing healthcare systems. It's much as it was, but there are some additional changes. The thing to remember with Part B is that it applies to all installations; it doesn't matter how old." He continued: "I'm often told a hospital installation dates from the time of HTM 2025, and that's why it doesn't conform. However, the minimum standards have been there ever since that HTM was published; in fact they were introduced because of the Stafford outbreak and Legionnaires' disease in 1986, and were in the Big White Book, for which I wrote a section on standards for ventilation plant." These had – he said – been carried forward in every HTM since.

Moving to the 'major themes' in HTM 03-01 Part A, he said: "One thing we have had to focus on particularly is supporting the Government's zero carbon policy – so there's quite a push in terms of energy use, and how we go about things to support this objective."

Also considered in compiling the new guidance, Malcolm Thomas explained, had been the EcoDesign Directive and regulations, which he pointed out were 'legal requirements'; he was surprised many equipment manufacturers still viewed them as 'options'.



He expanded: "So, you will find, scattered throughout, little blue boxes with little aide-memoires, which highlight why the preceding paragraph is important, particularly in a healthcare setting. They are very sound ideas, so please don't depart from them."

A clarification of design parameters

The new HTM also incorporated 'a clarification of design parameters'. "There's been problems in the past with what standards we actually want," he explained. "We've now got much more of a clarification of design parameters." In terms of 'the new elements', the HTM's authors had put in the user requirements, listed under 'surgical', 'medical', 'mental health', 'palliative care', 'and so on'. He said: "We have thus sought to answer the questions: 'What does the user want, and why have we provided ventilation?', 'What's it for?', 'Is it for infection control, comfort, or to remove odours?' What's it about?' Again, it is about trying to clarify for the designers exactly what is important, and what you can do some adjustment on." He continued: "We've also introduced the concept of the Ventilation Safety Group, mirroring what we already have with the Water Safety Group, i.e. a group of Trust stakeholders made up of people from Estates, Finance, and Infection Control, and other key

Taking advantage of new technology

He continued: "On carbon reduction, we changed quite a few things to try to get maximum benefit from new technology and reduced energy use – fans being a good example." He elaborated: "Those of us who grew up with belt-drive fans know we were stuck with a particular fan speed, regardless of whether it was optimal, and with specific outputs; there wasn't much you could easily do about either.

"Nowadays, we have a whole range of more efficient fans, and more coming along; control technology has moved on – we can be more accurate in how much air comes down the system, and we don't need to build in such a big margin to allow for system deterioration over time. We've striven to take advantage of all this in the new HTM." Malcolm Thomas explained that the authors had also striven to provide background information to assist the understanding of client needs.



SOFTWARE TO SATISFY THE MANAGEMENT, TESTING AND VERIFICATION OBLIGATIONS SET OUT IN THE RECENTLY UPDATED HTM-03-01

Including

- dashboards and comprehensive logbooks
- revised standards
- asset life cycle management

Enabling

- real-time, Trust-wide analysis of Compliance
- optimal safe theatre utilisation
- improved communication
- support for zero carbon strategies



personnel, all of whom have an input, and make some decisions on the ventilation systems and their operation."

Derogations

In circumstances where somebody wanted to derogate in future, they would now need to take the matter to the Ventilation Safety Group, which must agree and sign up to the derogation. He added: "The Group must also record what the derogation was, why it was agreed, and who agreed it. It thus takes away this 'Mr Jones said it was OK'-type approach. Notice too," he said, "that somebody from Finance is involved, because some of these things have ongoing financial commitments. For example, some of the ways of installing ventilation plant mean they need more regular cleaning over time, with a financial implication ongoing for the system's lifetime, so it's essential that the Finance people are involved and recognise that if you go down that path, there needs to be provision to undertake the maintenance correctly over a period of perhaps 20 years."

Guidance on refurbishments

Malcolm Thomas explained that while the new ventilation HTM covers refurbishments and change, the old one didn't. He and his counterparts had encountered 'a lot of problems' with people refurbishing theatres, where they had 'completely gutted' an existing such facility, installed new ceilings, plastered the walls, put in new doors, a new floor, new operating tables, lamps, 'and everything', but kept a 30-year old ventilation plant. He said: "This is like buying a new car, but taking the engine out of the old one because that will save you a bit of money." He continued: "The ventilation plants are not as expensive as an operating table; you wouldn't dream of using a 30-year-old operating table, so

why consider using 30-year-old ventilation plant? We should surely be taking advantage of new technology. We want new plant with good controls, not old plant 'mashed up to save a couple of bob'. That's an important aspect which is clearly spelt out.

Natural ventilation where possible

"We have also suggested various ventilation strategies; we would like natural ventilation where practical. Such ventilation can, however, 'be tricky in the case of hospitals', Malcolm Thomas acknowledged. As he put it: "You're relying on the wind blowing, and blowing in the right direction, not too much and not too little, so it's not easy, particularly in a hospital." However," he added, "mixed mode ventilation, taking advantage of natural ventilation while it's there, and then supporting it with a fan that will come on when it's needed, and perhaps some supplementary heating etc, can be one potential solution."

Natural ventilation wasn't 'just about opening a window'. The speaker elaborated: "It's about having ventilation openings, which may be supported with some ductwork attached, with a means of adjusting the ventilation rate when the natural ventilation is available, and taking advantage of it when it is." Where full ventilation, 'which costs money', was selected, the question arose about whether it needed to run 24 hours a day, seven days a week, 52 weeks a year. He said: "The answer, in most cases, is 'no'. If there's nobody there, you can turn it off – a really good energy-efficient way of doing it. This is not new; it was in EnCO₂de for many years."

Unnecessary plant operation

Noting that people still left theatre ventilation running '24/7' to keep the rooms sterile, which was 'absolutely not

required', Malcolm Thomas explained that he and the co-authors of HTM 03-01 (2021) had expanded the 'Operating theatres' section 'quite significantly'. He said: "We've, for example, changed the parameters for air change rates to reflect what we can do to take advantage of the latest technology. We don't need to have as much slack in the systems as previously. So, the advice is much more appropriate for today, although still in line with what Owen Lidwell found worked, and history has subsequently proven right." Some of the 'old information' for where older theatres were still in use had been retained, but the new HTM 03-01 also incorporated 'a whole new set of information'.

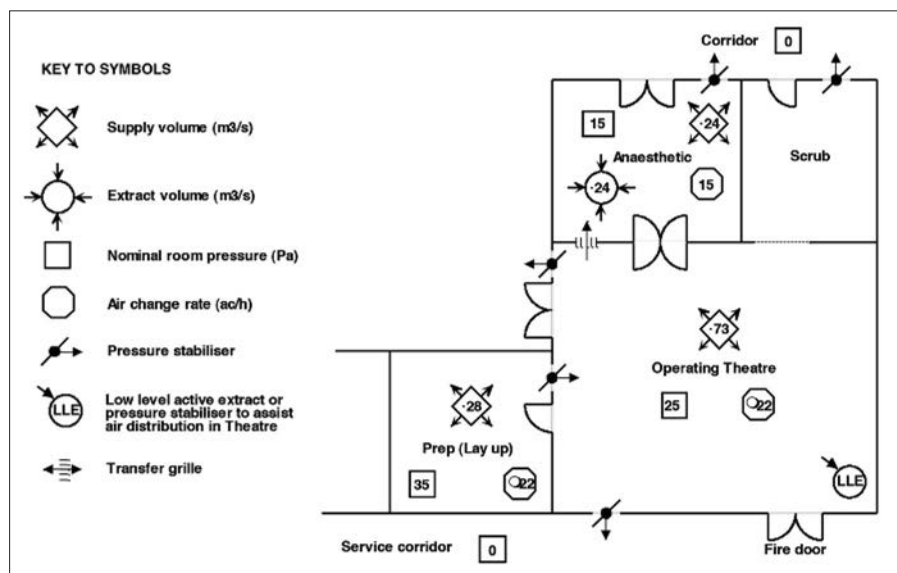
Installation guidance

Malcolm Thomas told attendees: "In a new 'Installation standards' section, we've spelt out some of the things that cause us numerous problems – including guidance on very simple things, which cost no money to do, but if not done right cost an awful lot of time and effort. So, for instance, with a basic thing like balancing damper handles, why install them at the top of the damper? When the ceiling is up, you then can't reach them. Air doesn't know where the handle is, but putting the handle on the bottom of a damper costs no more installation-wise, but means that when you come to balance, or subsequently re-balance, the system, you can reach the handle without killing yourself."

Turning to another key topic in the new HTM – 'Acceptance testing and validation', Malcolm Thomas explained that 'validation is a process of accepting the whole job, the whole project', so in the theatre, wasn't 'just about how much air goes in, but rather about where the air comes from: what the air-conditioning and air-handling unit is like, what the ductwork is like, and what the fabric of the theatre is like'. The speaker stressed that it was 'very different from commissioning', and entailed looking more holistically at 'Does it work, and can we at the end of the validation say it is safe to operate?'

Appendices expanded

The authors had also expanded the appendices 'to cover some of these things'. Here he showed a diagram of 'an example of one of new standard schemes, and the amount of air in the theatre'. He said: "The air change rate has changed, and above this, if you look in the appendices, there's a whole range of information that's much more definitive compared with what we have before. So, there are four schemes – single-corridor and two-corridor schemes for standard theatres and ultraclean, and another four



A ventilation diagram for a standard operating theatre taken from HTM 03-01 (2021).

Part A

- The Concept, Design, Specification, Installation and Acceptance testing of Healthcare ventilation systems
- Applies to all new installations and refurbishments and changes of use of existing installations
- It is not retrospective

Part B

- The Management, Operation, Maintenance and Routine testing of existing Healthcare ventilation systems
- Applies to ALL installations regardless of when they were installed
- Minimum standards for all installations

Malcolm Thomas urged all those with a professional interest in, or responsibility for, healthcare, to read and familiarise themselves both Parts A and B of the new HTM 03-01 – ‘including the appendices and the accompanying explanations’.

historical schemes for those of you with older, smaller, theatres.”

The authors of the new HTM had also created quite a lot of application-specific guidance – for instance dividing up applications into ‘Treatment and Procedure Facilities’, ‘Airborne Protective Facilities’, ‘Airborne Isolation Facilities’, ‘Maternity Facilities’, ‘Pharmacy Facilities’, ‘Sterile Services Facilities’, and ‘Extract systems and local exhaust ventilation’. Malcolm Thomas said: “We have presented that information in terms of tables.” Here, by way of example, he showed a slide of an ‘Airborne Isolation Facilities’ table, covering Isolation rooms, Categories 2 and 3. He explained: “If you want to know what the categories are, look at the bibliography in the index at the back of the HTM, and it’s all explained.” Down the side of the table were the areas or zones being discussed, with the next column highlighting the reasons and purpose of the ventilation, and the next ‘some typical design factors to help make it easier for people to understand what’s required’.

Part B

Turning to Part B and its ‘major themes’, Malcolm Thomas said that, in writing it, the authors had sought to ‘clarify things’, ‘plug up the holes’, and ‘explain more clearly what we require’. So,” he continued, “there is a legal requirement to keep records and information on ventilation systems, but many hospitals don’t, so they have broken the law.” In fact, he explained, Part B now includes a requirement for an inventory with a uniform system of identification. He said: “Go round some hospitals and they have 10 air-handling units all called ‘Air-handling unit number 1’ in 10 different plantrooms, so we obviously need to be a lot clearer. Part B thus suggests that each ventilation plant has a unique number,

corresponding to all the information about it, what it is, the spaces it serves, all the parameters and information about the equipment, the system performance over the years, and when we should ‘scrap it’. Then,” he continued, “we archive that information with its number plate, and put a new number plate on the new plant. We thus have an auditable trail. Generally, when you go around hospitals, a lot of information about systems is in people’s heads, so when they leave it goes with them.” This, Malcolm Thomas argued, was not only ‘not conducive to running an efficient system’, but was also dangerous.

Phased replacement

Part B of the 2021 HTM also discusses ‘mid-life refurbishment’, and phased plant replacement. The speaker explained: “We suggest that after 10 years, the air-handling unit should be taken out of use, cleaned, examined, and any corrosion treated, fitted with new controls, updated to get the best from the technology available, and then put back into use. After 20 years, plant should be replaced. If you don’t start thinking about this when you put the plant in the equipment doesn’t get replaced, and you then find 30-40-year-old plant still in use in the NHS. We want to take the best, get the most efficient systems, and take advantage of the latest technology; not cling to the older things.”

The Ventilation Safety Group

Malcolm Thomas explained that the Ventilation Safety Group had a key role here in getting a phased replacement programme going. He said: “With a brand new hospital, there may be 50 ventilation plants installed, all of the same age; you’ll have a mountain to climb to replace them all at the 20-year period, so you need to try to split that up somehow, and start

looking at the critical ones maybe slightly earlier.”

At any time they needed specialist guidance or help, NHS healthcare engineering teams could, of course, call on an Authorised Engineer (Ventilation) – ‘people with independent knowledge, totally independent of the Trust/Health Board’, and thus ‘there to tell you the truth’. He said: “You may not like what your AE (V) says about your ventilation, but they are there to tell you it like it is, so please listen to them. Similarly,” he added, “they should be involved in the process of providing plant to advise on what goes in. The reason I say this is – and I’ve been a hospital engineer – is that your knowledge here will be limited, and it’s very easy to be bamboozled by an outside design team into accepting something they think is alright. It may be that what’s being proposed is a great solution, but, conversely, it could be that it won’t benefit you long term. Authorised Engineers are there to help with those decisions.”

Observing standards

Nearing the end of his presentation, Malcolm Thomas said: “There are minimum standards for all plants – as I said at the beginning – and they should certainly be observed. They are there because there are legal requirements about access, cleanliness, and the efficiency of the plant, listed in both Parts A and B; most of the major pieces of legislation that affect and handling ventilation systems, in a hospital or anywhere else. In a hospital, we also have the Medicine Act, and the Health Act, which impose a duty of care on us for our patients and what we do in healthcare settings.” These, the speaker said, ‘sat alongside’ other legislation such as the Health & Safety At Work etc, the COSHH Regulations, *et al*.

Lastly, Malcolm Thomas explained, Part B of HTM 03-01 (2021) included a section on ‘Verification’. He said: “This requires you to ensure, every year, that the critical systems in your hospitals are still safe to use. They may be getting slightly older, but the things that matter within your ventilation system must still be working correctly, and then there is the annual routine inspection and maintenance. All the standards on these areas have been there for a considerable time, but need to be adhered to.”

He added: “So, to conclude, the HTM has been entirely revised, with many changes, and I would encourage all those with a professional interest in, or responsibility for, healthcare ventilation, to read and familiarise themselves with both Parts A and B, including the appendices and the accompanying explanations.” With this, he closed his presentation, and invited questions. 

The control by ventilation of airborne bacterial transfer between hospital patients, and its assessment by means of a particle tracer

III. Studies with an airborne-particle tracer in an isolation ward for burned patients

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SUMMARY

Airborne-particle transfer has been studied in a burns unit using potassium iodide particles. The observed rates of transfer were in good agreement with the values predicted by a theoretical model.

An estimate of the average transfer between rooms under conditions of normal activity and with correctly functioning ventilation showed that the isolation system was highly efficient, the proportion transferred being probably less than 1 in 10^5 . However, the ventilation often did not function as designed and under these conditions the efficiency was reduced by a maximum of a factor of ten. These rates of transfer do not seem great enough to account for the high rate of cross-infection found in this unit.

INTRODUCTION

Much effort has been expended in recent years in devising ventilation systems to reduce the airborne spread of bacteria in hospital wards, but methods for evaluating the efficiency of these are not altogether satisfactory and have only occasionally been attempted. In a preceding paper (Foord & Lidwell, 1972) a method has been described for studying airborne particle transfer between parts of a ward by use of potassium iodide particles. We now present the results of a series of experiments using this method in an isolation ward for burned patients at Akademiska sjukhuset, Uppsala. In spite of a complete ventilation system, including airlocks, earlier studies have revealed a considerable amount of cross-infection between patients in the ward (A. Hambræus, to be published). The purpose of the investigation was to determine the effectiveness of the ventilation system and hence the role of airborne bacteria as a possible cause of cross-infection. Comparison could also be made with the theoretical analysis of isolation system elaborated in the second paper of this series (Lidwell, 1972).

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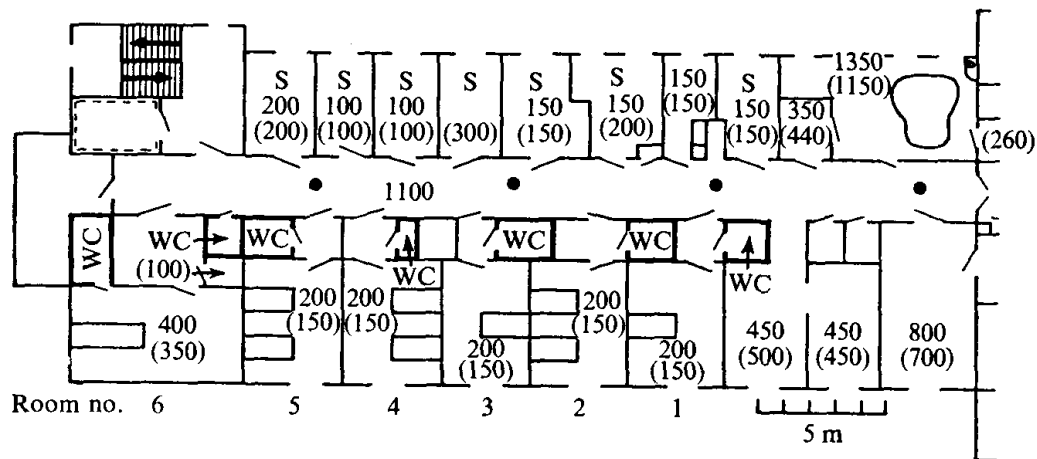


Fig. 1. Plan of the ward. Input ventilation is shown for each space as $\text{m}^3/\text{hr.}$, extract volumes are given in parentheses, an additional $100 \text{ m}^3/\text{hr.}$ was extracted from each of the patient room W.C.'s, except no. 6. The sampling sites, when room 1 was the source room, are indicated by $\bullet$; S = service room.

MATERIALS AND METHODS

Ward design and ventilation

Fig. 1 shows the plan of the isolation ward. It is entered via an airlock with double doors and a passage runs down the middle of the ward. There are five patients' rooms of similar dimensions and a sixth larger room containing an air bed. All of these have individual airlocks and they are situated along one side of the passage. On the opposite side of the passage are service rooms and the bathroom. The bathroom has three doorways; one of these opens directly to the passage for bed transport, and the other two open via airlocks; one into the passage (I) and the other into the ward airlock (II). The designed ventilation input and extract are shown in each part of the ward (the extract is in brackets). The net result is a near-balanced ventilation with little or no other air flow between the ward and the exterior.

Fig. 2 shows the air flow as designed for a typical patient room. The air input to the room is 200 m.³/hr. (which approximately equals 4 air changes/hr.). Of this input, 150 m.³/hr. is extracted directly from the room, the remaining 50 m.³/hr. passes into the airlock. A further 50 m.³/hr. is drawn from the passage into the airlock making up the total extract from the W.C. of 100 m.³/hr.

The ventilation of the bathroom is shown in Fig. 3. The designed input is 1350 m.³/hr. and the extract is 1150 m.³/hr. Airlock I has an input of 350 m.³/hr. and an extract of 440 m.³/hr., this results in a net deficit in airlock I of 90 m.³/hr. which is supplied as 45 m.³/hr. from both the bathroom and the passage. The extract from airlock II is 260 m.³/hr., this is provided as 130 m.³/hr. from both the bathroom and the ward airlock. This leaves a net surplus of air supply in the bathroom of (200-175) m.³/hr. = 25 m.³/hr. which escapes into the passage beneath the direct door.

Titanium tetrachloride smoke was used to determine the direction of air flow beneath the doors.

Isolation of burned patients

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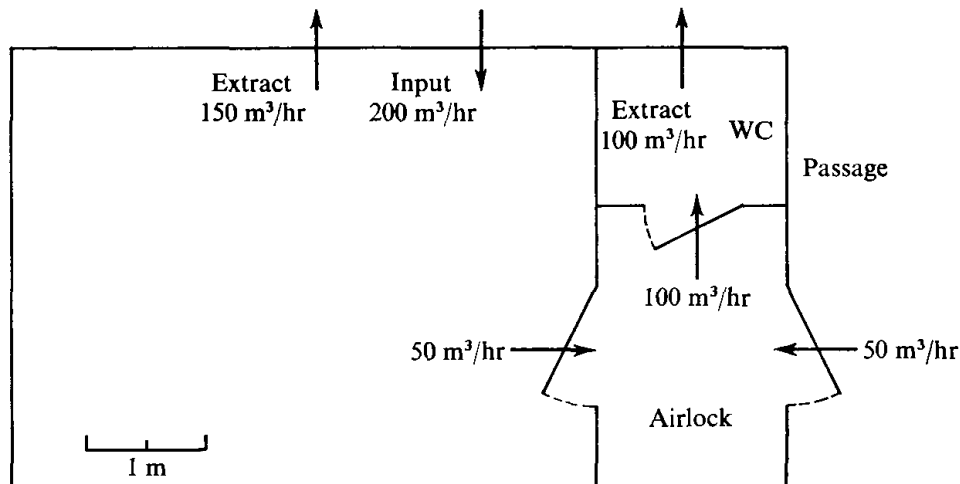


Fig. 2. Diagram showing the design ventilation of patient rooms 1-5.

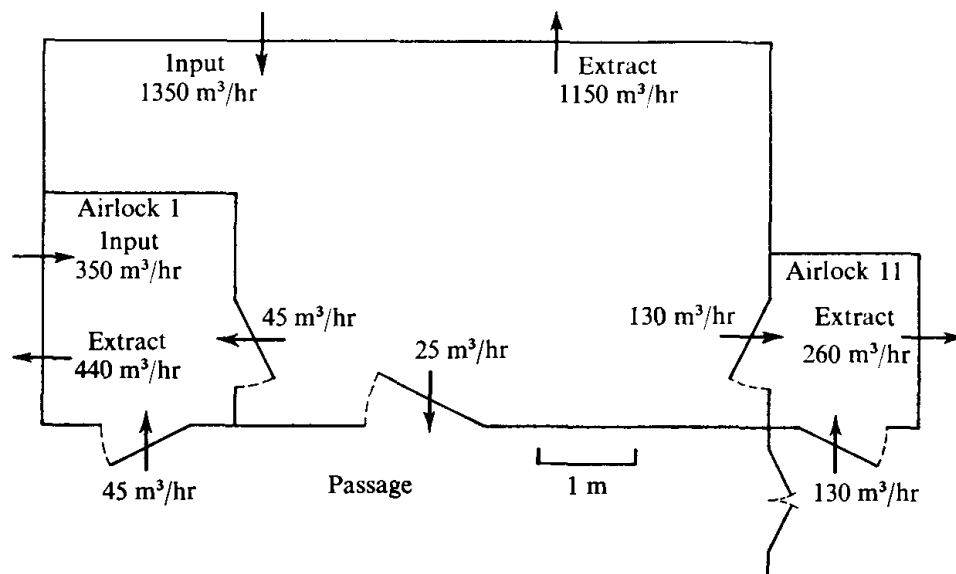


Fig. 3. Diagram showing the design ventilation of the bathroom.

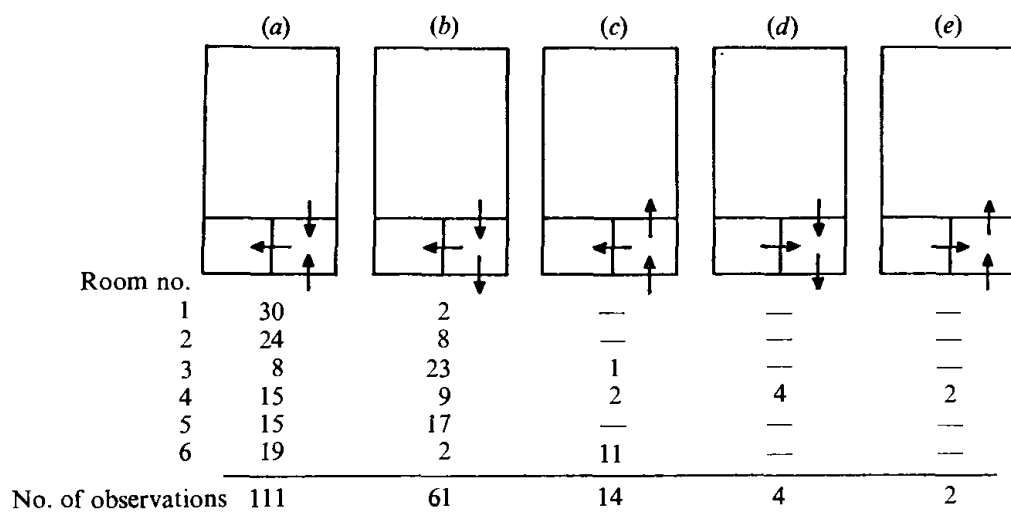


Fig. 4. Ventilation patterns observed for the patient rooms. (a), directions of air flow designed; (b), (c), (d) and (e), other observed air-flow patterns. The table shows the number of times the respective pattern was observed in the specified room.

Over a preliminary period of 32 days it was found that the designed ventilation was not maintained at all times and the frequency of variation is shown in Fig. 4. It can be seen that the commonest fault was a reversal of air flow beneath the door between the airlock and the passage, thus allowing escape of air from the room to the passage. We therefore included this type of ventilation in our experiments and all references to incorrect ventilation refer to this. The direction of air flow was checked before every experiment.

Particle generation

A spinning disk particle generator was used throughout the experiments. The rotation rate of the disk was 60,000 rev./min. and a main air-flow rate of 60 ft.³/min. (1.7 m.³/min.). The satellite air flow removes smaller satellite particles from the main air flow and this was found to operate satisfactorily at 6 ft.³/min. (0.17 m.³/min.).

Potassium iodide dissolved in methyl alcohol and supplied to the spinning disk at a rate of 1 ml./min. gave rise to a particle production rate of $c 10^7$ particles/min.

Sampling methods

Air sampling was carried out by trapping the particles on 2.5 cm. diameter membrane filters (Millipore Filter Corp.) of 3 μ m. pore size. Two types of sampler were used.

(a) Where the KI particle concentrations were high, known volumes of air were sucked through the millipore filters. Open-ended plastic filter holders were used (Foord & Lidwell, 1972). Owing to the high air-flow resistance of the filters the maximum air flow obtainable with the pumps which were available was 10 l./min. This was suitable for use with KI particle concentrations of more than 5/l.

(b) In situations where there were low particle concentrations the centripetal samplers described by Foord & Lidwell (1972) were used. These were designed to have a collection efficiency of 100 % at flow rates above 60–70 l./min. for 13 μ m. equivalent diameter particles (i.e. particles which have the same sedimentation rate as a 13 μ m. particle of specific gravity 1). A suction pressure of 20 cm. water gave a flow rate of 100 l./min. and under these conditions only 3 % of the air flow passed through the filter.

Staining. After particle collection the filters were immediately stained with 1 % palladium chloride in 0.1 % HCl.

Counting. Particle counting was performed with the aid of a low-power plate microscope and a grid. Up to 200 particles were counted.

Determination of particle size

Two ways of determining particle size are available:

- (a) By direct microscopy of particles deposited on a silicone grease coated slide.
- (b) By calculation of the sedimentation rate and hence the equivalent particle diameter by Stokes Law ($s \approx 0.002d^2$), where the sedimentation rate, s , is in units of m./min., and the diameter, d , is in units of μ m.

Methods of calculating the sedimentation rate of airborne particles are described

in 'Studies in Air Hygiene' (Bourdillon, Lidwell & Lovelock, 1948). Two independent methods of determining the sedimentation rate were used. First, from the die-away rate (K), which is the logarithmic rate at which particles disappear, $K \simeq \text{slope} \times 138/\text{hr}$. In an unventilated room K is due solely to sedimentation and thus $K = sA/V$, from which the equivalent diameter can be found (A is the area onto which sedimentation is occurring and V is the volume of air from which sedimentation occurs).

Alternatively, the sedimentation rate can be calculated from the number of particles sedimenting onto a known area when the number of particles in a unit volume of air is known. This can be represented as: no. of particles sedimenting = $s \times$ the concentration of particles in the air.

EXPERIMENTAL DESIGN

Preliminary studies to find an appropriate particle size

A small sealed room was used in which particles were generated. Different size particles are produced by varying the concentration of the potassium iodide solution fed to the spinning disk and the concentrations used were 2.0, 3.5 and 5.0 %. Particles were generated for 20 min. and 1 l. air samples were taken at 5 min. intervals during this time and for the 20 min. after particle generation had ceased. In addition filters were exposed on the bench for the last 5 min. of particle generation. The concentrations of KI gave particles with the following sedimentation rates: 2.0 % = 0.15 m./min.; 3.5 % = 0.23 m./min.; 5.0 % = 0.31 m./min.

A 5 % potassium iodide solution was used for the transfer experiments and this gave particles with a sedimentation rate close to the median found for airborne particles carrying *Staphylococcus aureus* in hospital wards (Noble, Lidwell & Kingston, 1963).

Studies on the transfer of particles from the room to the passage

Since the earlier study had shown the variability of air flow in the ward, it was decided to perform experiments using both the correctly ventilated air locks and also the commonest type of ventilation defect (i.e. that in which the air flow beneath the door between the passage and the airlock was reversed).

The generator was situated in the room chosen and adjusted to give a concentration of 500–1000 particles/l. in the room. There was no activity for the first 30 min. and then, for the following 30 min., one walk from the room to the passage was performed every second min. The dwell time in the airlock was 30 sec. Throughout the experiment samples were taken at the following sites; (a) in the room, samples taken at 5 min. intervals; (b) in the airlocks, samples were taken at 5 min. intervals during the period of no activity; (c) across the passage 2 m. from the room door, 7.5 m. up the passage, 7.5 m. down the passage, and at 15 m. either up or down the passage according to the room in use. These sites are shown in Fig. 1 for the experiments when the generator was in room 1. One 10 min. sample was taken between 20 and 30 min. and then during activity samples were taken at 5 min. intervals.

Particle transfer from passage to room

The generator was situated in the passage about 3 m. from the door of the room to be investigated. The periods of activity and non-activity were the same as before, as was the type of activity. Samples were taken at 1 m. from the door (at 5 min. intervals throughout the experiment), in the airlock (at 5 min. intervals during the period of no activity), and in the centre of the room where one 10 min. sample was taken between 20 and 30 min. and then 5 min. samples were taken continuously during the period of activity. Correct and incorrectly ventilated airlocks were used.

Transfer of particles from the bathroom to the passage

The generator was situated in the bathroom and there was no activity for the first 30 min. of generation, for the next 30 min. there was activity through the airlock I at the rate of one walk to the passage and back every 2 min. There was then a period of non-activity for 15 min. and for the last 20 min. there was activity through the direct door to the passage at the same rate as before. During this time samples were taken in the same six sites as they were in the room to passage experiments and the sampling times were also the same. The only exceptions to this were that no samples were taken in the airlock during the second period of non-activity and only for the last 10 min. of this period in the passage. During the last period of activity samples were taken once every 5 min. in the passage and in the bathroom.

Transfer of particles from passage to the bathroom

Particles were generated at about 3 m. from the bathroom doors which opened into the passage. Samples were taken between these two doors (about 1 m. from each). Samples were also taken in the airlock I and in the bathroom. The activity was the same as that in the bathroom to passage experiments and the sampling was the same as that in the passage to room experiments, except that no samples were taken in the airlock during the second period of non-activity. In the last two experiments correctly and incorrectly ventilated airlocks were used.

In addition to the above samples, blank samples were taken at each site before the start of each experiment.

Calculation of results

In all the experiments the particle concentration at any site started at zero and rose to a steady value in a short time. The steady values were determined by inspection of the data. For the source site, equilibrium was usually achieved within 10 min. of the start of generation, and at the receiving site a steady state was usually achieved after 10–15 min. of walking (depending on the site of sampling). The average particle concentration during the steady-state period was used in all calculations.

The behaviour of ventilation systems of the type under investigation has been studied theoretically by Lidwell (1972), making a number of simplifying assump-

tions. The analysis which follows is based on this study and has been carried out in collaboration with him.

The ratio α of the number of particles at the source to that at the receiving site gives a measure of the effectiveness of the system in protecting the patient from airborne infection, i.e.

$$\alpha = \frac{\text{Concentration of particles in the source room}}{\text{Concentration of particles in the receiving room}}$$

(large values of α indicate a high degree of protection).

Since the passage intervenes between the patient rooms, transfer of particles may be conveniently analysed by breaking the process down into two stages: (1) transfer from the source room to the passage; (2) transfer from the passage to the receiving room.

α' and α'' are used as symbols for these ratios, i.e.

$$(1) \quad \alpha' = \frac{\text{Concentration of particles in the source room}}{\text{Concentration of particles in the passage}},$$

$$(2) \quad \alpha'' = \frac{\text{Concentration of particles in the passage}}{\text{Concentration of particles in the receiving room}}.$$

Similar ratios can be calculated for bathroom to passage transfer and vice versa. Thus

$$\alpha' (\text{bathroom}) = \frac{\text{Concentration of particles in the bathroom}}{\text{Concentration of particles in the passage}},$$

$$\text{and} \quad \alpha'' (\text{bathroom}) = \frac{\text{Concentration of particles in the passage}}{\text{Concentration of particles in the bathroom}}.$$

The theoretical calculations predict that

$$\alpha \simeq v_1 v_2 / uv, \quad \alpha' \simeq v_2 / u, \quad \alpha'' \simeq v_1 / v,$$

where v_1 is the total rate of ventilation (both real and apparent due to sedimentation) in each patient room and v_2 is the total rate of ventilation in the passage (including the effects of sedimentation). v is the rate of air movement from the passage to the room, and u is the rate of air movement from the room to the passage. In addition to any continuous air flows due to incorrect ventilation conditions u and v will include air transferred by movement through the doors. This is related to the frequency of movement through the doors (m) and the amount of air swept through the door in the direction of movement on each occasion (w).

The ventilation input to the patient rooms is 200 m.³/hr. The apparent ventilation due to particles sedimenting at 0.3 m./min. onto the floor area of 16 m.² = 16 × 0.3 × 60 = 300 m.³/hr.

Similarly in the passage, the ventilation input is 1100 m.³/hr. and the apparent ventilation when the floor area is 90 m.² is 1600 m.³/hr. The input to the bathroom is 1350 m.³/hr. The apparent ventilation due to a floor area of 30 m.² is 550 m.³/hr.

Hence $v_1 = 200 + 300 = 500 \text{ m}^3/\text{hr}.$

and $v_2 = 1100 + 1600 = 2700 \text{ m}^3/\text{hr}.$

and $v_1 (\text{bathroom}) = 1350 + 550 = 1900 \text{ m}^3/\text{hr}.$

For a purely extract-ventilated airlock with air drawn equally from both sides it can be shown that $u = v = mw$ (Lidwell, 1972). However, the actual transfer of particles will be less than this because of the loss of particles by sedimentation within the airlock. The room airlock has a floor area of 4 m^2 and an extract ventilation of $100 \text{ m}^3/\text{hr}.$ The proportion of particles with a settling velocity of $0.3 \text{ m}/\text{min}.$ lost by sedimentation is then $0.42.$ If the air was drawn equally from both sides then the effective value of u and v for the transport of particles becomes $(1 - 0.42)mw = 0.58mw.$

The bathroom airlock had an air supply of $350 \text{ m}^3/\text{hr}.$ The extract of air from the bathroom airlock was $440 \text{ m}^3/\text{hr}.$ Assuming that the difference was drawn equally from both sides $45 \text{ m}^3/\text{hr}.$ will have come from the passage and $45 \text{ m}^3/\text{hr}.$ from the bathroom itself. As a consequence $u = v = 45/440 \times 2mw = 0.2mw.$ The floor area was 5 m^2 so the proportion lost by sedimentation was, making the same assumptions as earlier, $(60 \times 0.3 \times 5)/(60 \times 0.3 \times 5 + 440) = 0.17.$ The effective values of u and v for the transport of particles through the bathroom airlock are then given by $u = v = (1 - 0.17) \times 0.2mw = 0.19mw.$

The experimental value of m was $30/\text{hr}.$ and for the purposes of calculation we have assumed that $w = 1 \text{ m}^3.$

For the room airlock therefore the predicted value of u and v during the experiments was $30 \times 0.58 = 17 \text{ m}^3/\text{hr}.$ and for the bathroom airlock $30 \times 0.17 = 5 \text{ m}^3/\text{hr}.$ For the direct bathroom door the corresponding value would be $60 \text{ m}^3/\text{hr}.$ (there is no sedimentation loss to allow for in this instance).

Substituting these values in the equations for α' and α'' gives the following results:

- (1) room to passage $= \alpha' = \frac{v_2}{u} = \frac{2700}{17} = 160;$
- (2) passage to room $= \alpha'' = \frac{v_1}{v} = \frac{500}{17} = 29;$
- (3) room to room $= \alpha = \alpha' \times \alpha'' = \frac{2700 \times 500}{17 \times 17} = 4.7 \times 10^3;$
- (4) bathroom to passage $= \alpha' (\text{bathroom}) = \frac{2700}{5} = 540;$
- (5) passage to bathroom $= \alpha'' (\text{bathroom}) = \frac{1900}{5} = 380;$
- (6) bathroom to room $= \alpha = \frac{2700}{5} \times \frac{500}{17} = 1.6 \times 10^4;$
- (7) room to bathroom $= \alpha = \frac{1900}{5} \times \frac{2700}{17} = 6.1 \times 10^4.$

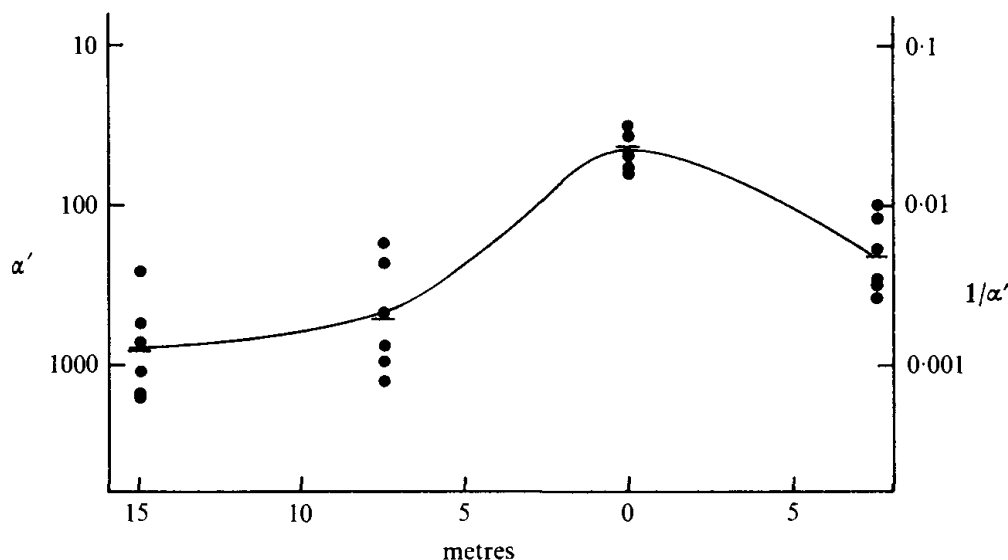


Fig. 5. Distribution of particles along the passage. Source in room 1 with correct ventilation and activity at 30 entries and exits/hr. Right-hand scale is the ratio of the particle concentration in the passage to that in the source room, i.e. $1/\alpha'$. The points show the approximately steady values attained in the individual experiments. The short horizontal bars are the log mean values as given in Table 1.

These values are calculated for the experimental movement through the doors of 30/hr. in each direction. The values of α' and α'' for correctly ventilated airlocks are inversely proportional to m and α is inversely proportional to m^2 .

For other values of m

$$\alpha'_m = \alpha'_{30} (30/m), \quad \alpha''_m = \alpha''_{30} (30/m), \quad \alpha_m = \alpha_{30} (30/m)^2.$$

If, however, the ventilation is unbalanced so that there is air flow between passage and room independent of movement of persons through the doors the transport of particles by this air flow is unaffected by a change in the value of movement through the door and

$$\frac{1}{\alpha'_m} = \frac{1}{\alpha'_0} + \left(\frac{1}{\alpha'_{30}} - \frac{1}{\alpha'_0} \right) \frac{m}{30},$$

and similarly for α'' .

Where α'_m denotes α' when the movement through the door is m /hr., α'_0 is the value of α' when there is no activity and α'_{30} corresponds to the experimental value of α' , when there are 30 entries and exits/hr. through the door, the number employed in the experiments.

RESULTS

Fig. 5 shows the way in which the ratio of particles in the room and passage vary with increasing distance of the sampling site from the room; it also shows variability of the estimates obtained in the several experiments. The values used were obtained from room to passage transfer experiments with a correct ventilation.

The mean values of α' and α'' for the various sampling positions for all the experiments performed are presented in Table 1. The values are log means of at least five experiments. The table also shows the log mean values of α' over all the positions. The corresponding values of α are calculated from these values and also shown in Table 1. As can be seen from the table there is no detect-

Table 1. *Particle transfer within the Burns Unit. Avd. 79 A*

Nos.	Transfer	Ventilation	Activity	α' at sampling position				α' Mean	α''	To	$(\alpha' \times \alpha'')^\dagger$	
				7.5 a	2	7.5 b	15 b				m	To B-room
1-4	Patient room/	Correct	None	$> 10^5$	$> 10^4$	$> 10^5$	$> 10^5$	$(> 10^5)$	$(> 10^5)$			—
		Correct	In/out through airlock	204	45	505	818	245	39	9.6		—
		Faulty	None	248	58	226	1200	251	$(> 10^5)$	> 2.5		—
		Faulty	In/out through airlock	71	20	46	780	83	66	5.5		—
5-10	Bathroom/passage	Correct	None	88	22	297	1050	155	$(> 10^5)$	> 1.5		$> 10^{10}$
		Correct	In/out through airlock	44	19	173	562	96	215	3.8		5.3×10^4
		Correct	In/out through direct door	39	10	292	741	96	63	3.8		1.5×10^4
		Faulty	None	38	21	151	751	98	$(> 10^5)$	> 1		$> 2.5 \times 10^7$
		Faulty	In/out through airlock	39	21	48	480	66	400	4.3		3.3×10^4
		Faulty	In/out through direct door	31	15	79	202	52	66	3.4		5.5×10^3

The value of 4 values.

† Left-hand column for both source and receiving room.

α' and α'' are, in each case, the log mean values of 5-7 experiments. α' mean = α' averaged over all sampling positions, log mean

column α values for transfer to a patient room; first 4 lines, from another patient room; last 6 lines from the bathroom. Right-hand column α values for transfer from a patient room to the bathroom. In all cases the same activity and type of ventilation assumed to hold

sitions, log mean

bathroom. Right-hand column α values for transfer from a patient room to the bathroom. In all cases the same activity and type of ventilation assumed to hold

able transfer of particles from room to passage or passage to room when the ventilation functions correctly, i.e. α' is $> 10^5$, α'' is $> 10^5$. When a steady state has been achieved under activity α' is 245 and α'' is 39. For an incorrectly ventilated room with no activity α' is 251, i.e. about the same value as α' during activity for a correctly ventilated room, and during activity this falls to 83. However, α'' for an incorrectly ventilated room is 66, which is considerably higher than that for a correctly ventilated room. When the source room and receiving room are both correctly ventilated α is 9.6×10^3 ; the corresponding α for incorrectly ventilated rooms is 5.5×10^3 . An incorrectly ventilated source room and a correctly ventilated receiving room gives an α of $83 \times 39 = 3.2 \times 10^3$, and a correctly ventilated source room and an incorrectly ventilated receiving room gives an α of $245 \times 66 = 1.6 \times 10^4$. The bathroom α' when the airlock is ventilating correctly is rather low, 155; this is due to the fact that particles are always passing from the bathroom into the passage underneath the direct door; because of this α' bathroom due to activity does not vary greatly between correct or incorrect ventilation or activity through the airlock or the direct door. α'' bathroom, however, is lower if the ventilation is correct than if it is incorrect, 215 as opposed to 400. There is also a difference between α'' bathroom if the activity is performed through the airlock or through the direct door. The value of α for transfer from the bathroom to a patient room during activity (entering and leaving the bathroom via airlock I) is 3.8×10^3 , when ventilation to rooms is correct. For transfer from a patient room to the bathroom under similar conditions the value of α is 5.3×10^4 .

DISCUSSION

As stated above there were two objectives in this work, to obtain an estimate of the degree of protection from airborne cross-infection provided by the ventilation system used in this ward and to compare the experimentally determined values for particle transfer with the values predicted by a theoretical analysis.

Owing to incomplete mixing of air in the passage there was a rapid fall in particle concentration with increasing distance from the door of the source room (Fig. 5). Because of this it is necessary to derive average values of α' . To estimate the average cross-infection risks of all the rooms, the logarithmic mean of α' at the different points was used since the risk of nasal acquisition (and hence the risk of infection) is probably more nearly related to the logarithm of the concentration of bacteria in the air (Lidwell, 1963; Lidwell *et al.* 1971) than to the arithmetic value. To compare the results with theory it is best to take an arithmetic average of the particle concentrations at the sampling points, i.e. the average of $1/\alpha'$ because the points are equidistant along the passage and the theoretical value of α' is based upon the assumption of complete mixing of the air. These values are given in Table 2. This average value was also used to calculate values of u ($u = v_2/\alpha'$). In deriving the experimental value of α' for the bathroom the particle transfer due to air passing beneath the direct door (i.e. $1/\alpha'$ with no activity) was subtracted from the particle transfer when there was activity. It is not possible to estimate the transfer when the ventilation is incorrect as the amount of extra transfer between the room and the passage (or vice versa) is not

Table 2. *Comparison of observed and predicted values (for designed ventilation)*

		α'	u	α''	v
Room (airlock)	Observed value	143	19	39	13
	Predicted value	160	17	30	17
Bathroom (airlock)	Observed value	170	16	215	9
	Predicted value	640	5	450	5
Bathroom (direct door)	Observed value	59	41	63	21
	Predicted value	45	60	23	60

The α' values have been derived as the arithmetic average of the particle concentrations at the different sampling positions, i.e. by summation and averaging of $1/\alpha'$, see text.

Predicted values of u and v assume a value of 1 m.^3 for w , the volume of air transferred through a door on opening it, passing through and shutting it again.

known. For the room experiments, correlation of predicted and experimental values of α' and α'' is good.

For the bathroom the correlation is not so good but the ventilation of this room was certainly not in accordance with the specification and the leakage under the door into the passage meant that the values of α' had to be derived as a difference between two experimentally determined values. The general closeness of the estimates to the experimental results suggests that the theoretical model is broadly correct, but that errors are present in the estimation. Thus, the value of w is only an approximation and may be subject to considerable variation depending upon thermal difference across the door, size of the door and room, angle to which door is opened etc. Values of v_1 and v_2 were taken from the engineer's plan and in view of the variable ventilation state of the ward may have borne little relationship to the true values of v_1 and v_2 . We were unfortunately unable to check the accuracy of the figures.

Experimental errors were due to two main contributions: (1) relatively small air samples were taken; (2) random air movements caused great variation in the particle concentration at different sites. A number of factors caused these air movements, amongst them were thermal currents, disturbances due to opening of doors, movements of staff and uncontrolled day to day variations in ventilation.

Estimation of the cross-infection risk

The estimated value of α for transfer of particles from one room to another with correct ventilation is $> 10^9$ when there is no activity (i.e. transfer of particles was undetectable) and 9.6×10^3 when the rate of activity is 30 walks/hr. However, normal activity in the ward is much less than this and observations in this unit indicate a value of 3–5 door openings/hr., about half that found in a two-bed isolation room (Lidwell & Towers, 1969) and we have deduced that a reasonable estimate of the normal value is 5 walks/hr., i.e. $m = 5$. This leads to an α of 3.4×10^5 between correctly ventilated rooms with normal activity. It would seem that this should provide good protection against cross-infection due to airborne contamination since a value of 1 colony forming unit (c.f.u.)/l. in a source room would give rise to a concentration of only 3×10^{-6} c.f.u./l. in the receiving room. This estimate of the concentration of bacteria-carrying particles in the room is

equivalent to only 0.15 c.f.u. in the whole volume of the room (5×10^4 l) or 1 c.f.u. inhaled every three weeks at an inspiration rate of 10 l./min. If $1/3$ m.² of body surface were exposed to contamination by settling and the airborne particles were of the size commonly found (settling velocity 0.3 m./min.) then the dose received in this way would be no more than 1 c.f.u. in 50 hr.

If the airlocks do not function correctly then the value of α will be different. The results of experiments upon the type of incorrectly ventilated airlocks investigated showed that in the absence of all activity α' for a room with an incorrectly ventilated airlock was as much as α' for a room with a correctly ventilated airlock when the level of activity was 30 walks/hr. However, α'' for such an incorrectly ventilated airlock during activity was higher than the corresponding value for a correctly functioning airlock. Thus the worst situation for which we can derive an estimate will be when the source room has an incorrectly ventilated airlock, and the receiving room has a correctly ventilated airlock. With a normal activity of 5 walks/hr the value of α would then be 4.4×10^4 . Thus if one airlock is functioning incorrectly the risk in all the other rooms is about ten times greater than under correct conditions, e.g. for a concentration in the source room of 1 c.f.u./l. a patient in a receiving room would inhale 1 c.f.u. every 2 days and about 5 c.f.u. might settle on $1/3$ m.² of exposed body surface each 24 hr.

There are two other possible ways in which contaminated air might reach the patient. Large amounts of bacteria may be dispersed during bathing in the bathroom and be transferred throughout the ward. Alternatively the patient might become infected in the bathroom with bacteria transferred from another patient room. In the first case there is continuous contamination of the corridor from the bathroom due to air passing beneath the direct door even when there is no activity through the correctly ventilated airlock. But it is greater when there is activity and when the airlock is ventilated incorrectly. The airlock, however, was usually ventilated correctly, and under normal conditions there was little activity through the airlock and none through the direct door. For the purposes of calculation we have assumed the activity through the bathroom airlock to be 5 walks/hr. although this is probably too high a value. This leads to a value of α for transfer from the bathroom to a patient room of 3.9×10^4 . In the second case the value of α for transfer from a patient room to the bathroom, again assuming 5 walks/hr. through the bathroom airlock, would be 1.9×10^6 if the patient room ventilation functions correctly and 2.4×10^5 if the airlock is incorrectly ventilated.

In neither of the above 3 cases is the risk of cross-infection much higher than the risk run by patients when in patient rooms, if one room with an incorrectly ventilated airlock is occupied by a disperser.

Conclusion

It would seem from the above results that, under normal conditions, the isolation system was highly effective at preventing the airborne transfer of particles and even when the ventilation was not operating correctly the particle transfer was very small. Since there has been a considerable cross-infection rate over the past years it would seem likely that other routes of infection have been responsible for this.

REFERENCES

- BOURDILLON, R. B., LIDWELL, O. M. & LOVELOCK, J. E. (1948). Studies in air hygiene. *Medical Research Council Special Report Series*, no. 262.
- FOORD, N. & LIDWELL, O. M. (1972). An airborne particle tracer for cross infection studies. *Journal of Hygiene* **70**, 279.
- LIDWELL, O. M. (1963). *Infection in Hospitals*, pp. 43–46. Oxford, Blackwell.
- LIDWELL, O. M. (1972). Ventilation in subdivided isolation units. *Journal of Hygiene* **70**, 287.
- LIDWELL, O. M. & TOWERS, A. D. (1969). Protection from microbial contamination in a room ventilated by a uni-directional airflow. *Journal of Hygiene* **67**, 95.
- LIDWELL, O. M., POLAKOFF, S., DAVIS, J., HEWITT, J. H., SHOOTER, R. A., WALKER, K. A., GAYA, H. & TAYLOR, G. W. (1971). Nasal acquisition of *S. aureus* in a subdivided and mechanically ventilated ward: endemic prevalence of a single staphylococcal strain. *Journal of Hygiene* **68**, 417.
- NOBLE, W. C., LIDWELL, O. M. & KINGSTON, D., 1963. The size distribution of airborne particles carrying micro-organisms. *Journal of Hygiene* **61**, 385.



Development of Particle Tracer Techniques to Measure the Effectiveness of High Containment Laboratories

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Abstract

Biosafety Level 3 (BL-3) laboratories are designed to prevent the escape of pathogenic microorganisms by operating at negative pressure so that if microorganisms become airborne, they remain within the laboratory. However, the authors are not aware of any published evidence or international guidance on the level of pressure differential required for BL-3 laboratories. This uncertainty was reflected in a survey of BL-3 laboratories in the United Kingdom where a range of pressure differentials between 30 and 100 Pascals (Pa) were found. In this paper, an attempt is made to address this issue. The authors have developed techniques to quantify the effectiveness of containment laboratories in preventing the egress of airborne microorganisms. A potassium iodide (KI) aerosol tracer method was adapted to measure the degree of containment in an experimental facility and in five working BL-3 laboratories. The level of laboratory containment was expressed as the laboratory protection factor (LPF). Using this technique, it was found that providing an anteroom increased the LPF by approximately one order of magnitude. No direct relationship was found between the magnitude of negative pressure and LPF. There was, however, a direct relationship between inflow velocity and LPF: A volumetric inflow of 10 m³/min into a laboratory through an anteroom gave a LPF of greater than 10⁵. The KI aerosol tracer method offers a simple and appropriate means of validating the performance of BL-3 laboratories in terms of the LPF.

Introduction

Manipulations utilizing category 3 pathogenic microorganisms that may lead to the generation of infectious aerosols must be carried out within primary containment such as microbiological safety cabinets and sealed centrifuge rotors. Secondary containment is also required; this involves protecting the surrounding rooms and environment in the event of the breakdown of the primary containment or after an accidental release. The construction, design, and operation of these facilities are described in a range of national and international guidelines (Advisory Committee on Dangerous Pathogens, 1995; US Department of Health and Human Services, 1999; World Health Organization, 1993). BL-3 laboratories need to be physically separated from the surrounding environment and specific rules govern entry to this facility. These can involve passage through two sets of doors that create an anteroom to accommodate personnel changing from their normal clothing into protective clothing.

BL-3 containment laboratories are designed to prevent the egress of pathogenic microorganisms by keeping the room at a negative pressure with respect to the outside environment and ensuring a high air-change rate. Negative pressure is maintained in containment rooms partially by increasing the air flow extracted from the room and partially by minimizing the leakage of air through gaps between the door and door frame and any vents in the doorleaf. In

addition, the ventilation is designed so as to replace the air at such a rapid rate that any aerosol generated within the room is quickly diluted and removed. The combination of these two factors should allow laboratory personnel to evacuate the laboratory safely after a breach of primary containment and return to the laboratory to deal with the accident after a given time, confident that any generated aerosol has been removed.

Due to the lack of experimental evidence, no information is provided in international and national microbiological containment guidelines on the magnitude of negative pressure required for effective containment of category 3 agents. Also, no documented evidence is available to show the effects of changing the magnitude of negative pressure on containment. Regulations are also vague on whether providing an anteroom between the laboratory and the outside environment is required to enhance the overall containment. This contrasts with the highly detailed national and international standards for the design of primary containment equipment such as centrifuges and microbiological safety cabinets (British Standards Institute (BSI), 1992; International Electrical Commission (IEC), 1993; National Sanitation Foundation (NSF), 1983). This also contrasts with the regulations pertaining to the design of cleanrooms for the manufacture of medical products and electronic components.

As part of this study, an informal survey of BL-3 laboratories in 10 institutions (including universities, research institutes, and pharmaceutical companies) throughout the United Kingdom (UK) showed that a wide range of pressure differentials—between 30 and 100—Pa were routinely used. Marked differences in laboratory design in the public and private sectors were noted. Anterooms were linked to all these laboratories and were used as changing and temporary storage facilities. In university and hospital laboratories, the BL-3 facilities generally comprised an anteroom and laboratory having no independent ventilation system but relying on a ducted Class I microbiological safety cabinet in the main laboratory to create a negative pressure, normally of approximately 30 Pa. In some instances, the practice was to ensure the cabinet was operating for an additional 10 minutes after the day's work was com-

pleted. In contrast, most pharmaceutical and research laboratories in commercial organizations had independent ventilation systems that were continuously monitored by sensors and alarm systems. Microbiological safety cabinets in these facilities were continuously operated 24 hours a day to maintain the desired air balance. In one facility, entry to the laboratory was achieved through a sequence of three anterooms. The total negative pressure gradient in this case was 100 Pa between the laboratory and the corridor.

The use of excessive negative pressures to ventilate containment facilities can create problems. These may include:

1. Increased energy costs due to heating losses
2. Structural damage to wall and ceiling surfaces and sealants
3. Significant quantities of airborne particulate matter that can be drawn in from the surrounding environment

The aim of the present study was to develop test methods to measure the degree of containment of BL-3 laboratories. These techniques may be used to investigate the effects of various design factors on the containment provided by these laboratories. The information gained should prove useful to the laboratory designer.

The study was comprised of two stages:

1. Initial studies were carried out in an experimental laboratory complex where the air flow and differential air pressures could be altered whenever required. This facility was sealable and so could be decontaminated readily after use.
2. Further studies were carried out in operating containment laboratories of various sizes and designs and having a wide range of airflows and pressure differentials.

The effectiveness of open-fronted microbiological safety cabinets is routinely tested in the UK, using monodispersed aerosols of potassium iodide (KI) (BSI, 1992). The KI methodology was originally developed to study movement of particulate contaminants between rooms in burns units in hospitals (Foord & Lidwell, 1972). The effectiveness of open-fronted microbiological safety cabinet performance is measured in terms of the operator protection factor (OPF), which is the ratio of KI particles gener-

ated within the cabinet to those detected outside the cabinet. An OPF of greater than 10^5 is regarded as being adequate (ACDP, 1995). Using the same principle, the OPF can also be determined using aerosolized bacterial spores. These procedures were adapted to assess the performance of the high-containment laboratories in this study.

The effectiveness of the containment of laboratories was assessed in terms of the laboratory protection factor (LPF), which is defined as the ratio of the number of particles generated in the laboratory to the number of particles collected in the area outside the laboratory. This protection factor was measured using airborne particle tracers containing either aerosol-stable microorganisms such as spores of *Bacillus subtilis* var niger (Cox, 1987) or KI.

Since the use of microbial tracers was impractical in working laboratories, only the KI tracer technique was used in this setting. The advantages of this technique over the microbial methods are rapid results and no contamination of the laboratory under test, avoiding any need for subsequent decontamination.

Materials and Methods

Experimental Laboratory

This laboratory was designed to allow volumetric inflows and pressure differentials to be easily adjusted independently of each other. The room complex (Figure 1) consists of three units that simulate

the laboratory, the anteroom, and a corridor. The dimension of the “laboratory” was 3.0 m x 3.1 m x 2.3 m high, the “anteroom” was 3.7 m x 1.7 m x 2.3 m high, and the “corridor” room was 3.0 m x 2.4 m x 2.5 m high. (Note that in the remaining portions of this paper, the environmental laboratory rooms are referred to within quotes to differentiate them from the working laboratory rooms.) The pressure differentials were monitored by calibrated Magnahelic (Michigan City, USA) manometers, and the volumetric inflows were calculated from the air flows measured by a rotating-vane anemometer as detailed below (under calculation of airflow). This “anteroom” and “laboratory” were operated at the following respective combinations of negative pressures—0,0; 15,30; 20,40; and 40,70 Pa—for microbiological tests. In experiments to assess the effect of inflow velocity on room containment using KI, the pressure differentials were held at -30 Pa, -60 Pa, while the volumetric inflow was varied between 6.1 and 14.7 m³min⁻¹. This was achieved by adjusting ventilation grilles incorporated in the laboratory doors.

Test Laboratories

Tests were carried out in five BL-3 laboratories with anterooms (Laboratories A-E) and one BL-2 laboratory without an anteroom (Laboratory F). The characteristics and experimental variables of the

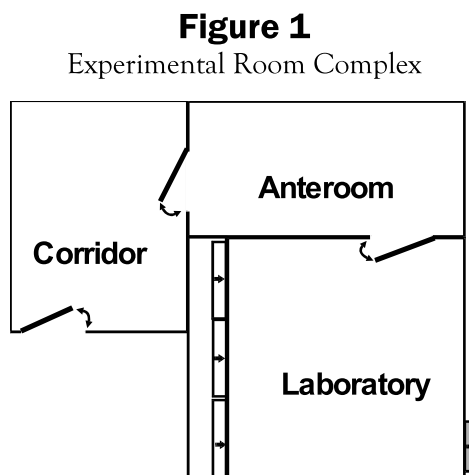


Table 1

BL-3 Laboratories Tested for Containment Using the KI Test Methodology

Laboratory	Anteroom ΔP^+ (Pa)	Laboratory ΔP (Pa)	Laboratory Inflow Through Door ($\text{m}^3 \text{min}^{-1}$)	Laboratory Volume (m^3)	Ach ¹
A	-40	-50	10.8	58.9	11
B	-20	-30	8.2	95.9	8.4
C ²	-25	-50	15.4	97.8	23.3
D	-50	-120	12.7	102.2	19.3
E	-25	-60	2.4	127.6	19.3
F	none	NA	4.9	158.4	5.5

⁺ Pressure differential, ¹ Air changes per hour, ² Ventilated anteroom 32.6 ach, NA—not applicable

laboratories are given in Table 1. The pressure differentials were measured on Magnahelic (Michigan City, USA) manometers. All the laboratory extract and supply air flows were measured using a rotating-vane anemometer (Model AV2, Airflow Developments, High Wycombe, England), and the laboratory inflows and air changes were calculated from these data and the room volumes as detailed below. Each laboratory was tested using the potassium iodide (KI) technique also detailed below.

Potassium Iodide Method-Principle

The potassium iodide (KI) method was developed by Foord and Lidwell (1972) to study the movement of particles in hospitals and was later adapted by Clarke and Goff (1981) to test microbiological safety cabinets *in situ*. In 1992, the method was adopted as the British Standard and is currently used in the UK (BSI, 1992). An integrated piece of equipment using these principles is commercially available for testing microbiological safety cabinets (Containment Technologies, Wimborne, UK). This equipment was adapted for use in this study. The principal to operate the equipment is as follows: A solution of 1.5% (w/v) potassium iodide in 95% (v/v) aqueous ethanol is fed dropwise at a regulated rate to a spinning disc at a fixed speed. Droplets of a defined size are flung off the spinning disc. The number and size of the droplets depend upon the injection flow rate and the speed and diameter of

the disc, respectively. The water and the ethanol instantly evaporate from the droplets formed, providing solid monodispersed particles of average size (7 microns). The aerosol generator is designed to produce 6.2×10^6 KI particles in a 10-minute period.

Air-containing particles that escape from the containment space are sampled by four centripetal membrane filter samplers drawing 100 liters min^{-1} through a 3.0-micron, 25 mm-diameter cellulose nitrate membrane filter (Whatman, Maidstone, England (cat. No: 7188 002)). After each test, the filters are immersed in a solution of 0.1% palladium chloride in 0.1 M hydrochloric acid which reacts with any KI to form brown spots that can be easily identified and counted using a hand lens.

Measurement of Laboratory Protection Factor Using the KI Method

The spinning disc aerosol generator was placed at a height of 0.8 m inside the laboratory and 1 m from the door of the environmental room or containment laboratory. Two of the centripetal sampling heads were placed in the anteroom, 0.3 m from the door and 1 m from the wall at heights of 0.3 m and 0.8 m. The other two sampling heads were placed in the corridor area at the same heights (1 m from the door and 0.8 m from the wall). Experiments were carried out for either 5-minute or 10-minute periods. This technique was also used in the working laboratories.

Measurement of Laboratory Protection Factor Using the Microbial Aerosols

Microbial aerosols were generated within the experimental laboratory using a Collison nebulizer (May, 1973) operating at a pressure of 180 kPa containing a suspension of *Bacillus subtilis* var niger spores in distilled water at a concentration of 3.16×10^7 spores ml^{-1} . The nebulizer was placed 1 m from the laboratory door at a height of 0.8 m from the floor. Two slit samplers constructed in the HPA workshops (BSI, 1992), operating at a flow rate of 25 liters min^{-1} and containing tryptone soya broth agar (TSBA) plates that were placed in the anteroom and in the "corridor." Experiments were carried out for a period of 10 minutes. The nebulizer was weighed and the spore suspension was assayed before and after the experiment to calculate the number of spores aerosolised.

Microbial Tracer

Spores of *Bacillus subtilis* var niger (ATCC 9372) were used as the challenge microorganism. The spore suspension was prepared as described by Sharp et al. (1989) and washed three times in distilled water and heated to 60°C for 1 hour before using to kill any vegetative forms that were likely to be inactivated by aerosolisation (Sharp et al., 1989). The suspension was assayed by serial dilution and plating out onto TSBA plates (Oxoid, Basingstoke, England). The plates were incubated at 37°C for 18 hours and the distinctive orange colonies were then counted to determine the spore concentration.

Laboratory Test Conditions

The performance of the experimental room complex and the various test laboratories were assessed in three distinct operating modes.

1. With the laboratory doors closed as is the normal situation for a working laboratory
2. When an operator enters the anteroom during the tests and exits after 1 minute
3. When an operator enters the laboratory and exits after 1 minute. This is intended to model a situa-

tion where a laboratory worker enters the laboratory, discovers an accident situation, and leaves after removing his or her contaminated clothing.

In each laboratory, the pressure differentials and the volumetric airflow through the doors were measured and noted.

Calculation of Air Flow

The air flow in each room was measured using the rotating vane anemometer. The volumetric flow ($\text{m}^3 \text{min}^{-1}$) passing through inlet and extract grilles was determined by multiplying the average of a minimum of four face velocity readings by the area of the grille. The volumetric inflow through the door was then calculated from the difference between the total volumetric outflow and inflow through any supply grilles. As all the rooms tested were sealed, it can be assumed that the bulk of the make up air volume was drawn through the door.

Calculation of the Protection Factor

The laboratory protection factor is a measure of the effectiveness of the laboratory to prevent release of aerosols into the rest of the premises. It is calculated according to the following formula:

$$\text{LPF} = P_a/P_s \quad (1)$$

Where,

LPF = laboratory protection factor

P_a = Number of particles aerosolised

P_s = Number of particles sampled outside the laboratory

The KI aerosol generator is designed to consistently generate 6.2×10^5 aerosol particles per minute. The number of spores aerosolised in the experimental room studies was calculated by weighing the Collison nebulizer and its contents before ($M_{o,g}$) and after use ($M_{e,g}$) (i.e., weight loss, assuming a density of 1g ml^{-1} ; this allows the volumetric output ($V = M_o - M_e$) to be calculated). Since the concentration of spores in the suspension (C_s) is known, then the aerosol output of the spores (P_s spores) can be calculated:

$$P_s = V \times C_s \quad (2)$$

For the purpose of this study, it was assumed that all airborne particles that escaped from containment were collected by the air samplers. Hence, the number of spores or particles outside the test area represents the number released into the environment. Realistically, this is unlikely despite the fact that the samplers were placed at the same height as the aerosol generator where the highest aerosol concentrations would be found. However, it would be unrealistic to assume perfect mixing in the anteroom and, therefore, normalize the particle release for the room volume. Furthermore, this would be impossible for the corridor measurements. Therefore, the calculated LPF may be slightly higher than the actual LPF.

Results

Microbiological Tests

With the doors of the experimental room complex closed, no airborne spores were detected outside even when there was no pressure differential between the rooms. When an operator entered and exited the experimental room complex, there was a release of aerosol from the “laboratory” into both the “anteroom” and the “corridor” at all pressure differentials (Figure 2). However, no relationship between increasing differential and biological LPF (bLPF) in the “anteroom” or “corridor” could be identified. In all cases, the bLPF in the “corridor” exceeded 1×10^6 . For “anteroom” entry there was a

Figure 2

The effect of magnitude of pressure differential on biological laboratory protection factor during laboratory entry tests in the experimental room complex measured in the anteroom (●) and corridor (○).

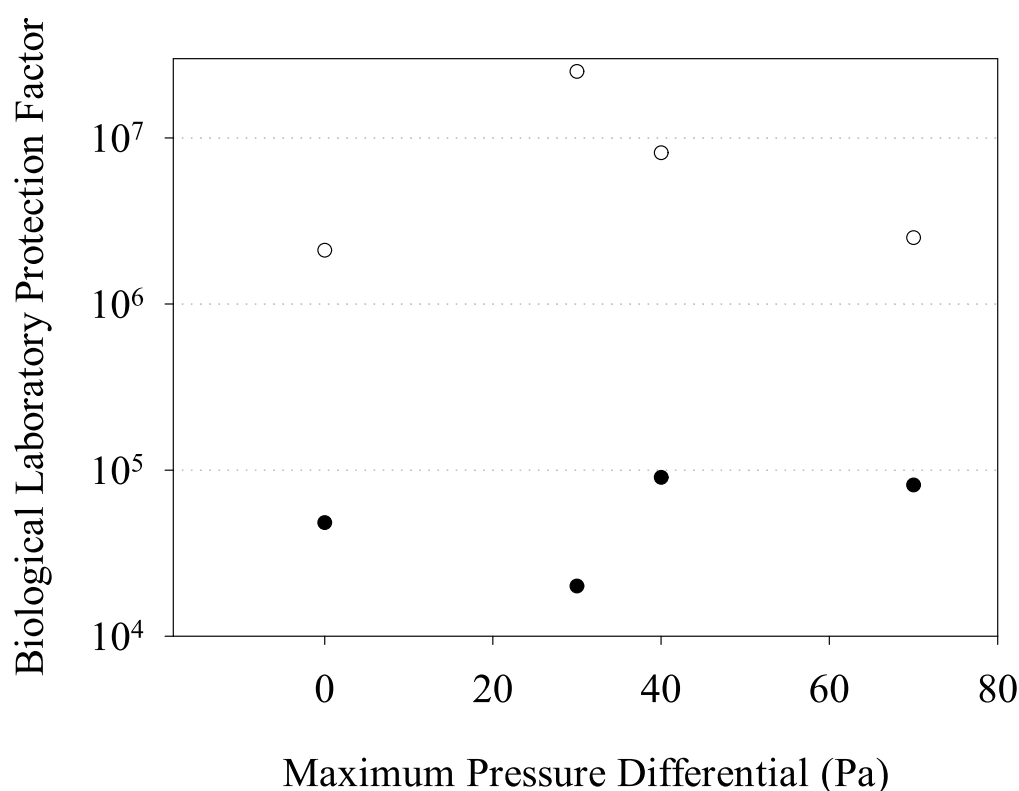


Table 2

Biological Laboratory Protection Factors in Experimental Room for Anteroom Entry

ΔP (Pa)		Laboratory Protection Factor	
Anteroom	Corridor	Anteroom	Corridor
0	0	3.4×10^5	1.0×10^7
-20	-40	2.4×10^7	$> 2.0 \times 10^9$
-40	-70	8.0×10^6	3.2×10^{10}

Table 3

Laboratory Protection Factor for Operating Laboratories

Laboratory	Laboratory Protection Factor		
	Doors Closed (Corridor)	Lab Entry and Exit (Anteroom)	Lab Entry and Exit (Corridor)
A	$> 3.1 \times 10^6$	$< 4.4 \times 10^2$	6.1×10^4
B	1.6×10^6	$< 4.4 \times 10^2$	1.5×10^4
C	1.6×10^6	$< 4.4 \times 10^2$	9.6×10^4
D	$> 3.1 \times 10^6$	$< 4.4 \times 10^2$	5.8×10^4
E	NA	$< 4.4 \times 10^2$	7.6×10^3
F (BL2)	$> 3.1 \times 10^6$	NA	1.5×10^3

NA—not applicable

lower bLPF at static pressure than when a pressure differential was applied (Table 2).

KI Tests in Working Laboratories

The KI tests were carried out in the working laboratories (described in Table 1) for static and for laboratory-entry tests. The results are shown in tabulated form in Table 3 and plotted as LPF vs. maximum pressure differential in Figure 3. There was minimal or no release of material from laboratories when the doors were left closed, even from the BL-2 laboratory without an anteroom. The LPF measured in the corridor during the laboratory entry test varied from 7.6×10^3 to 9.6×10^4 for the BL-3 laboratories (1.5×10^3 for the BL-2 laboratory). Figure 3 shows that the LPF was not dependent on the magnitude of pressure differential.

Table 4 lists the LPFs for anteroom entry tests for the BL-3 laboratories. Again, there was no direct

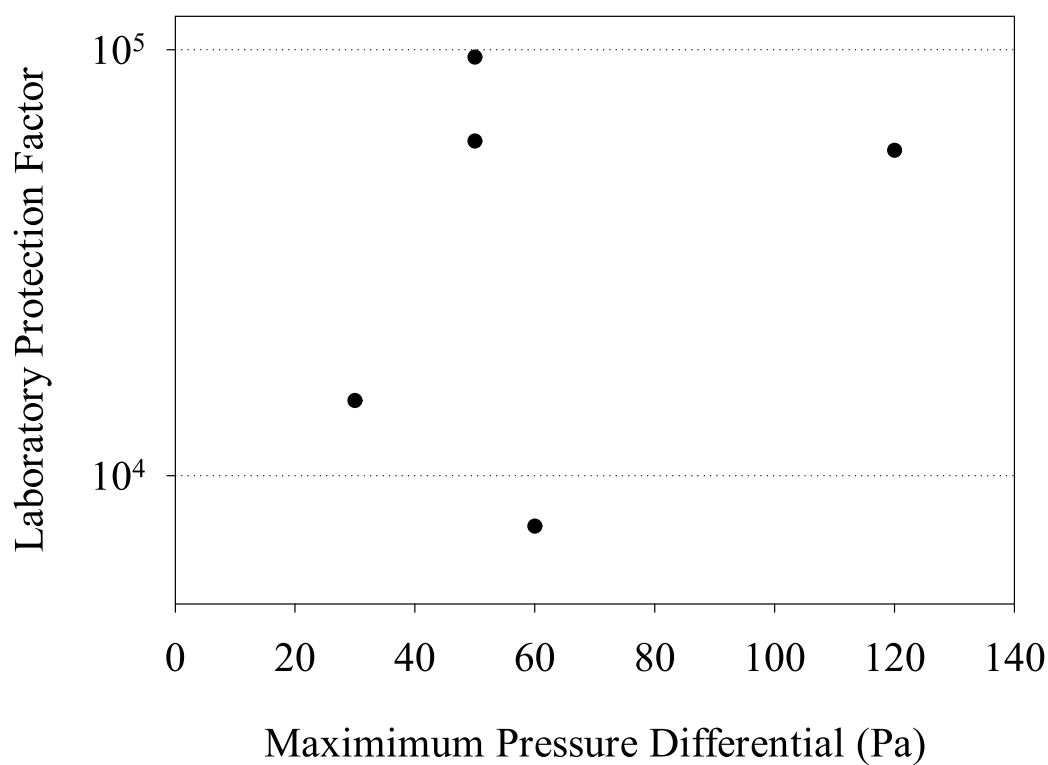
relationship between magnitude of pressure differential and LPF.

Effect of Volumetric Inflow

The KI test method was also used to measure the effect of altering the laboratory inflow rate in the experimental room complex. The pressure differential was kept constant at -30 Pa in the “anteroom” and -60 Pa in the “laboratory” while the inflow was altered. The results of these tests for “laboratory” entry are shown in Figure 4. The results of the operating laboratory studies are also shown in this figure. The results of the anteroom entry tests are shown in Figure 5 combined in the same way. Each of these graphs shows a direct relationship between volumetric inflow and LPF. The results obtained in the working laboratories and the experimental room are similar.

Figure 3

The effect of magnitude of pressure differential on laboratory protection factor during laboratory entry tests in the BL-3 laboratories.

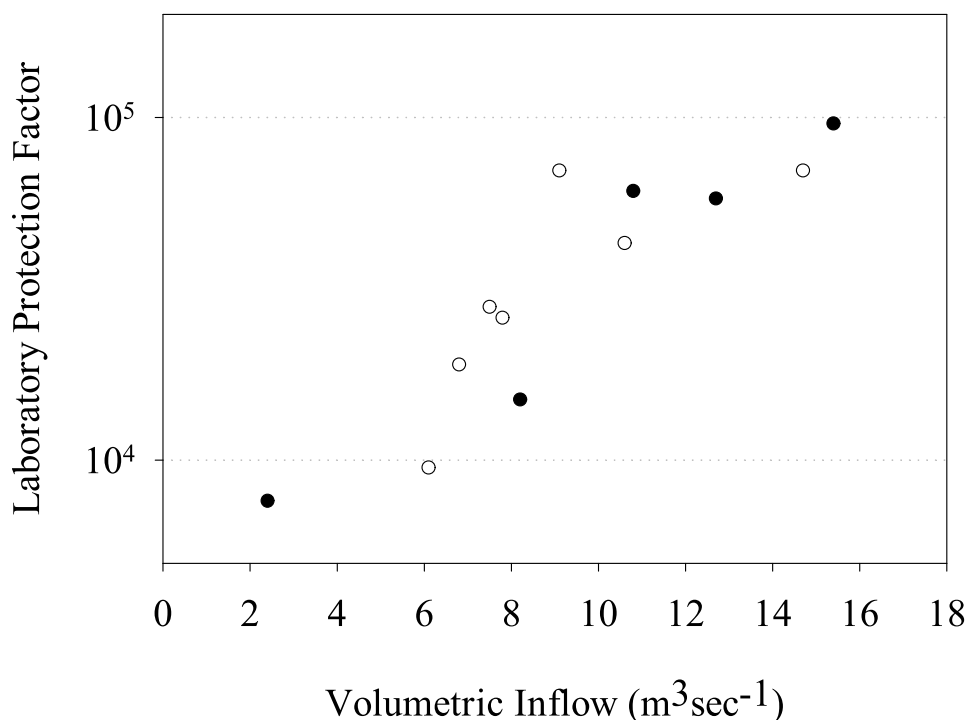
**Table 4**

Laboratory Protection Factors in Operating BL-3 Laboratories for Anteroom Entry

Laboratory	Laboratory Protection Factor	
	Anteroom	Corridor
A	9.1×10^4	$>3.1 \times 10^6$
B	3.6×10^4	1.0×10^6
C	9.1×10^4	5.2×10^6
D	7.8×10^5	2.1×10^6
E	$< 2.4 \times 10^3$	1.0×10^5

Figure 4

The effect of volumetric inflow on laboratory protection factors during laboratory entry tests in the BL-3 laboratories (●) and the environmental room complex (○)



Discussion

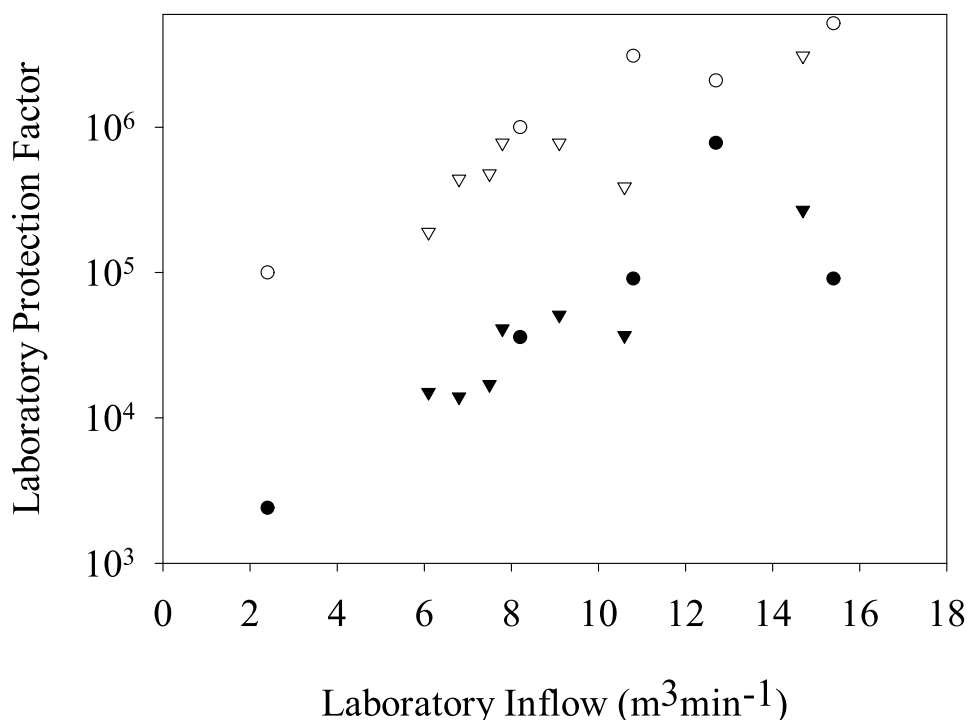
This study demonstrates that the KI method can be usefully applied to quantify the secondary containment provided by negative-pressure laboratories. This technique has been shown to be much more sensitive than the microbiological method described in the experimental room complex. The increased sensitivity is caused by at least two factors. First, the high sampling rate of the centripetal samplers allows more of the released aerosol to be collected. Second, the higher effective particle size of the KI particles (7 microns) makes them more penetrative against directional air flows than microbial spores (ca1 micron) due to their greater inertia. The KI method is also more sensitive and representative of microbial aerosol particles than various gas tracer methods that

have been used to measure air transfer from rooms (Keene & Sansone, 1984). Thus, the KI test method may be considered a useful technique for commissioning and regular validation of containment laboratories.

The significant feature of this study is the finding that the LPF, a measure of containment, is dependent on the laboratory inflow and not the magnitude of the pressure differential. Since negative-pressure laboratories are normally designed on the basis of magnitude of pressure differential, this finding has major implications for containment-laboratory designers. This result can be explained by analyzing the effects produced when the doors of negative-pressure laboratories are opened. At negative pressure, or even at equal pressure, particles will not leak from the room through door gaps when the

Figure 5

The effect of volumetric inflow on laboratory protection factors during anteroom entry tests in the BL-3 laboratories (circles) and environmental room complex (triangles) measured in the anteroom (closed symbols) and corridor (open symbols).



pressure differential is static (i.e., when the door is closed). Release of particles is possible only when a door is opened or when the room pressure becomes positive as a result of ventilation malfunction. The latter may be identified by sensors linked to alarmed manometers. However, if an accident occurred resulting in the release of an aerosol, the staff involved are likely to leave the laboratory immediately. When the occupants leave through the laboratory door, the pressure differential will be reduced and will eventually become zero. In fact, in some cases the room pressure may momentarily become positive. During the evacuation period, some airborne material may be carried in eddy currents created by the departing occupants. Without differential pressure this airborne material can be prevented from escaping from the laboratory only by providing sufficient air flow

into the room through the open door.

The effect of opening the laboratory doors when the occupants leave can be demonstrated by calculating the velocity through the open doors of the individual laboratories from the laboratory inflow data in Table 1. The inflow velocity through the laboratory door (area 1.9 m²) of laboratory E, the laboratory with the lowest volumetric inflow, was only 0.02 m s⁻¹. In laboratory C, with the highest volumetric inflow, the inflow velocity was 0.14 m s⁻¹. All these inflow velocities are less than those required for Class 1 microbiological safety cabinets (0.7-1.0 m s⁻¹). However, in safety cabinets these inflows are created over the face of the cabinet before, during, and after the entire working period. In the case of the containment laboratory, the doors will normally be open only for a very small portion of the working period,

albeit sometimes subsequent to accidents. Therefore, these smaller velocities may be just as effective as shown by the experimental results.

When an operator entered the anteroom from the corridor, a release of aerosol from the laboratory into the anteroom and a slight release of aerosol into the corridor occurred (Table 4). The likely mechanism is as follows: When the outside door was opened, there was a transient flow of air out of the laboratory caused by the pressure fluctuation that could be observed from the laboratory manometer. This would cause some of the airborne material to enter the anteroom and subsequently the corridor when the person left.

Containment laboratory ventilation design has traditionally been based on maintaining negative pressures. The pressure differential between a laboratory and its surroundings can be increased in two main ways. The first is to increase the amount of air being drawn into the room. This is the more expensive method and can cause structural problems and contamination problems by drawing dirty ambient air into the laboratory. The second and less expensive method to increase negative pressure requires a lower exhaust flow rate in association with tightly sealing the laboratory door. This method is adequate as long as the laboratory door is closed. However, when the door is opened the pressure differential is rapidly lost and particles released within the laboratory cannot be prevented from escaping, along with air flow going outward through the door. Therefore, the main design criterion to prevent release of material from a laboratory should be the inward air flow. Pressure differential indicators would only have a secondary purpose as a monitor of the correct performance of the laboratory since the magnitude of the pressure differential should be proportional to the laboratory in a fixed system.

These studies also highlight the benefit of including an anteroom in the laboratory suite as shown in Table 3. All the BL-3 laboratories had higher LPF than the BL-2 laboratory F without an anteroom. This was demonstrated even in laboratory E which had a lower inflow than laboratory F. The overall LPF is increased by approximately 10-fold when an anteroom is incorporated into the facility.

In many BL-3 laboratories, negative pressure in

the laboratory is achieved by using Class I microbiological safety cabinets. Assuming that the volumetric throughput into standard Class I cabinets is between 0.7 and 1 m s^{-1} through a front aperture of approximately $0.2 \text{ m} \times 1.2 \text{ m}$ (BSI, 1992; NSF, 1983), the flow through the laboratory door would be 10.1 to $14.4 \text{ m}^3 \text{ min}^{-1}$. This is within the higher range for the laboratories at the Health Protection Agency, Porton Down and therefore should allow the same degree of protection as long as all air is channelled through the laboratory door and there are no other major laboratory air supply ducts.

The UK design guidelines published for operating theatres are very relevant to the needs of laboratory design since they also have a requirement for secure directional air flow rooms (NHS Estates, 1994). In this standard, door sizes, door crack width, air velocity between rooms, and resultant pressure differentials are all defined. This allows the designer to build operating theatres and validate them to an accepted standard. This type of approach can be and should be used for containment laboratories to ensure adequate containment without entailing unnecessary extra costs. The following design guidelines are suggested from the results of this study.

- Anterooms should be provided for all BL-3 laboratories.
- Laboratories should be designed to have a volumetric inflow through a standard door of about $10 \text{ m}^3 \text{ min}^{-1}$ and have a fixed alarmed negative pressure of approximately 30 Pa .

It is important that this type of information is provided by the national and international standards bodies in order to enable architects, safety advisers, and laboratory users to ensure that high category laboratories are constructed with an adequate level of containment.

The LPF can also be used in an assessment of the risks of release of airborne microbial aerosols from laboratories after escaping primary containment. The LPF is a measure of the comparative risk of material release from a containment laboratory. The LPF can be used in conjunction with the "spray factor" concept originally reported by Dimmick (1973) to carry out risk assessments. The spray factor is the proportion of a suspension aerosolised in an accident. This is well illustrated by the following ex-

ample: If a flask is dropped, it is estimated that 1 microorganism in 10^6 may be aerosolised (ACDP, 2001). In this case the spray factor is 10^6 . When a similar flask containing 50 mls of a 10^{10} per ml suspension of a pathogen is dropped, then 5×10^5 microorganisms will be aerosolised ($50 \times 10^{10} \times 10^{-6}$). If the LPF is 1×10^4 , then 50 microorganisms will be released into the corridor. If the LPF is higher (i.e., 1×10^5), the release will only be 5 microorganisms.

The use of quantitative risk assessment for the design and operation of microbiology containment laboratories, as demonstrated in this paper, should lead to a rational basis for biocontainment that does not entail excessive cost for the operators.

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References

- Advisory Committee on Dangerous Pathogens. (1995). *Categorisation of biological agents according to hazard and categories of containment* (4th ed.). London: HSE Books.
- Advisory Committee on Dangerous Pathogens. (2002). *The management, design and operation of microbiological containment laboratories*. London: HSE Books.
- British Standards Institute. (1992). *British standard 5726:1992 microbiological safety cabinets*. Milton Keynes: BSI.
- Clark, R. P., & Goff, M. R. (1981). The potassium iodide method for determining protection factors in open-fronted microbiological safety cabinets. *Journal of Applied Bacteriology*, 51, 439-460.
- Cox, C. (1987). *The aerobiological pathway of microorganisms*. Chichester, England: John Wiley and Sons.
- Dimmick, R. L. (1973). Laboratory hazards from accidentally produced airborne microbes. *Developments in Industrial Microbiology*, 15, 44-47.
- Foord, N., & Lidwell, O. M. (1972). The control by ventilation of airborne bacterial transfer between hospital patients, and its assessment by means of a particle tracer. I. An airborne-particle tracer for cross-infection studies. *Journal of Hygiene*, 70, 279-287.
- International Electrical Commission. (1993). IEC 1010-2-020. *Safety requirements for electrical equipment for measurement, control and laboratory use. Part 2. Particular requirements. Section 2.20 Specification for laboratory centrifuges*.
- Keene, J. H., & Sansone, E. B. (1984). Airborne transfer of contaminants in ventilated spaces. *Laboratory Animal Science*, 34, 453-457.
- May, K. R. (1973). The Collison nebuliser: Description, performance and application. *Aerosol Science*, 4, 235-243.
- National Sanitary Foundation. (1983). *Standard 49. Class II (laminar flow) biohazard cabinetry*. Ann Arbor, Michigan: Author.
- NHS Estates. (1994). *Health technical memorandum. 2025b. Ventilation in healthcare premises—Design considerations*. London: HMSO.
- Sharp, R., Scawen, M., & Atkinson, A. (1989). Fermentation and downstream processing of *Bacillus*. In C. Harwood (Ed.), *Bacillus*. (pp. 255-292). New York: Plenum Publishing Company.
- U.S. Department of Health and Human Services. (1999). *Biosafety in microbiological and biomedical laboratories* (4th ed.). Washington, DC: U.S. Government Printing Office.
- World Health Organization. (1993). *Laboratory biosafety manual* (2nd ed.). Geneva: Author.

Modeling environmental contamination in hospital single- and four-bed rooms

Abstract Aerial dispersion of pathogens is recognized as a potential transmission route for hospital acquired infections; however, little is known about the link between healthcare worker (HCW) contacts' with contaminated surfaces, the transmission of infections and hospital room design. We combine computational fluid dynamics (CFD) simulations of bioaerosol deposition with a validated probabilistic HCW–surface contact model to estimate the relative quantity of pathogens accrued on hands during six types of care procedures in two room types. Results demonstrate that care type is most influential ($P < 0.001$), followed by the number of surface contacts ($P < 0.001$) and the distribution of surface pathogens ($P = 0.05$). Highest hand contamination was predicted during *Personal care* despite the highest levels of hand hygiene. Ventilation rates of 6 ac/h vs. 4 ac/h showed only minor reductions in predicted hand colonization. Pathogens accrued on hands decreased monotonically after patient care in single rooms due to the physical barrier of bioaerosol transmission between rooms and subsequent hand sanitation. Conversely, contamination was predicted to increase during contact with patients in four-bed rooms due to spatial spread of pathogens. Location of the infectious patient with respect to ventilation played a key role in determining pathogen loadings ($P = 0.05$).

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Key words: HCAI; Indirect transmission; Hand contamination; CFD; Markov chain; Bioaerosol.

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Practical Implications

We present the first quantitative model predicting the surface contacts by HCW and the subsequent accretion of pathogenic material as they perform standard patient care. This model indicates that single rooms may significantly reduce the risk of cross-contamination due to indirect infection transmission. Not all care types pose the same risks to patients, and *housekeeping* performed by HCWs may be an important contribution in the transmission of pathogens between patients. Ventilation rates and positioning of infectious patients within four-bed rooms can mitigate the accretion of pathogens, whereby reducing the risk of missed hand hygiene opportunities. The model provides a tool to quantitatively evaluate the influence of hospital room design on infection risk.

Introduction

Risk of healthcare-acquired infections (HCAI) is omnipresent in healthcare facilities worldwide, and understanding transmission routes is key to effective control. While the transmission routes for some diseases are well documented, the precise mode of transmission is uncertain for many infections, particularly for those pathogens that cause HCAI. Although it is probable that the majority of transmission occurs via a contact route (Sax et al., 2009), there is increasing rec-

ognition that the hospital environment plays an important role.

Evidence suggests that at least 20% of HCAs potentially could have arisen from an environmental reservoir (Harbarth et al., 2003) and several recent studies have highlighted the importance of surface contamination and indicated a causal link to subsequent patient infection (Bhalla et al., 2004a). However, there is currently little robust understanding as to how healthcare worker (HCW)–surface contacts and activities in the healthcare environment result in HCW or

patient exposure to such pathogens. Studies of human behavior in the healthcare environment have largely acknowledged the lack of a comprehensive survey which collects the minutiae of hand-to-surface contacts (Duckro et al., 2005; Pittet et al., 1999; Smith et al., 2012). Major studies have however, highlighted that environmental contamination, through the deposition of bioaerosol on surfaces, cannot be underestimated in the contribution to fomite-based infection transmission (Dancer, 2008; King et al., 2013; Otter et al., 2011; Rusin et al., 2002). Surfaces such as bed rails have been linked with harboring microorganisms that cause hospital infections, and many frequently used surfaces in hospitals have been found to sustain viable pathogens including staphylococci, enterococci (Duckro et al., 2005; Hayden et al., 2008; Pittet et al., 2006), and *Clostridium difficile* (Roberts et al., 2008). In addition, indirect infection transmission shows a distinct possibility of being exacerbated by incomplete or non-existent surface cleaning (Bogusz et al., 2013). Pathogens have been also shown to accrue on HCW hands as they touch surfaces (Pittet et al., 1999), and there is evidence they can subsequently be transmitted to patients (Hayden et al., 2008).

Hospital designs are tending toward incorporating single rooms, based on the premise that single room enables 24/7 admissions without disruption to other patients, and the design will improve confidentiality for clinical discussion, examinations, and treatment (Chaudhury, 2005). In reviewing the literature, Chaudhury (2005) further report single rooms to promote a therapeutic environment that is patient and family centered increasing recovery and reducing infections and risks and enhancing the healthcare professional and patient relationship. This evidence is supported by Ulrich and Zimring (2008), when considering the NHS Estates perspectives and further purport that single rooms provide increased levels of protection and prevention from infection.

In addition, research has explored these issues in depth, where there is an increasing body of evidence which points toward a relationship between hospital room design and infection control (King et al., 2013; Pittet et al., 2006; Shih et al., 2007; Tian et al., 2006). Ventilation is well recognized as a control strategy for airborne infection (Zhang et al., 2009) and is recommended for diseases such as tuberculosis, measles, SARS, and more recently influenza (Yang et al., 2011). Aerial dispersion of bioaerosols has been associated with non-respiratory pathogens in hospitals including methicillin-resistant *Staphylococcus aureus* (MRSA) (Sherertz et al., 1996) and *C. difficile* (Roberts et al., 2008), and subsequent contamination of surfaces has been recognized as a potential transmission route for some infections (Bhalla et al., 2004b). However, research into the combined role of airborne dispersion, pathogen contamination of hospital room surfaces,

Modeling environmental contamination in hospital rooms

and interaction with human behavior is still in its infancy (Zartarian et al., 2012). Furthermore, the influence of airflow patterns and ward design on the risk of this combined transmission route is not well understood. Single-bed rooms are widely advocated over four-bed patient environments for their infection control potential, yet there are little data to allow quantification of the touted benefits (Ulrich and Zimring, 2008).

This research focuses on the combined interaction between deposition of airborne microorganisms, room design, and human behavior by considering the question: Are single-bed patient rooms more effective than their four-bed counterparts at reducing the risk of infection from environmental contamination? The study compares hospital single- and four-bed room environments by modeling likely contamination on the hands of healthcare workers resulting from pathogens released from an aerosol source and deposited on surfaces. The model combines computational fluid dynamics (CFD) simulations of room airflow and particle deposition (King et al., 2013) data from HCW hand-surface contact patterns established through a hospital observational study and a dermal pathogen accretion model to simulate contamination of HCW hands. The resulting probabilistic pathogen accretion model (PAM) is used to compare the effect of room layout and ventilation rate on HCW hand contamination during six different types of patient care.

Methodology

Patient rooms

Two room scenarios are considered: a typical hospital single room and a standard four-bed room. Both room layouts are based on the UK Department of Health standard, HBN04-01 (Department of Health Estates and Facilities Division, 2008), and computer aided design models are illustrated in Figure 1.

Rooms are assumed to be fully occupied, with one infectious patient in each scenario. In both rooms, modeling is conducted with the ventilation at 6 air changes per hour (ac/h), as per the UK Department of Health guidance, HTM03-01 (Department of Health, 2007) and at a reduced rate of 4 ac/h. In the case of the four-bed ward (*cases 3–10*), the relative influence of ventilation design was also considered through changing the location of the infectious patient. All cases together with a brief description are shown in Table 1.

Environmental contamination

Computational fluid dynamics (CFD) simulations were carried out to predict the likely spatial deposition pattern resulting from bioaerosols released from a quiescent patient in the single- and four-bed room. The

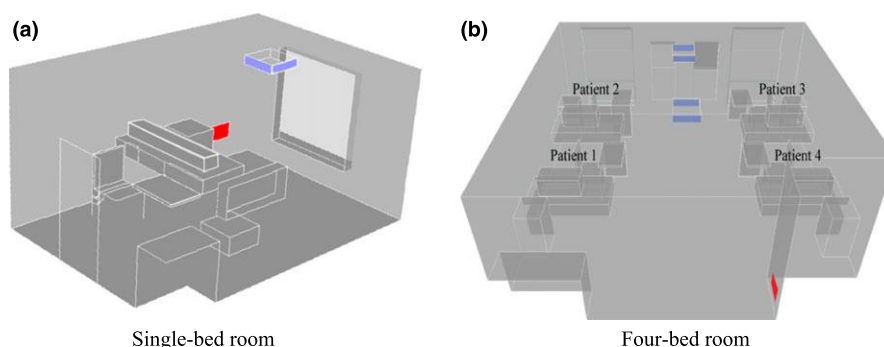


Fig. 1 Typical room layouts from HBN04-01, as used in CFD simulations, showing simplified furniture arrangement, ceiling mounted supply and wall mounted extract. (a) single room and (b) four bed room

Table 1 Case study scenarios

Case N°	Room type	Room dimensions	ac/h	Infectious patient
1	Single-bed	4.7 × 3.8 × 2.8 m	4	Patient's head
2	Single-bed		6	Patient's head
3	Four-bed	6.8 × 7.6 × 2.8 m	4	Patient 1
4	Four-bed		4	Patient 2
5	Four-bed		4	Patient 3
6	Four-bed		4	Patient 4
7	Four-bed		6	Patient 1
8	Four-bed		6	Patient 2
9	Four-bed		6	Patient 3
10	Four-bed		6	Patient 4

CFD methodology is detailed below and has previously been shown to compare well to experimental measurements of bioaerosol deposition in chamber studies (King et al., 2013). In this previous study hospital, single-bed and two-bed rooms were replicated inside an aerobiology chamber at the University of Leeds (4.2 × 3.2 × 2.2 m) with steady ventilation at 6 ACH. *Staphylococcus aureus* was aerosolized by a Collision Nebuliser (CN 25; BGI Inc., Waltham, MA, USA) (mean diameter 2.5 μm) and released into the room for 30 min at the head of a supine heated mannequin. Deposition of bacterial colonies was quantified on key surfaces by means of nine agar-filled petri dishes per surface CFD simulations conducted in Fluent v.13 (ANSYS, Canonsburg, PA, USA) and following the methodology outlined below were used to model deposition of 2.5 μm particles released at the same location and with the same geometry as the experimental scenarios. Normalized concentrations on surfaces were seen to compare well between the experiments and CFD model, giving confidence that the CFD modeling approach can predict a realistic spatial deposition pattern in a ventilated room.

In the current study, steady-state airflow simulations were carried out using Fluent v.13 (ANSYS) for the model hospital room geometries shown in Figure 1. Meshing, carried out in ANSYS Workbench v13, was fully hexahedral. Grid density and construction has

been shown to heavily influence flow results (Roache, 1997); therefore, a mesh independence study was based on the formulation set out in King et al. (2013). For this three hexahedral, grids with nominal cell sizes of 50, 25, and 20 mm were compared. Velocity variation was found to differ less than 5% between the 25 and 20 mm meshes at selected points within the bulk flow. A maximum cell volume of $1.5625 \times 10^{-5} \text{ m}^3$ was used within the bulk domain, and $1 \times 10^{-6} \text{ m}^3$ was used 10 cm away from all horizontal surfaces. Final cell count for all simulations was approximately 4 and 8 million volumes for the single- and four-bed rooms, respectively.

Mechanical ventilation was modeled through a simplified four-way ceiling supply diffuser (Zhang et al., 2009) with velocity boundary conditions specified to give the air change rates in Table 1. Air was assumed to be extracted via a wall-mounted grille, with a pressure boundary condition of -10 Pa . Turbulence was modeled with a Reynolds' Stress (RSM) closure model and standard wall functions; this model was shown in the previous study to compare better with experimental bioaerosol deposition data than the more commonly used k-epsilon model (King et al., 2013). Human patients lying supine on the beds were represented through simplified blocks emitting a heat flux of 56 W/m^2 . Air entering the room was at 20°C and all walls were adiabatic. Bioaerosols were modeled using a Lagrangian particle tracking method with discrete random walk. In each case, 10,000 2.5 μm diameter inert particles were released via a volume source located 10 cm above the patient's head and given an inlet velocity of 1 m/s in the positive vertical direction to represent exhalation.

Table 2 Surface categories and modeled surfaces in CFD geometries

Equipment	Patient	Near patient	Far patient	Hygiene areas
Location on bed wall (1 × 0.4 m)	Mannequin	Bed Chair Tray Bedside table	Window Workstation	Sink Towel dispenser

Nine surfaces of interest were defined within the CFD model, as indicated in Table 2, and the modeled particle concentration was determined on the surfaces for each scenario in Table 1. These surfaces were based on those monitored during the observation study outlined below.

CFD simulations were carried out on a University of Leeds' high-performance facility (ARC1 with 672 AMD cores and 128 GB memory), were considered converged when residuals for continuity and all other variables dropped below 1×10^{-4} , and remained below this for at least 100 iterations. All variables are scaled with respect to the sum of the errors in all cells. In addition, continuity is scaled with respect to the largest absolute value within the first five iterations and so can be considered normalized (ANSYS 2010).

HCW–surface contacts

The likelihood of healthcare workers having contact with surfaces during patient care was developed from surface contact data accrued during an observational study carried out at a National Health Service (NHS) single-bed accommodation hospital ward during the first quarter of 2012. Healthcare workers were observed during episodes of care categorized into six areas described in Table 3, following standardized categories set out in Pittet et al. (1999) and Dancer et al. (2010).

In each observed care episode, hand-to-surface contacts with surfaces set out in Table 4 and the sequence

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with which they happened were recorded. Typical locations of these surfaces are shown in Figure 2. The occurrence and type of hand hygiene after each care episode was also recorded. Over 400 individual care episodes were observed.

Data from the observations were used to generate representative contact patterns to model the likely sequence of surface contacts by a HCW in a patient room. HCW were found to touch surfaces in a non-random sequential or directed manner, insofar that moving from one surface category to another has a higher probability than a transition to somewhere else. By assigning each surface category a numerical value from 1 to 5, where *Equipment* = 1, *Patient* = 2, *Hygiene areas* = 3, *Near-bed surfaces* = 4, and *Far-bed surfaces* = 5, the movement of the HCW between surfaces can be represented by means of a weighted probability.

The movement of HCW between surfaces is modeled using a Markov chain approach (Allen, 2008). Using the defined weighted probabilities, the movement of a HCW between surfaces can be simulated based on the property that, given the present state, the future and past states are independent. This is termed the Markov Property:

$$P(X_i = x_i | X_j = x_j). \quad (1)$$

Given the five surface categories, the probabilities can be expressed in a transition matrix (P) indicating the maximum likelihood of directed contact between any pair of surfaces. For example, if the HCW is currently touching surface category 1, p_{12} is the probability that they will then touch surface category 2. This probability is derived from the observed data by counting the occurrences of the transition 1→2 for each HCW in the observational study and dividing by the total number of surface transitions throughout their episode of care. Thus, $\hat{P}_{ij} = \frac{x_{ij}}{\sum_m x_{ik}}$, where $m = 1 \dots 5$ states, and indices i, j , and k are dummy indices to indicate summation.

The observed data enabled surface contact transition matrices to be created for single-patient rooms, but to compare single- and four-bed rooms, HCW behavior in the four-bed room must be modeled. This was undertaken by assuming that care approaches were similar in the two room types and adjusting the transition probabilities based on other published information. Smith et al. (2012) conducted an observational study of HCWs in a four-bed room applying the same surface category criteria as used here. However, they note that patient charts become near-bed objects as these are often at the foot of the patient's bed rather the far side of the room; in our single-bed rooms, chart positions were modeled as a far-bed surfaces as the chart was located on the workstation (Figure 2) in the observation study. Therefore, this adjustment is made

Table 3 Six care types with examples of procedures within each type

Direct care	Housekeeping	Mealtimes	Medication rounds	Miscellaneous	Personal care ^a
Blood pressure measurement	Equipment cleaning	Distribution of meals	Distributing medication	Call bell request	Toileting
Weighing patients	Cleaning patient surfaces		Injections	Response to pressure mattress alarms	Patient changing
Blood sugar saturation					

^aNote that limited observations were made for personal care episodes for patient privacy reasons.

Table 4 Surfaces within each surface category during the monitoring study

Surface category				
Equipment	Patient	Near patient	Far patient	Hygiene areas
IV stand	Clothing	Bedrail	Window	Alcohol gel
Hoist		Bedding	Curtain	Soap dispenser
BP cuff/stand		Tray	Light switch	Tap
Notes trolley		TV	Chart	Sink
Medication trolley		Chair	Door/handles	Paper towel dispenser
		Bedside table		

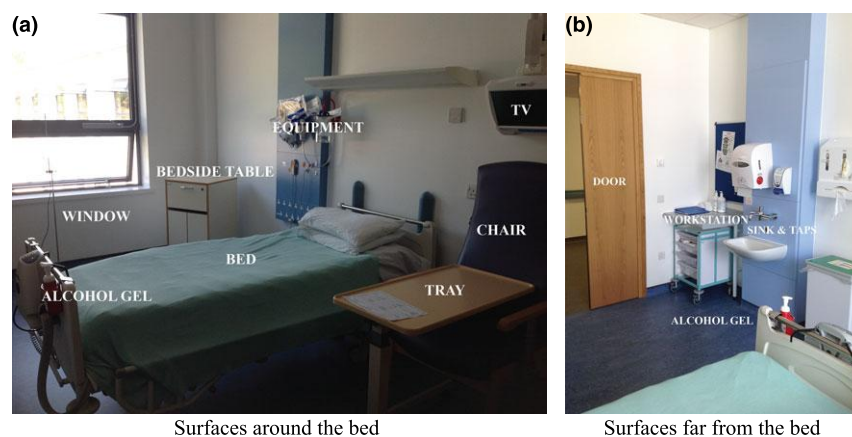


Fig. 2 Typical location of surfaces in the single room which were monitored for HCW contacts. (a) room surfaces close to the bed and (b) surfaces close to the door

to the probability densities derived from the healthcare observations. A Wilcoxon rank-sum nonparametric test comparing Smith et al.'s (2012) data to the current study shows that no statistical difference exists at the 5% level ($P = 0.068$), highlighting that the only difference in HCW behavior between single- and four-bed rooms is the positioning of patient charts. Consequently, this demonstrates the similarity between nurse behavior in single- and four-bed rooms. All four-bed simulations use this adjusted behavior in line with Smith et al. (2012).

Pathogen accretion model

Colonization of HCW's hands through contact with a contaminated surface is considered to be a dynamic process in which multiple factors may vary. The number of microorganism colony forming units, Y (cfu), accrued on HCWs hands from environmental or patient surface contacts during patient care can be shown via sensitivity analysis to depend primarily on six variables (Pessoa-Silva et al., 2004).

$$Y = Y(n, A, V, \lambda, \beta, h). \quad (2)$$

The number of surfaces touched, n . Each type of care shows a variable pattern of surface contact frequencies and sequences. Probabilistic distributions for these were obtained from the observational study as outlined above.

Surface contamination, V (cfu/cm²). The concentration present on each room surface is dependent on the scenario in question. These are obtained from sampling the lognormal distribution based on the CFD simulations for each scenario, as described above. It must be highlighted that this study considers no microbial die-off due to environmental stress as this is a time-dependent phenomenon. Therefore, V is assumed to be

proportional to the amount released initially in each case. The parameter V is regarded as the initial condition for the PAM model simulations, with the surfaces already contaminated at the point the HCW is assumed to enter the room. In addition, if each particle is treated as one cfu, the resulting deposition in cfu/cm² is comparable to actual hospital values (Mulvey et al., 2011).

Hand-surface contact area, A (cm²). This is assumed to exhibit a continuous distribution based on experimental values from Brouwer et al. (1999). They show that this can be modeled as a lognormal distribution with an arithmetic mean of 7 cm² and standard deviation of 1.9 cm² [corresponding to $\ln N \sim (0.84, 1.3)$]. For each surface contact, it is assumed that either hand may be in contact with the surface and no distinction is made for right- or left-handedness.

Surface-to-Hand Transfer efficiency, λ . It is reasonable to assume that not all of the pathogens in contact with the area of skin touching the surface are transferred to the hands. Transfer efficiency, which represents the percentage of surface contaminant transferred to the hand during a contact event, has been shown to be one of the most important parameters when modeling dermal exposure (Xue et al., 2006). Unfortunately, it is one of the most troublesome to accurately measure (Beamer et al., 2009). Transfer efficiency could be a function of multiple ambient parameters such as surface physiology, contact frequency, duration and pressure, concentration of transferrable material on surface, temperature, and humidity. Rusin et al. (2002) conclude from experimental studies that the transfer efficiency from surfaces to hands also varies between microorganism species. In three separate experiments, they reported the transfer of Gram-positive bacteria, Gram-negative bacteria, and bacteriophage to be 38.5%, 65.8%, and 27.6–40%, respectively, from

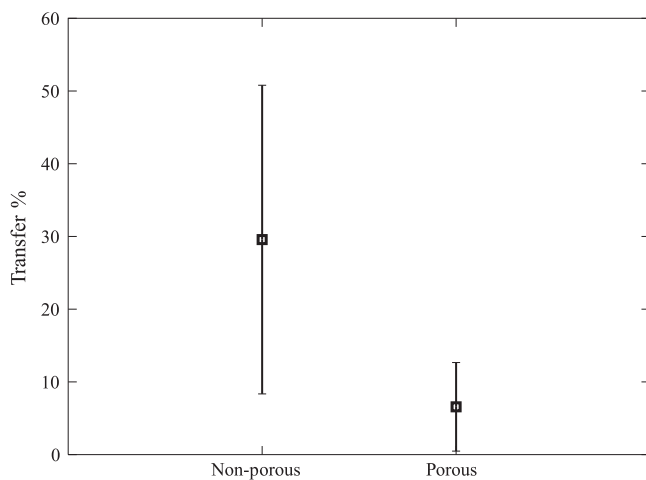


Fig. 3 Surface-to-hand transfer efficiency (λ). Data derived from Rusin et al. (2002)

non-porous surfaces. However, they indicate the transfer rate reduces to below 10% when porous fomites are evaluated. As there are insufficient data available in the literature to model the influence of specific parameters, the model employs the distribution developed by Rusin et al. (2002), as shown in Figure 3, to represent the variability in transfer efficiency.

Hand-to-surface transfer efficiency, B . A significant quantity of material residing on hands may also be transmitted to the surface during contact (Otter et al., 2013). Montville and Schaffner (2003) demonstrate that a difference exists between the direction of transfer, with statistically significantly lower transmission shown during transfer from hands to fomites than vice versa. They also highlight the influence of inoculum size on the efficiency of transfer, showing that when high levels are used, transfer rates are more accurately characterized (Montville and Schaffner, 2011). Surface-to-hand transfer efficiencies (β) are sampled from Monteville et al.'s empirical data. Therefore, during hand-to-surface contact, a proportion of pathogens already acquired by the HCW may be deposited from the hand onto the surface (Rusin et al., 2002). Random sampling is conducted from data in Montville and Schaffner (2003).

Antisepsis efficacy, h (%). This refers to the efficiency of reducing microbial contamination of HCWs' hands after performing one of three types of hand hygiene: hand washing with either bland or medicated/antibacterial soap, removal of non-surgical gloves, or dry rubbing with a waterless alcohol agent (minimum 61% ethanol by volume). Here, hand hygiene efficacy is based on data from published studies where significant sample sizes are available (Girou et al., 2002; Montville and Schaffner, 2003; Sickbert-Bennett et al., 2005). Microorganism type has been shown to exert a differ-

Modeling environmental contamination in hospital rooms

ence on hand hygiene efficacy, which is likely to be due to their individual adherence properties (Boks et al., 2008). Particular difference is noticed between bacteria and viruses (or bacteriophage), where removal of the latter is often an order of magnitude lower. Nevertheless, bacteria have the primary concern of many infection control teams, where MRSA or *C. difficile* often rank highest on the prevention list. Consequently, the model is non-organism specific, whereby resident or background microflora is ignored. Whether or not hand antisepsis actually occurs following an episode of patient care is based on the probabilities derived from the observation study and depends on care type.

Following a variance based sensitivity analysis using total effect Sobol indices (Nossent et al., 2011), the function shown in Equation 2 can be used to model pathogen accretion (Y) by means of a recurrence relationship given in Equation 3. This represents the hand pathogen loading at any time-step after contact with any one surface.

$$Y_i = \lambda_i V_i A_i + \beta_i Y_{i-1}, \quad (3)$$

where $i = 1 \dots n$ is the surface contact count. For purposes of remaining succinct, let $\sigma = \lambda AV$ then assuming that the transfer of pathogens to the surface from the HCW occurs sequentially and is independent of the surface loading then Y can be described as follows:

$$\begin{aligned} Y_i &= \sigma_i + \beta_i * (\sigma_{i-1} + \beta_i * (\sigma_{i-2} + \dots)) \\ &= \sigma_i + \beta_i \sigma_{i-1} + \beta_i \beta_{i-1} \sigma_{i-2} + \dots \\ &= \sum_{j=0}^i \left(\prod_{k=j+1}^i \beta_k \right) \sigma_j. \end{aligned} \quad (4)$$

HCW touching surfaces during an episode of patient care forms the driving force within this model. The model was programed using Matlab (MathWorks, Natick, MA, USA). For each scenario, a Monte Carlo simulation of 1,000 HCW care episodes was conducted for each care type, modeling the mechanics of pathogen transfer based on the input parameters set out above.

Results and discussion

Bioaerosol deposition

Surface deposition concentrations, cfu/cm² predicted from the CFD simulations following the release of 10,000 cfu, can be seen in Figure 4. These show the breakdown of particle concentration for the five different surface categories and, in the four-bed case, for each infectious patient position in turn (Figure 4b–e). Deposition in the single room (Figure 4a) appears to be mainly focused on the equipment area and the

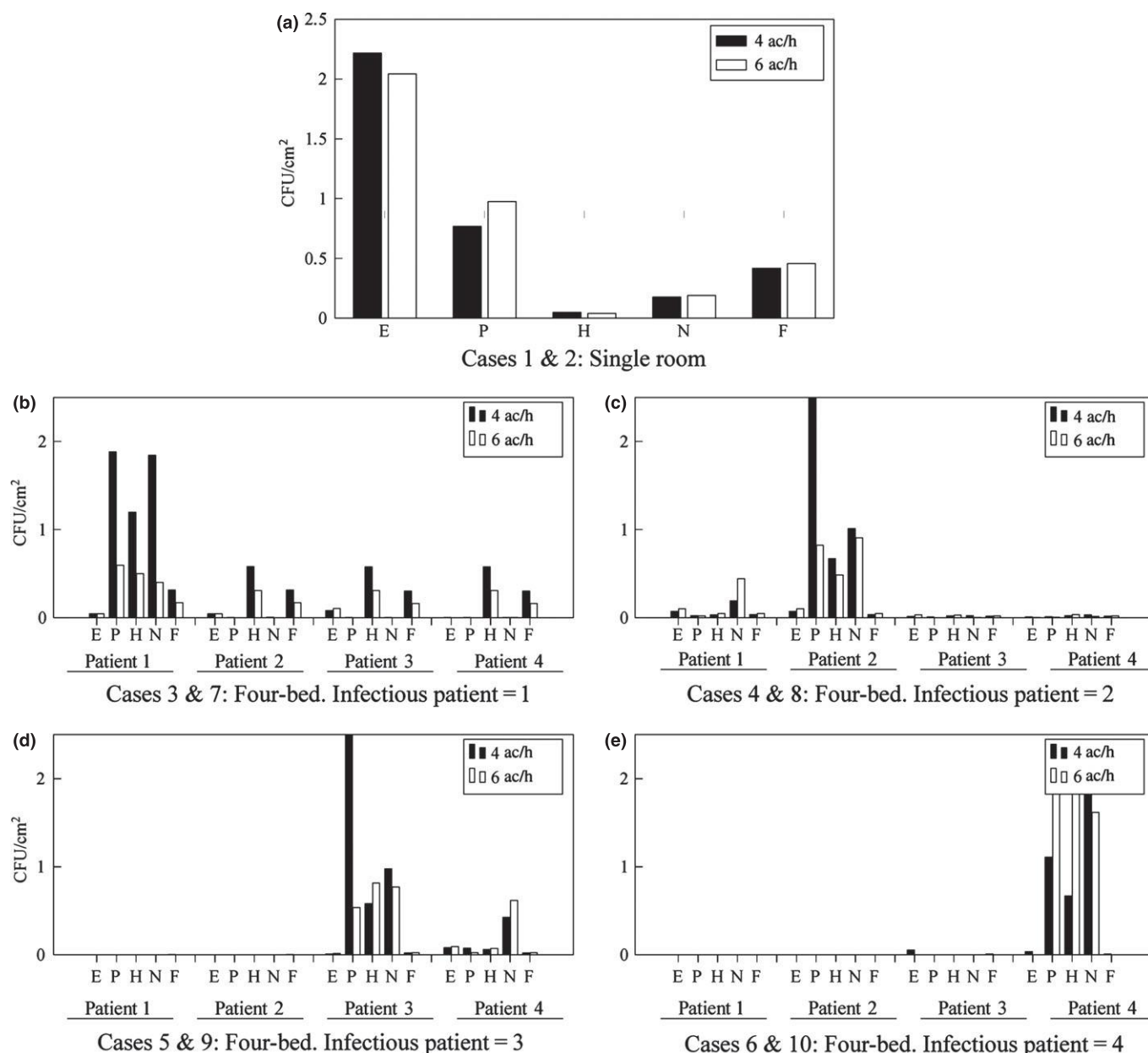


Fig. 4 Predicted particle deposition (cfu/cm²) on horizontal surfaces within the single- and four-bed accommodation for an initial release of 10,000 cfu. Comparison shown between 4 ac/h and 6 ac/h for each case. (a) case 1 & 2 in the single room, (b) cases 3 & 7 in the four-bed room where the infectious patient is in position 1, (c) cases 4 & 8 in the four-bed room where the infectious patient is in position 2, (d) cases 5 & 9 in the four-bed room where the infectious patient is in position 3 and (e) cases 6 & 10 in the four-bed room where the infectious patient is in position 4. E = Equipment, P = Patient, H = Hygiene areas, N = Near-patient surfaces, F = Far-patient surfaces

patient themselves, and the model predicts little difference in the deposition pattern between 4 and 6 ac/h. In the case of the four-bed room, predicted surface concentrations are highest in the vicinity of the source patient in all cases. Surfaces opposite the source position demonstrate a sharp drop-off; here, particles appeared to be maintained airborne and directed toward the extract. This is particularly the case when *patient 2* is the source (Figure 4c), where a seemingly dichotomous partition within the room can be observed, and few particles are deposited on *patients 3*

and 4. Equally when *patient 3* is the source (Figure 4d), negligible counts can be found in the vicinity of *patient 1* or *patient 2*, and when *patient 4*, closest to the extract, is the source, there are very few counts in the vicinity of any of the other patients. However, the distribution when *patient 1* is the source (Figure 4b) is noticeably different with deposition predicted across the room.

Wong et al. (2010) suggest that as the air change rate increases, the deposition increases further from the source. A one-way nonparametric Wilcoxon signed-rank

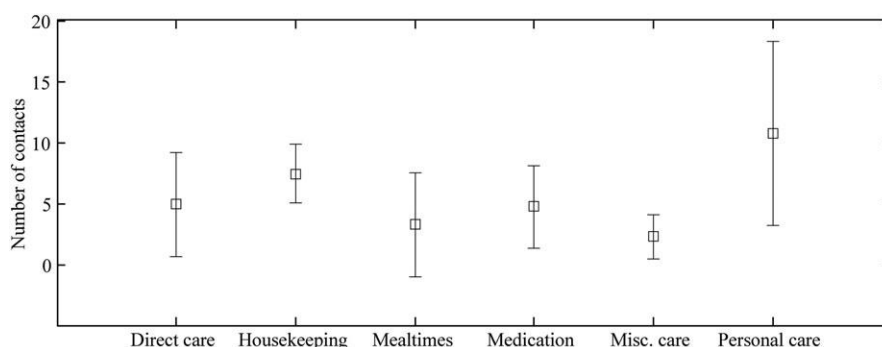


Fig. 5 Mean and standard deviation of surface contacts observed and used in the model

Table 5 Transition matrices $\hat{P}_{ij}$, showing directed probabilities of moving from surface i to surface j for each type of care

$\begin{pmatrix} 0.18 & 0.31 & 0.08 & 0.15 & 0.28 \\ 0.47 & 0.11 & 0.01 & 0.25 & 0.16 \\ 0.18 & 0.24 & 0.22 & 0.19 & 0.16 \\ 0.24 & 0.18 & 0.06 & 0.34 & 0.18 \\ 0.25 & 0.18 & 0.12 & 0.18 & 0.28 \end{pmatrix}$ (a) Direct care	$\begin{pmatrix} 0.3 & 0 & 0 & 0.40 & 0.30 \\ 0 & 0 & 0 & 0.70 & 0.33 \\ 0 & 0 & 0.17 & 0.17 & 0.67 \\ 0.23 & 0.05 & 0 & 0.64 & 0.10 \\ 0.27 & 0.13 & 0.20 & 0.27 & 0.13 \end{pmatrix}$ (b) Housekeeping	$\begin{pmatrix} 0 & 0 & 0 & 0 & 0 \\ 0 & 0 & 0 & 1 & 0 \\ 0 & 0.14 & 0.36 & 0.36 & 0.14 \\ 0 & 0.20 & 0.07 & 0.60 & 0.13 \\ 0 & 0.14 & 0.14 & 0.57 & 0.14 \end{pmatrix}$ (c) Mealtimes
$\begin{pmatrix} 0.03 & 0.28 & 0.22 & 0.34 & 0.13 \\ 0.14 & 0.03 & 0.12 & 0.56 & 0.15 \\ 0.05 & 0.17 & 0.17 & 0.39 & 0.23 \\ 0.07 & 0.35 & 0.11 & 0.25 & 0.22 \\ 0.14 & 0.14 & 0.16 & 0.37 & 0.20 \end{pmatrix}$ (d) Medication round	$\begin{pmatrix} 0 & 0.43 & 0 & 0.29 & 0.29 \\ 0 & 0 & 0.13 & 0.75 & 0.13 \\ 0 & 0.06 & 0.19 & 0.55 & 0.19 \\ 0.03 & 0.11 & 0.14 & 0.35 & 0.38 \\ 0.23 & 0.08 & 0.12 & 0.42 & 0.14 \end{pmatrix}$ (e) Misc. care	$\begin{pmatrix} 0 & 0 & 0 & 1 & 0 \\ 0 & 0 & 0.22 & 0.44 & 0.33 \\ 0 & 0.19 & 0.57 & 0.10 & 0.14 \\ 0.03 & 0.19 & 0.09 & 0.50 & 0.19 \\ 0 & 0.06 & 0.13 & 0.56 & 0.25 \end{pmatrix}$ (f) Personal care

test does not uphold this conclusion here, and there is no clear difference between the two air change rates. However, a statistically significant difference is exhibited in the four-bed room ($P = 0.04$) between surface concentrations for different infectious patients at the same air change rates.

Surface contact sequences

Observational study data indicated the probability of contact with different surface categories ($P = 0.04$) along with hand hygiene method ($P = 0.02$) was dependant on care type. Statistical differences were also significant between the total number of surface contacts and the likelihood of hand hygiene being performed for different care types. It should be noted that this is not analogous to hand hygiene compliance as the research team are not able to pass judgment on what hygiene procedures should be followed for a particular care episode. Figure 5 shows the mean and standard deviation of surface contacts observed and used in the model:

Table 5 shows transition matrices $\hat{P}_{ij}$ for all care types derived from all observed HCW surface–contact sequences. Briefly recapping, the transition states are as follows: 1 = *Equipment*, 2 = *Patient*, 3 = *Hygiene areas*, 4 = *Near-bed surfaces*, and 5 = *Far-bed surfaces*.

Using these directed probabilities, Figure 6 shows a typical example sequence of surface contacts by a

HCW during an episode of care in a single room by means of a stochastic simulation.

Hand hygiene

The observational study data showed statistically significant differences in hand antiseptic choice between care types ($P < 0.001$), with some variation within each care type, as shown in Figure 6. Alcohol rub was used abundantly throughout all but *personal care*, where hand washing with soap and water predominated. Glove usage accounted for only 2% of observed episodes of care, half of which were during *housekeeping*. These probabilities are incorporated into the PAM model to account for the likelihood of HCWs undertaking some form of antiseptic after each episode of care (Figure 7).

Model validation

Published data which measures contamination levels of HCWs' hands are scarce. In particular, Pittet et al. (1999) is the only known published study that quantifies both cfu values along with the time spent in the room by the HCW. However, their methodology does not include surface swabbing and hence a specific value for surface contamination, V , is not known. Nevertheless, assuming that other variables such as HCW hand

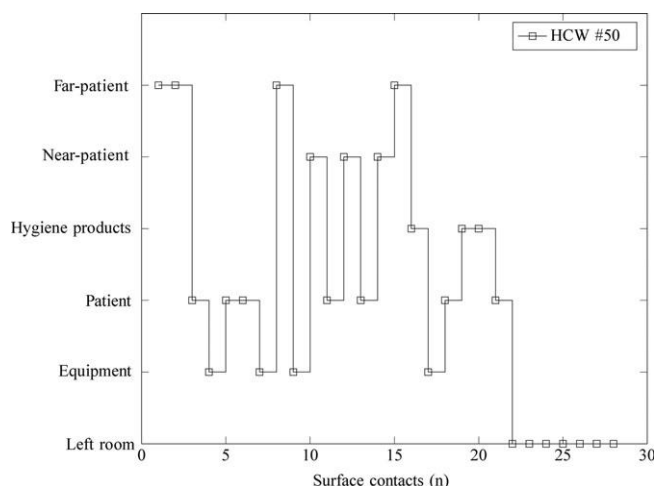


Fig. 6 Example of surface contacts of HCW #50 performing an episode of *direct care*

surface area, surface types, and nursing behavior are comparable between scenarios, it is reasonable to compare the distribution shape by means of a Kendall-tau nonparametric test of the simulated cfu from PAM and the measured data by Pittet et al. (1999). Specifically, this is a measure of rank correlation or the similarity of the orderings of the data when ranked by each of the quantities. This approach is used for comparing the differences between individual observations with respect to each other to gain an insight into the overall data distribution.

Initial comparison shows a less-than-perfect fit ($P \sim 0.2$), and therefore, the data from both PAM and Pittet et al. were split into 4 groups corresponding to: lower quartile ($\leq 25\%$), lower-mid quartile ($25\% < x \leq 50\%$), upper-mid-quartile ($50\% < x \leq 75\%$), and upper quartile ($75\% < x \leq 100\%$).

Good comparison is shown particularly at lower (first quartile) values ($P = 1 \times 10^{-3}$), where a higher concentration of data exists. Both lower-mid and upper-mid quartiles compare well ($P = 0.01$ and $P = 0.04$). Higher values of cfus (upper quartile) become less frequent and the comparison is poorer ($P = 0.12$). The reader must note that detection levels by glove juice methods and subsequent culture techniques carried out by Pittet et al. (1999) have led to truncated data, which is likely the reason for less optimal comparison at this level. If these data were extrapolated, PAM potentially may approximate the behavior better in the upper quartiles ($P \sim 0.02$). However, pending greater sources of data, it is not unreasonable to conclude that at least through the first two quartiles or the first 50% of cfu colonization levels, PAM is a capable and realistic model.

Application of PAM to single- and four-bed rooms

Air change rate. Results from PAM are all normalized with respect to the mean contamination level on HCWs' hands after *direct care* in the single room at 6 ac/h. This can be considered the 'base case' and enables comparison between rooms, ventilation, and care types.

Figure 8 depicts predicted normalized cfu on HCW hands, Y , compared against the average of *direct care* for each subsequent type of care within the single room. Additionally, the comparison is made between a ventilation rate of 4 and 6 ac/h. Initially, there appears only to be a small reduction in hand contamination from 4 to 6 ac/h when comparing medians, and comparison of the upper quartile shows small differences depending on care type. However, comparison of extrema using a Kruskal-Wallis nonparametric test reveals that predicted hand contamination levels under

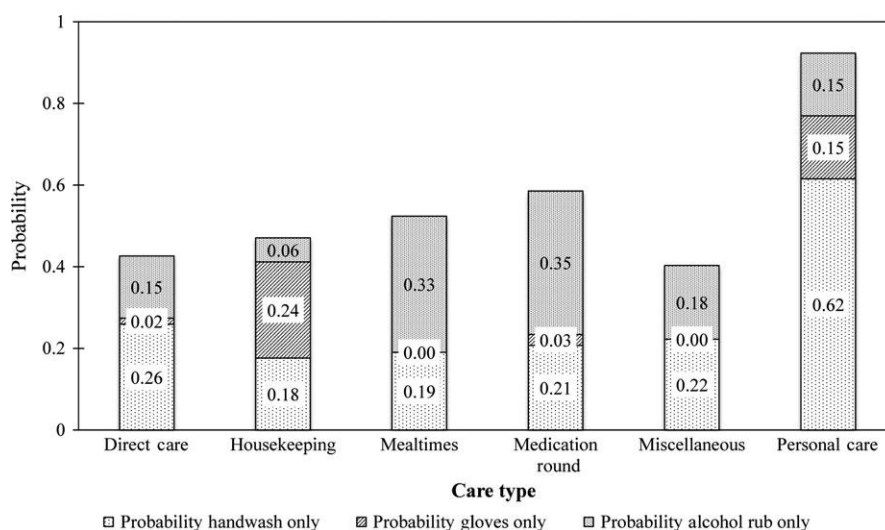


Fig. 7 Cumulative probability of hand hygiene category subdivided by care type

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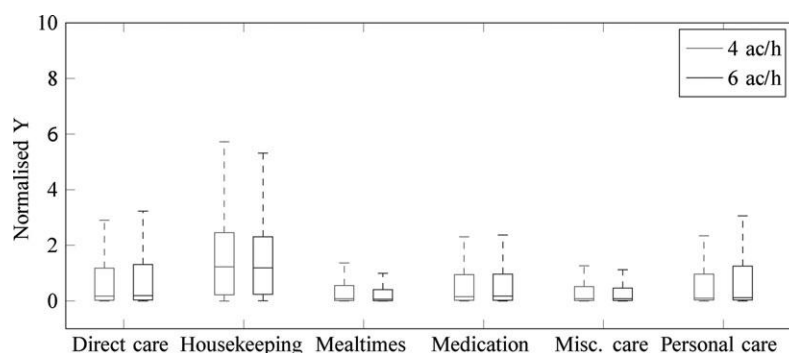


Fig. 8 Boxplots showing predicted normalized cfu values on HCW hands for a single room before hand hygiene, comparing 4 and 6 ac/h

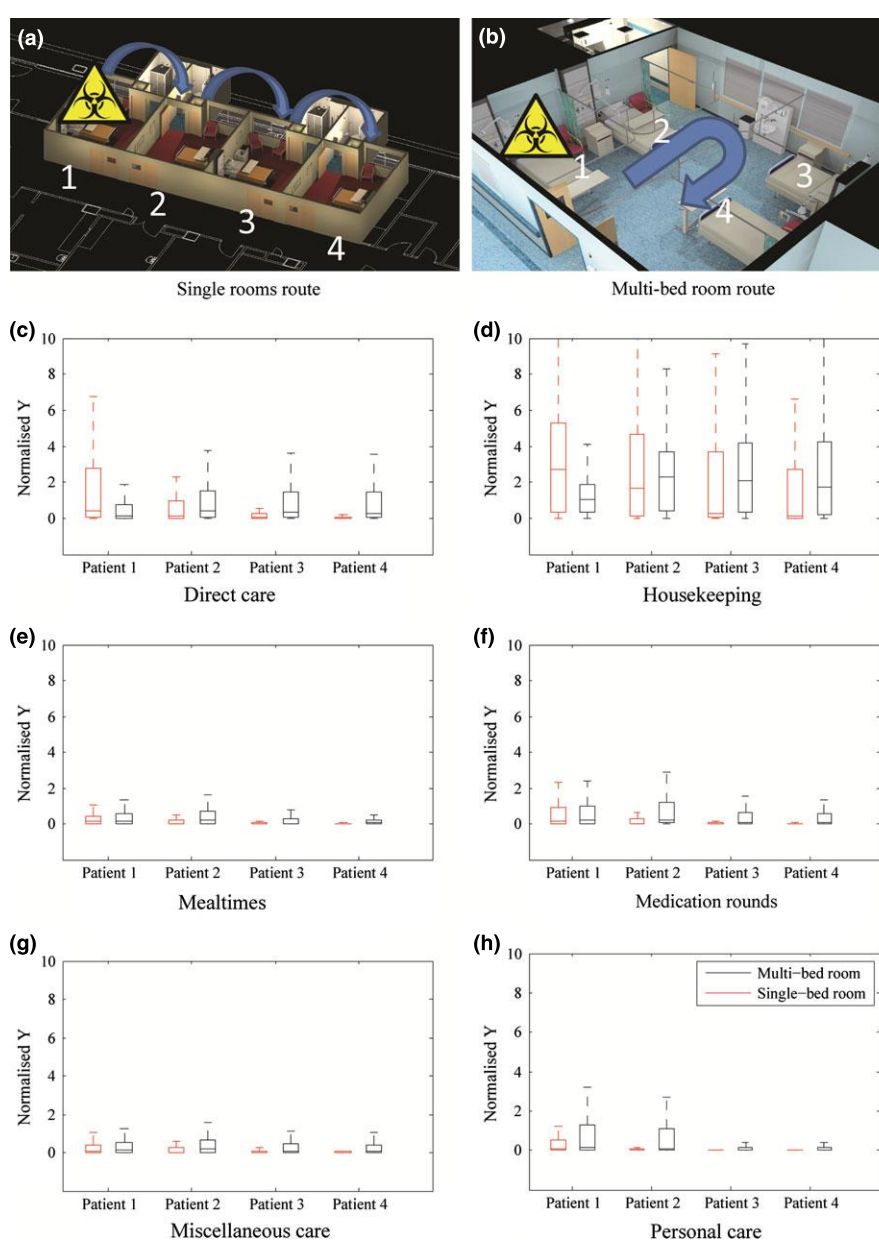


Fig. 9 HCW route for all care types in the single- and multi-bed rooms at 6 ac/h (a, b). Boxplots (outliers omitted) of cumulative normalized Y values after different episodes of care (c-h). Multi-bed plots are an average of four episodes of care, varying the infectious patient location

a ventilation rate of 4 ac/h are consistently higher throughout ($P < 0.05$).

Room type. In Figure 9, we consider two design options: four patients located in four single rooms or colocated in one-four-bed room. In each case, the simulation assumes that one patient is infectious and that the HCW provides care to all four patients in turn. The model assumes the worst case scenario where the first patient attended to is the infectious one (Figure 9a,b). All other parameters in the model, including hand washing are as set out in the methodology. Figure 9c–h shows the normalized contamination on HCW hands (Y values) for progression through the series of four patients in single- and four-bed rooms with no airborne cross-transmission between the rooms. The results show that cfu values are likely to be monotonically decreasing as the HCW progresses between patients in the single rooms. Environmental contamination due to the patient is only present in room 1, and hand antisepsis removes contamination in the majority of cases and minimizes further environmental contamination in subsequent rooms. In the case of the multi-bed room, the results are quite different. Rather than an expected decrease due to hand hygiene, the aerial spread of microorganisms to neighboring bed bays allows for subsequent accretion of pathogenic material by the HCW regardless of hand hygiene. This accretion is also likely to happen without the HCW awareness; they may take additional precautions if they know that patient 1 is infectious, but are not likely to modify care for other patients in the same way.

Discussion

The study conducted here demonstrates the potential for quantifying the effect of room design on potential infection risk by means of an indirect metric, namely hand contamination.

Bioaerosol deposition patterns

CFD modeling of the application scenarios revealed that a ventilation rate of 6 ac/h showed little significant improvement over 4 ac/h on deposition quantities or spatial variation in three of the four considered scenarios in the four-bed room. A decrease in spread locus was noticed particularly when the infectious patient was placed closest to the outlet vent, highlighting the greater downward momentum on particles exerted by comparatively higher local air velocities at 6 ac/h. This indicates that both the ventilation diffuser locations and ventilation rate may be important in influencing deposition as well as extraction of airborne microorganisms. It is recognized that exact cfu/cm² values cannot be obtained via this method due to the absence of knowledge regarding the concentration of the infec-

tious source. Here, we used a normalization metric to consider the relative spatial deposition. It is also important to note that the CFD simulations were steady-state models of the airflow that did not account for movement of people and only considered the deposition of small (2.5 μ m) diameter particles. We made these assumptions here based on validation experiments for the CFD models (King et al., 2013). In reality, infectious particles will be released in a size distribution that will include smaller and larger particles which will change the spatial deposition patterns; larger particles are likely to increase deposition close to the patient. A CFD model incorporating a polydisperse particle release based on known particle size data from respiratory (Han et al., 2013; Xie, 2008) and environmental (Hathway et al., 2013) sources could enable an estimation of the resulting spatial contamination, which can then be applied in PAM. However, without experimental validation of the CFD model, these results would have to be treated with caution.

Ventilation method and transient flows due to activity are also factors. Under the HTM 03-01UK guidance (Department of Health, 2007), minimum air change rates of 6ACH are specified, but how and if these are achieved can vary. Hospital ventilation strategies in the UK often incorporate both natural and mechanical ventilation methods. While verification of mechanical flow rates is largely feasible, in naturally ventilated environments, measurement is more challenging. Although the small number of studies (Escombe et al. 2007, Qian et al. 2010, Gilkeson et al. 2013) suggest that high ventilation rates are achievable, these may not have predominant or established airflow pathways in some cases. When combined with activity such as human movement, opening and closing doors, changes in buoyancy due to heat sources, and use of fans for comfort, these variations in airflow patterns may change the dispersion of airborne microorganisms and further confound surface contamination patterns. An observation and sampling study conducted on a multi-bed respiratory ward (Hathway et al., 2013) found that airborne microorganisms and particles varied with the different activities on a ward, with increases during healthcare worker activity and personal care, but little change with visitors on the ward. Nevertheless, the approach presented here gives a realistic mechanism for exploring potential deposition at design stage and identifying design options that are likely to minimize contamination.

Observational study

The first hand data accrued from the observational study is of fundamental importance for the modeling of human hand-to-surface contact events, allowing insight into the different types of care and how these also the behavior of nurses and doctors. These data

then formed the basis of a stochastic model of HCW behavior as they moved from one surface to another and consequently forms the driving force behind the subsequent model for pathogen accretion. While the data are only from one hospital with a single-bed ward environment, comparison with other studies suggests the data are realistic and representative of typical health care in other hospital environments. However, it should be acknowledged that in applying the model to other hospital wards, it may be necessary to make adjustments to the location of surfaces and contact patterns. For example, in the current study, the position of the patient charts and information in the single rooms was treated as a far-bed surface based on the practice in the observation study, while in the four-bed room, it was treated as near-bed based on Smith et al.(2012). In other hospitals, the position of charts may vary depending on room design, local practices, and care needs. Similarly, in wards where care routines differ substantially from those considered here, it may be necessary to conduct a further observational study to create new hand-to-surface contact patterns that are more representative of the environment.

Probabilistic model

The pathogen accretion model (PAM) was developed from the growing understanding of hand contamination from surface contacts. This model focuses on the physical process of accruing pathogens onto either the skin or gloved surfaces of HCWs' hands as they perform episodes of standard patient care. The model provides a framework which allows for the quantitative comparison of hospital room design including single- vs. four-bed accommodation by means of HCW hand contamination. Application of PAM to the scenario rooms showed that differences were not clear cut and the positioning of the infectious patient had most effect on the final results. The spatial deposition of particles is influenced by the location of the ventilation supply inlet relative to the source. Locating a susceptible patient closer to the supply air is likely to reduce the risk of environmental contamination due to bioaerosol release from a neighboring patient. Locating the infectious patient in a four-bed room without an unobstructed air pathway from the bed to the ventilation outlet caused the highest level of surface contamination of all scenarios tested. These findings concur with experiments and simulations conducted in King et al. (2013).

It is crucial to highlight that this is a flexible framework model, built from the increasing understanding of the mechanics behind pathogen transmission; however, the results are dependent on several data inputs to the model which all have a degree of uncertainty. Initial validation was successful against the limited available data in the published literature, but it is

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acknowledged that full validation of the model is very challenging as the microbiome, ventilation design, physical layout, and personnel variation of every hospital is highly specific. Data for the surface contamination patterns and the HCW hand-surface contact patterns were derived from CFD models and the observational study, respectively, as part of the study. While this leads to a reasonable degree of confidence in these data in the particular scenarios examined, both parameters are influenced by a number of factors as outlined above. The other model elements relied on published data to provide suitable inputs. As far as possible, these were applied as distribution functions to account for variability; however, the influence of factors such as temperature, humidity, and surface porosity are not explicitly considered in the model and cannot be determined from the current results. With further data, it may be possible to include these factors, for example, into the transfer efficiency parameters.

It should also be emphasized that the current model does not simulate the pathogen accretion process over a particular time period. The CFD deposition pattern is used to generate a likely surface contamination pattern for a given room, and the PAM then simulates the contact sequence and likely resulting accretion. The resulting hand contamination is presented in the study as a normalized parameter to enable relative comparison between scenarios, as the model does not include transient factors that may influence the actual microbial concentration on HCW hands. In reality, microbial viability on surfaces and on hands will be a factor, and this is influenced by temperature and humidity as well as surface properties. Hand hygiene may also influence microbial viability; alcohol gels are known to exert residual microbiocidal effects due to remaining residue on HCWs' hands (Bogusz et al., 2013) which would also influence the actual microbial concentrations. The aerosol release of microorganisms will also be a continuous and transient process, with surfaces never having a steady-state concentration due to ongoing deposition interspersed with cleaning activities. Although this means that the model cannot explicitly model infection risk, the current formulation enables exploration of the likely importance of different design and care factors and incorporates the combined effects of airflows and human activities. In particular, it enables direct and quantitative comparison between different ward designs under the same care conditions. The framework also allows for increasingly precise specification of surface contamination levels, transfer parameters, and HCW contact patterns with input of further data from sampling and observation studies.

Conclusions

The aim of this study was to provide a mathematical model which quantifies the relative contamination

levels of healthcare workers' hands from surfaces within hospital rooms. This is achieved through a multidisciplinary approach coupling CFD simulations with clinical observation of HCW movement and Markov chain Monte Carlo modeling of hand contamination. An observational study of patient care in a single-bed hospital ward showed that hand hygiene choice and frequency varied strongly. HCWs performing short episodes of care had a predilection for alcohol rub. In other care types, the usage of alcohol rub or soap and water was 50/50. HCW surface contact patterns in rooms were modeled by a Markov chain and fed into a mathematical model to calculate the pathogen colonization level on hands after patient care.

A parametric study indicates that hand contamination levels depend highly on care type ($P < 0.0001$), the number of surface contacts ($P < 0.001$), and the distribution of surface pathogens ($P = 0.05$). Highest hand contamination was predicted during *Personal care* despite this having the highest levels of hand hygiene. This is due to the greater number of contacts on the more highly contaminated near-bed surfaces. Increasing the ventilation rate is likely to have a small benefit on environmental contamination in a single-bed room, while the relative location of infectious patients and ventilation supply and extract grilles had a significant effect in a four-bed room ($P = 0.05$). Comparison of four patients housed in single rooms against a four-bed room suggests contamination on the HCWs' hands is likely to decrease monotonically after care in single rooms, but is likely to increase during contact with subsequent patients in four-bed rooms.

The results support the hypothesis that single-patient rooms reduce the risk of HCAI, highlighting that this benefit may extend to risk of infection due to environmental contamination not just the more obvious airborne and direct contact transmission routes. The findings also suggest that ventilation design and room layout may affect environmental contamination and subsequent contact transmission risks in multi-bed environments. This has implications for those designing wards as well as operational aspects in terms of the most suitable location for infectious or susceptible patients.

This study makes a significant contribution to the body of evidence that support the NHS in making decisions about hospital design and whether or not to incorporate single rooms.

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Conflict of interests

None to report.

References

- Allen, L.J.S. (2008) *An Introduction to Stochastic Processes with Applications to Biology*, 2nd edn, Upper Saddle River, NJ, Chapman and Hall/CRC.
- ANSYS. (2010) *ANSYS FLUENT Theory Guide*, Canonsburg, PA, ANSYS Inc.
- Beamer, P., Canales, R.A. and Leckie, J.O. (2009) Developing probability distributions for transfer efficiencies for dermal exposure, *J. Expo. Sci. Environ. Epidemiol.*, **19**, 274–283.
- Bhalla, A., Pultz, N.J., Gries, D.M., Ray, A.J., Eckstein, E.C., Aron, D.C. and Donskey, C.J. (2004a) Acquisition of nosocomial pathogens on hands after contact with environmental surfaces near hospitalized patients, *Infect. Control Hosp. Epidemiol.*, The University of Chicago Press, **25**, 164–167.
- Bhalla, A., Pultz, N.J., Gries, D.M., Ray, A.J., Eckstein, E.C., Aron, D.C., Donskey, C.J., Lepelletier, D., Perron, S., Huguénin, H., Picard, M. and Caillon, J. (2004b) Concise communications which strategies follow from the surveillance of multidrug-resistant bacteria to strengthen the control of their spread? A French experience, *Infect. Control Hosp. Epidemiol.*, **25**, 162–177.
- Bogusz, A., Stewart, M., Hunter, J., Yip, B., Reid, D., Robertson, C. and Dancer, S.J. (2013) How quickly do hospital surfaces become contaminated after detergent cleaning ?, *Healthc. Infect.*, **18**, 3–9.
- Boks, N.P., Norde, W., van der Mei, H.C. and Busscher, H.J. (2008) Forces involved in bacterial adhesion to hydrophilic and hydrophobic surfaces, *Microbiology*, **154**, 3122–3133.
- Brouwer, D.H., Kroese, R. and Van Hemmen, J.J. (1999) Transfer of contaminants from surface to hands: experimental assessment of linearity of the exposure process, adherence to the skin, and area exposed during fixed pressure and repeated contact with surfaces contaminated with a powder, *Appl. Occup. Environ. Hyg.*, **14**, 231–239.
- Chaudhury, H. (2005) Advantages and disadvantages of single-versus multiple-occupancy rooms in acute care environments: a review and analysis of the literature, *Environ. Behav.*, **37**, 760–786.
- Dancer, S.J. (2008) Importance of the environment in meticillin-resistant *Staphylococcus aureus* acquisition: the case for hospital cleaning, *Lancet Infect. Dis.*, **8**, 101–113.
- Dancer, S.J., Mulvey, D., Redding, P., Robertson, C. and Woodall, C. (2010) P11.06 Finding a benchmark for monitoring hospital cleanliness, *J. Hosp. Infect.*, Elsevier Ltd, **76**, S34.
- Department of Health (2007) *Heating and Ventilation Systems Health Technical Memorandum Specialised Ventilation for Healthcare Premises. Part A: Design and validation*. The Stationery Office, London: Department of Health.
- Department of Health Estates and Facilities Division (2008) *In-patient Care Health Building Note 04-01: Adult In-patient*

- Facilities*. The Stationery Office, London: Department of Health Estates and Facilities Division.
- Duckro, A.N., Blom, D.W., Lyle, E.A., Weinstein, R.A. and Hayden, M.K. (2005) Transfer of vancomycin-resistant enterococci via health care worker hands, *Arch. Intern. Med.*, **165**, 302–307.
- Escombe, R.A., Oeser, C., Gilman, R.H., Navincopa, M., Ticona, E., Martínez, C., Cavedes, L., Sheen, P., Gonzalez, A., Noakes, C., Moore, D.A.J., Friedland, J.S. and Evans, C.A. (2007) The detection of airborne transmission of tuberculosis from HIV-infected patients, using an in vivo air sampling model, *Clin. Infect. Dis.*, **44**, 1349–1357.
- Gillkeson, C.A., Camargo-Valero, M.A., Pickin, L.E. and Noakes, C.J. (2013) Measurement of ventilation and airborne infection risk in large naturally ventilated hospital wards, *Build. Environ.*, Elsevier Ltd, **65**, 35–48.
- Girou, E., Loyeau, S., Legrand, P., Oppein, F. and Brun-buisson, C. (2002) Efficacy of handrubbing with alcohol based solution, *Br. Med. J.*, **325**, 1–5.
- Han, Z.Y., Weng, W.G. and Huang, Q.Y. (2013) Characterizations of particle size distribution of the droplets exhaled by sneeze, *J. R. Soc. Interface*, **10**, 1–11.
- Harbarth, S., Sax, H. and Gastmeier, P. (2003) The preventable proportion of nosocomial infections: an overview of published reports, *J. Hosp. Infect.*, **54**, 258–266.
- Hathway, E.A., Noakes, C.J., Fletcher, L.A., Sleight, P.A., Clifton, I. and Elliott, M.W. (2013) The role of nursing activities on the bioaerosol production in hospital wards, *Indoor Built Environ.*, **22**, 410–421.
- Hayden, M.K., Blom, D.W., Lyle, E.A., Moore, C.G. and Weinstein, R.A. (2008) Risk of hand or glove contamination after contact with patients colonized with vancomycin-resistant enterococcus or the colonized patients' environment, *Infect. Control Hosp. Epidemiol.*, **29**, 149–154.
- King, M.-F., Noakes, C.J., Sleight, P.A. and Camargo-Valero, M.A. (2013) Bioaerosol deposition in single and two-bed hospital rooms: a numerical and experimental study, *Build. Environ.*, Elsevier Ltd, **59**, 436–447.
- Montville, R. and Schaffner, D.W. (2003) Inoculum size influences bacterial cross contamination between surfaces, *Appl. Environ. Microbiol.*, **69**, 7188–7193.
- Montville, R. and Schaffner, D.W. (2011) A meta-analysis of the published literature on the effectiveness of antimicrobial soaps, *J. Food Prot.*, **74**, 1875–1882.
- Mulvey, D., Redding, P., Robertson, C., Woodall, C., Kingsmore, P., Bedwell, D. and Dancer, S.J. (2011) Finding a benchmark for monitoring hospital cleanliness, *J. Hosp. Infect.*, Elsevier Ltd, **77**, 25–30.
- Nossent, J., Elsen, P. and Bauwens, W. (2011) Sobol' sensitivity analysis of a complex environmental model, *Environ. Model. Softw.*, **26**, 1515–1525.
- Otter, J.A., Yezli, S. and French, G.L. (2011) The role played by contaminated surfaces in the transmission of nosocomial pathogens, *Infect. Control Hosp. Epidemiol.*, **32**, 687–699.
- Otter, J.A., Yezli, S., Salkeld, J.A.G. and French, G.L. (2013) Evidence that contaminated surfaces contribute to the transmission of hospital pathogens and an overview of strategies to address contaminated surfaces in hospital settings, *Am. J. Infect. Control*, Elsevier Inc, **41**, S6–S11.
- Pessoa-Silva, C.L., Dharan, S., Hugonnet, S., Touveneau, S., Barbe, K.P., Pfister, R. and Pittet, D. (2004) Dynamics of bacterial hand contamination, *Infect. Control Hosp. Epidemiol.*, **25**, 192–197.
- Pittet, D., Dharan, S., Touveneau, S., Sauvan, V. and Perneger, T.V. (1999) Bacterial contamination of the hands of hospital staff during routine patient care, *Arch. Intern. Med.*, **159**, 821–826.
- Pittet, D., Allegranzi, B., Sax, H., Dharan, S., Pessoa-Silva, C.L., Donaldson, L. and Boyce, J.M. (2006) Evidence-based model for hand transmission during patient care and the role of improved practices, *Lancet Infect. Dis.*, **6**, 641–652.
- Qian, H., Li, Y., Seto, W.H., Ching, P., Ching, W.H. and Sun, H.Q. (2010) Natural ventilation for reducing airborne infection in hospitals, *Build. Environ.*, Elsevier Ltd, **45**, 559–565.
- Roache, P.J. (1997) Quantification of uncertainty in computational fluid dynamics, *Annu. Rev. Fluid Mech.*, **29**, 123–160.
- Roberts, K., Smith, C.F., Snelling, A.M., Kerr, K.G., Banfield, K.R., Sleight, P.A. and Beggs, C.B. (2008) Aerial dissemination of *Clostridium difficile* spores, *BMC Infect. Dis.*, **8**, 7.
- Rusin, P., Maxwell, S. and Gerba, C. (2002) Comparative surface-to-hand and fingertip-to-mouth transfer efficiency of gram-positive bacteria, gram-negative bacteria, and phage, *J. Appl. Microbiol.*, **93**, 585–592.
- Sax, H., Allegranzi, B., Chraïti, M.-N., Boyce, J., Larson, E. and Pittet, D. (2009) The World Health Organization hand hygiene observation method, *Am. J. Infect. Control*, **37**, 827–834.
- Sherertz, R.J., Reagan, D.R., Hampton, K.D., Robertson, K.L., Streed, S.A., Hoen, H.M., Thomas, R. and Gwaltney, J.M. Jr (1996) A cloud adult: the *Staphylococcus aureus*-Virus interaction revisited, *Ann. Intern. Med.*, **124**, 539–547.
- Shih, Y.-C., Chiu, C.-C. and Wang, O. (2007) Dynamic airflow simulation within an isolation room, *Build. Environ.*, **42**, 3194–3209.
- Sickbert-Bennett, E.E., Weber, D.J., Ger-gen-Teague, M.F., Sobsey, M.D., Samsa, G.P. and Rutala, W.A. (2005) Comparative efficacy of hand hygiene agents in the reduction of bacteria and viruses, *Am. J. Infect. Control*, **33**, 67–77.
- Smith, S.J., Young, V., Robertson, C. and Dancer, S.J. (2012) Where do hands go? An audit of sequential hand-touch events on a hospital ward, *J. Hosp. Infect.*, Elsevier Ltd, **80**, 206–211.
- Tian, Z.F., Tu, J.Y., Yeoh, G.H. and Yuen, R.K.K. (2006) On the numerical study of contaminant particle concentration in indoor airflow, *Build. Environ.*, **41**, 1504–1514.
- Ulrich, R.S. and Zimring, C. (2008) *Health-care Leadership: A Review of the Research Literature on Evidence-Based Healthcare Design*. Georgia Tech, College of Architecture, Atlanta, GA.
- Wong, L.T., Chan, W.Y., Mui, K.W. and Lai, A.C.K. (2010) An experimental and numerical study on deposition of bio-aerosols in a scaled chamber, *Aerosol Sci. Technol.*, **44**, 117–128.
- Xie, X. (2008) *Evaporation and Movement of Respiratory Droplets in Indoor Environments*, Hong Kong SAR, The University of Hong Kong.
- Xue, J., Zartarian, V.G., Ozkaynak, H., Dang, W., Glen, G., Smith, L. and Stallings, C. (2006) A probabilistic arsenic exposure assessment for children who contact chromated copper arsenate (CCA)-treated playsets and decks, Part 2: sensitivity and uncertainty analyses, *Risk Anal.*, **26**, 533–541.
- Yang, W., Elankumaran, S. and Marr, L.C. (2011) Concentrations and size distributions of airborne influenza A viruses measured indoors at a health centre, a day-care centre and on aeroplanes, *J. R. Soc. Interface*, **8**, 1176–1184.
- Zartarian, V., Smith, L. and Xue, J. (2012) *The Stochastic Human Exposure and Dose Simulation Model for Multimedia, Multi-pathway Chemicals (SHEDS-Multimedia): Residential Module SHEDS-Residential version 4 Technical Manual*. Washington DC, US Environmental Protection Agency.
- Zhang, T.T., Lee, K. and Chen, Q.Y. (2009) A simplified approach to describe complex diffusers in displacement ventilation for CFD simulations, *Indoor Air*, **19**, 255–267.



ORIGINAL ARTICLES

An outbreak of multi-drug-resistant tuberculosis in a London teaching hospital

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Summary: We describe the epidemiology and control of a hospital outbreak of multi-drug-resistant tuberculosis (MDR-TB). A human immunodeficiency virus (HIV)-negative patient with drug-sensitive tuberculosis developed MDR-TB during a period of unsupervised therapy. She was admitted to an isolation room in a ward with HIV-positive patients, but the room, unbeknown to hospital staff, was at positive-pressure relative to the main ward. Seven HIV-positive contacts developed MDR-TB. The diagnosis in the second patient was delayed, partly because acid-fast bacilli in his sputum were assumed to be *Mycobacterium avium-intracellulare*. All the available *Mycobacterium tuberculosis* isolates were indistinguishable by molecular typing. Nearly 1400 staff and patient contacts were offered screening, but the screening programme detected only one of the cases. Despite therapy, the index patient and two of the contacts died. HIV-positive patients are more likely than others to develop tuberculosis after exposure, and the disease may progress more rapidly. In these patients the possibility that acid-fast bacilli may represent *M. tuberculosis* must always be considered. Patients with tuberculosis (suspected or proven) should not be nursed in the same wards as immunosuppressed patients, and should be isolated. MDR-TB cases must be isolated in negative-pressure rooms. Hospital side-rooms may be positive-pressure as a fire safety measure; infection control teams must be aware of the airflows in all isolation rooms, and must be consulted during the design of hospital buildings. Good communication between infection control teams and clinicians is important, and all medical and nursing staff must be aware of the principles of management of patients with proven or suspected tuberculosis and MDR-TB.

Keywords: Tuberculosis; multidrug resistant tuberculosis; drug resistance; cross-infection; infection control; HIV; airflow; isolation; supervised therapy; contact tracing; typing.

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Introduction

The steady decline in tuberculosis in Western countries has reversed in recent years with an excess of reported over-predicted cases, particularly in inner cities.¹⁻³ There are many reasons for this, including increasing immigration from countries with a high prevalence of tuberculosis, poverty and social deprivation, and inadequately resourced public health services.⁴ Furthermore, poorly supervised therapy and the addition of single drugs to failing regimens has led to the emergence of multi-drug-resistant tuberculosis (MDR-TB).⁵ Because these strains are less responsive to standard therapy, patients remain infectious for longer.

The emergence of human immunodeficiency virus (HIV) and acquired immunodeficiency syndrome (AIDS) has paralleled the re-emergence of tuberculosis. There have been several reports of outbreaks of tuberculosis in HIV patients in the USA, Spain, South America and London.⁶⁻¹⁶ In most cases these outbreaks have centred on hospitals where AIDS patients are nursed together, and increasingly involve multi-drug-resistant strains.

We report an outbreak of MDR-TB amongst HIV patients at St Thomas's Hospital in London, in which a major factor was inadequate isolation on a ward where HIV patients were being nursed.

Patients and methods

The outbreak

St Thomas's Hospital is a teaching hospital with approximately 800 inpatient beds, serving a large urban population. The HIV outpatient unit provides care for 700 regular attenders. The hospital has several wings of different ages and design; for many years patients with known or suspected tuberculosis have been nursed in side-rooms, with no known cases of cross-infection before 1995. Until recently, HIV-positive inpatients were admitted to East and South Wing wards, but latterly they were admitted to a particular ward ('Ward 1') in the North Wing

under the care of the respiratory physicians. This ward has 28 beds arranged in five bays, and four single rooms with adjacent bathrooms.

Patients

Patient 1

The first case was an HIV-seronegative female in her 20s, recently arrived from West Africa. In December 1994 she was admitted with open pulmonary tuberculosis with a fully sensitive strain of *Mycobacterium tuberculosis*. She was started on rifampicin, isoniazid and pyrazinamide, and improved. However, she failed to attend her outpatients appointment in February 1995, and in March she presented complaining of cough and night sweats. Her sputum showed large numbers of acid-fast bacilli (AFB), and the chest X-ray showed increased cavitation. She was admitted to a side-room on a ward in the East Wing (Ward 2), and ethambutol was added to her therapy. She was discharged in mid-April. Shortly afterwards her most recent isolate was reported to be resistant to rifampicin, isoniazid, clofazimine and rifabutin, and in May her treatment was changed to a combination of ethambutol, pyrazinamide and ciprofloxacin. By June she had deteriorated; she was admitted to a side-room on Ward 3 in the East Wing, and streptomycin was added. In September 1995 Ward 3 was refurbished and she was transferred to a side-room in Ward 1 in the North Wing. By January 1996 the organism had become resistant to pyrazinamide, cycloserine and ciprofloxacin. She remained on Ward 1 until April 1996 when she was transferred to another hospital. She later returned to St Thomas's and was nursed in a negative-pressure room. Despite therapy she died in December 1997.

Patient 2

A 34-year-old man with AIDS was an inpatient on Ward 1 for four weeks between October and November 1995, with a diagnosis of *Pneumocystis carinii* pneumonia. Culture of his sputum for mycobacteria at this time was negative. He was nursed in a side-room adjacent to that of Patient 1. In February 1996 he developed fever and cough, with sputum

containing numerous AFBs which were assumed to be *Mycobacterium avium-intracellulare*. He deteriorated and was re-admitted to Ward 1 in March 1996. Despite repeated requests, he kept the door open, frequently left the room and visited other patients. In mid-March his sputum sample taken in February yielded a mycobacterium species, identified as *M. tuberculosis* by gene probing (Accuprobe, Gen-probe Inc., San Diego, USA) and he was given rifampicin, isoniazid and pyrazinamide. One week later the organism was shown to be resistant to rifampicin and isoniazid. It was immediately concluded that Patient 2 had probably been infected by Patient 1. Urgent examination of airflows showed that the isolation rooms on Ward 1 were positive pressure relative to the main ward.

Subsequent cases and outcome

A further six patients with MDR-TB were identified over the following eight months (Table I). Four were identified in St Thomas's Hospital, and two elsewhere. The four who presented to St Thomas's Hospital were transferred to other hospitals with appropriate isolation facilities as soon as the diagnosis was suspected. All six patients were HIV-positive males. Five presented with respiratory or constitutional symptoms; one was asymptomatic, and was detected as part of the screening programme. Two patients, Patients 2 and 4, have subsequently died.

Contacts between patients

All the cases had been on a ward at the same time as Patient 1, and three also at the same time as Patient 2 while he was infectious with AFBs in his sputum. Patient 8 was not a patient at St Thomas's, but had counselled Patient 2 while he was infectious on Ward 1. Patient 3 had also been in contact with Patient 2 in the HIV clinic, and may have acquired his infection there. At least one, and possibly two infectious were acquired following exposure to a patient in a neutral pressure room. The duration of contact for each patient is

shown in Table I. Sixty-four HIV positive patients were known to have had inpatient contact with an infectious case, giving an overall clinical case attack rate of 11% (7/64) in this group (Table II).

Molecular typing of the *M. tuberculosis* isolates

Isolates from seven patients were typed by restriction fragment length polymorphism at the Royal Free Hospital and the Public Health Laboratory Service (PHLS) Mycobacterium Reference Unit, Dulwich.¹⁷ All isolates were indistinguishable, including the sensitive and resistant strains from Patient 1. The organism from Patient 8 failed to grow and was unavailable for typing, but *M. tuberculosis* and mutations within the *rpoB* gene associated with rifampicin resistance were detected in his sputum by the polymerase chain reaction (PCR) and solid-phase hybridization techniques; in view of his close contact with Patient 2, he was probably part of the outbreak.

Management of the outbreak

A committee was formed to define, investigate and manage the outbreak. The main elements of the management of the outbreak were as follows.

Transfer of known cases

As soon as the outbreak was identified, the two known cases were transferred to hospitals with adequate negative-pressure isolation rooms.

Review of isolation room airflow

Airflows in hospital side rooms were urgently reviewed. It was found that all the side-rooms in the North Wing wards were under positive pressure relative to the main wards. Side-rooms in the East Wing were in balance with the main wards. There were no negative-pressure rooms available in the Trust, so proposals for the conversion of the side-rooms on Ward 1 to negative pressure were brought forward. Four such rooms with >12 air-changes per hour and en-suite facilities were opened in January 1997.

Table 1 Secondary cases of MDR-TB: clinical and epidemiological information

	Contact with Patient 1 (days)	Contact with Patient 2 (days)	Interval to symptoms (weeks)	Delay to clinical diagnosis of MDR-TB (weeks)	CD4	Chest X-Ray appearances	Outcome
Patient 2	33	—	11	7	<50	Rt hilar and basal infiltrates	Died
Patient 3	2	<1 (outpatient)	53*	4	100	Rt lung infiltrates	Survived‡
Patient 4	20	6	10	2	<50	Lt hilar and basal infiltrates	Died
Patient 5	18	10	12	3	<50	Rt apical and hilar infiltrates	Survived‡
Patient 6	12	—	28†	<1	100	Lt upper zone cavitation	Survived‡
Patient 7	4	—	33	4	250	Miliary appearance	Survived‡
Patient 8	<1	<1 (visitor to ward)	24	<1	170	Clear	Survived‡

All were males infected with HIV.

* Precise date of initial exposure uncertain. Interval given refers to earliest possible exposure.

† Time to detection at screening clinic; patient was asymptomatic.

‡ Alive at the time of writing, 20 months after the recognition of the outbreak.

Table II Clinical case attack rates in inpatient HIV-positive contacts of Patients 1 and 2

Source of exposure	Number exposed	Number infected	Attack rate (%)
Patient 1—Ward 2	2	1	50
Patient 1—Ward 3	11	1	9
Patient 1—Ward 1	51	4	8
Patient 2—Ward 1	9	2	22
Patient 1 or 2	64	7	11

Review of Trust tuberculosis policy

The Trust policy for tuberculosis was reviewed. All patients with signs of chest disease are now assessed for risk of tuberculosis and MDR-TB before admission to hospital. Patients who present to outpatients or casualty with suspected tuberculosis are kept in isolation while an urgent auramine stain of sputum is performed; if MDR-TB is suspected and AFB are seen, the patient is transferred to a negative-pressure isolation facility. Patients with known or suspected drug-sensitive tuberculosis can continue to be nursed in neutral-pressure side-rooms as they have been for many years; the positive-pressure rooms are no longer used for tuberculosis isolation. Immunocompromised patients are no longer nursed on the same ward as those with known or suspected tuberculosis. A negative-pressure room was constructed in the outpatients for cough inducing procedures such as induced sputum collection and bronchoscopy, and dust/mist/fume particulate filter face masks were made available for nursing MDR-TB patients.

Contact tracing and screening programme

Because of the length of stay of Patient 1, a large number of other patients and staff were exposed to MDR-TB: 792 staff, 61 HIV-positive inpatients and 226 HIV-negative inpatients had possible exposure. Screening was offered to all surviving contacts, and to all surviving HIV-positive patients who had attended the HIV clinic between January and March 1996. Screening consisted of a health questionnaire and a tuberculin skin test; those who were immunodeficient or had symptoms were also offered a chest X-ray. One case (Patient 6)

was identified during screening of HIV-positive contacts, but so far no cases have been identified in any of the other groups.

Antibiotic prophylaxis

Prophylaxis with ethambutol and para-aminosalicylic acid was offered to immunodeficient contacts; they were informed of its unproven efficacy and possible side-effects. Only seven patients accepted prophylaxis, and none continued for more than two weeks.

Public relations, press release, telephone helplines

A press release was issued at the same time as the recall letters were posted, and telephone helplines were set up in the HIV unit. Interest by the media and public was intense but short-lived.

Internal enquiry and changes to infection control

The Trust commissioned an internal enquiry into the outbreak. Their report was completed in October 1996 and was made available to the public. Following the recommendations of the report, the infection control team was enlarged, its practices were reviewed, and communication links between the infection control nurses, microbiologists, clinicians and the community thoracic nursing team were strengthened. Other recommendations were incorporated in the revised tuberculosis policy and in the new isolation facilities, as previously described.

Discussion

Although the dangers of tuberculosis and MDR-TB are well recognized; this outbreak

illustrates the importance of following the correct management procedures for these patients.

Poor motivation, language barriers and social isolation may lead some patients to default from therapy and present later with MDR-TB. Supervised therapy has been shown to improve outcome and reduce the emergence of drug resistance.^{18,19} Patient 1 developed MDR-TB during a period of unsupervised therapy. She was admitted to hospital and single drugs added sequentially to her treatment; subsequent isolates showed further resistance. She remained infectious in hospital for many months, and was eventually transferred to a ward with HIV patients. Staff were unaware that the side-rooms on this ward were at positive pressure relative to the main ward. The problem was further compounded by the reluctance of Patient 2 to be isolated. It was this combination of inadequate isolation and proximity with HIV patients that led to the outbreak.

In the last decade, several similar outbreaks of tuberculosis and MDR-TB have been described in hospitals or other institutions, mostly in the USA.^{6–16,20} One outbreak involved 357 patients attending 41 different hospitals.¹² Most outbreaks have involved HIV patients, emphasizing their vulnerability to tuberculosis: once infected, these patients progress to disease more frequently and more rapidly than those who are HIV-negative.⁷ The chest X-ray appearance may be atypical, and the AFB in the sputum may be misinterpreted as mycobacteria other than *M. tuberculosis*, leading to delayed diagnosis. Mortality rates of 80–90% have been reported in these patients,²⁰ but rapid diagnosis and aggressive treatment can improve outcome.²¹ Factors contributing to these outbreaks include contact between HIV-positive patients or staff with tuberculous patients, delayed diagnosis resulting in inadequate therapy and prolonged infectiousness, and inadequate isolation. In some outbreaks, inadequate airflow in isolation rooms have also played a part.⁸ This outbreak demonstrated all of these factors and underlined how easily tuberculosis can become drug resistant and how readily it can be transmitted to patients infected with HIV.

Even though this was a relatively small outbreak, we identified nearly 1400 staff and patient contacts. Tracing and screening the contacts was a major undertaking, involving many hospital departments over several months. We identified no secondary cases in HIV-negative contacts, but infection in these patients may not manifest for many years, if at all.

Hospital staff were unaware that the isolation rooms in the North Wing (built 20 years ago) were engineered to be at positive pressure relative to the main wards to protect against fire hazards. It is essential for infection control teams to know the airflow of all isolation rooms in their institutions, and to be consulted on infection control aspects of new building work.

During the outbreak, molecular techniques were increasingly used for the rapid diagnosis of tuberculosis and MDR-TB. These techniques are useful, but only when applied appropriately; they are not a substitute for clinical skills in making the initial diagnosis. The outbreak also stimulated us to rewrite our tuberculosis policy, emphasizing the dangers of MDR-TB and the susceptibility of HIV patients. However, policies by themselves do not guarantee good practice; it is the responsibility of senior medical and nursing staff to ensure that those working with or for them are aware of the proper management of patients with tuberculosis.

In conclusion, patients who have open tuberculosis must not be nursed near patients with HIV. The airflow characteristics of all isolation rooms should be known by infection control and clinical staff, and positive-pressure rooms must not be used for containment isolation. HIV patients with AFBs in their sputum should be managed as if they might have tuberculosis until the true diagnosis is made, and the risk of drug resistance must be assessed. Patients who might have MDR-TB must be nursed in negative-pressure rooms. Antituberculous therapy must be supervised when there is any doubt about the patient's adherence to therapy, and single drugs should not be added to failing treatment regimens. Good communication between microbiologists, infection control staff, physicians and nurses is essential; local infection

control policies for tuberculosis should be developed, disseminated and adhered to by all staff.

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References

1. Raviglione MR, Snider DE, Kochi A. Global epidemiology of tuberculosis – morbidity and mortality of a world-wide epidemic. *J Am Med Assoc* 1995; **273**: 220–226.
2. Hayward AC, Watson JM. Tuberculosis in England and Wales 1982–1993: notifications exceeded predictions. *CDR Review* 1995; **5**: R29–R33.
3. Pearson AD, Hamilton GR, Healing TD, Maguire HC, Feltham RK. Summary of a report of the Working Party on Tuberculosis of the London Group of Consultants in Communicable Disease Control. *J Hosp Infect* 1966; **33**: 165–79.
4. Drobniowski F, Pablos-Mendes A, Raviglione M. Epidemiology of tuberculosis in the world. *Sem Resp Crit Care Med* 1997 (in press).
5. Iseman MD. Treatment of multi-drug resistant tuberculosis. *N Engl J Med* 1993; **329**: 784–791.
6. Anonymous. An outbreak of hospital acquired multidrug resistant tuberculosis. *CDR weekly* 1995; **5**: 161.
7. Daley CL, Small MP, Schecter GF, *et al.* An outbreak of tuberculosis with accelerated progression among persons infected with the human immunodeficiency virus. An analysis using restriction-fragment-length polymorphisms. *N Engl J Med* 1992; **326**: 231–235.
8. Ikeda RM, Birkhead GS, DiFerdinando GT, *et al.* Nosocomial tuberculosis: an outbreak of a strain resistant to seven drugs. *Infect Control Hosp Epidemiol* 1995; **16**: 152–159.
9. Valway SE, Richards SB, Kovacovich J, Greifinger RB, Crawford JT, Dooley SW. Outbreak of multidrug-resistant tuberculosis in a New York State prison, 1991. *Am J Epidemiol* 1992; **140**: 113–22.
10. Anonymous. Multidrug-resistant tuberculosis outbreak on an HIV-ward—Madrid, Spain, 1991–1995. *Morb Mortal Wkly Rep* 1996; **45**: 330–3.
11. Beck-Sagué C, Dooley S, Hutton MD, *et al.* Hospital outbreak of multidrug-resistant *Mycobacterium tuberculosis* infections. Factors in transmission to staff and HIV-infected patients. *J Am Med Assoc* 1992; **268**: 1280–1286.
12. Frieden TR, Sherman LF, Maw KL, *et al.* A multi-institutional outbreak of highly drug-resistant tuberculosis. Epidemiology and clinical outcomes. *J Am Med Assoc* 1996; **276**: 1239–1235.
13. Aita J, Barrera L, Reniero A, *et al.* Hospital transmission of multi-drug-resistant tuberculosis in Rosario, Argentina. *Medicina (B. Aires)* 1996; **56**: 48–50.
14. Anonymous. Nosocomial transmission of multi-drug resistant tuberculosis among HIV-infected persons—Florida and New York, 1988–1991. *Morb Mortal Wkly Rep* 1991; **40**: 585–591.
15. Pablos-Mendes A, Sterling T, Frieden TR. The relationship between delayed or incomplete treatment and all-cause mortality in patients with tuberculosis. *J Am Med Assoc* 1996; **276**: 123–8.
16. Dooley SW, Jarvis WR, Snider DE. *Mycobacterium tuberculosis*. In Mayhall CG, Ed. *Hospital Epidemiology and Infection Control*. Baltimore: Williams and Wilkins, 1996. 1200–1223.
17. Van Embden JDA, Cave MD, Crawford JT, *et al.* Strain identification of *Mycobacterium tuberculosis* by DNA fingerprinting: recommendations for a standardized methodology. *J Clin Micro* 1992; **31**: 406–409.
18. Frieden TR, Fujiwara PI, Washko RM, Hamburg MA. Tuberculosis in New York City: turning the tide. *N Engl J Med* 1995; **333**: 229–33.
19. Morse DI. Directly observed therapy for tuberculosis. *BMJ* 1996; **312**: 719–20.
20. Anonymous. Outbreak of multidrug-resistant tuberculosis at a hospital—New York City, 1991. *Morb Mortal Wkly Rep* 1993; **42**: 427–434.
21. Drobniowski FA. Is death inevitable with multi-resistant TB plus HIV infection? *Lancet* 1997; **349**: 71–72.

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Nosocomial Transmission of Multidrug-Resistant *Mycobacterium tuberculosis* in Spain

Before 1990, outbreaks of multidrug-resistant tuberculosis (MDRTB) were uncommon (1); since then, more than 10 outbreaks have been reported, all in hospitals and prisons in the eastern United States (2-7). Persons traditionally considered at risk for MDRTB (foreign-born TB patients and those inadequately treated for TB) have not been associated with these outbreaks. Instead, the presence of patients with active TB near immunocompromised patients in HIV-dedicated wards has led to MDRTB-infected HIV patients whose TB cases often go unrecognized. The patients receive inadequate treatment in facilities without effective procedures for isolating acid-fast bacilli; these circumstances favor nosocomial transmission. Health officials in other geographic areas where HIV and TB are major public health threats have been alerted to this emerging problem, and surveillance systems have been designed (8).

Spain has the highest reported incidence rate of AIDS in Europe (143.4 cases per million in 1994) (9). Although in Spain TB is not notifiable at the national level, reported rates in the autonomous community of Madrid for 1994 were among the highest in Europe (33.5/100,000) (10). During a 45-month period starting in September 1991, a number of patients and one health care worker became infected with MDRTB in a 120-bed, infectious disease reference hospital in urban Madrid. In May 1995, the Field Epidemiology Training Program of the Spanish Ministry of Health was invited to assist the Madrid Department of Health and hospital officials in investigating the outbreak. This report describes the findings of the epidemiologic and molecular laboratory investigation and analyzes risk factors associated with the outbreak. The study was designed in three parts: 1) a description of the reported MDRTB cases, including a laboratory investigation of isolates; 2) a case-control study comparing HIV-infected patients who also had MDRTB to HIV-infected patients who did not have MDRTB; and 3) a study of tuberculin conversion among hospital employees.

We reviewed the medical records and laboratory specimen testing results of a series of patients with MDRTB in the HIV-dedicated ward of the hospital for January 1991 through June 1995.

Cases were defined as patients with culture-confirmed TB and drug resistance to at least rifampin and isoniazid and with no previous history of inadequate treatment. Demographic and clinical variables were collected to characterize the cluster. Drug susceptibility testing and DNA subtyping analysis were performed with resistant strains available at the time of the study. Drug susceptibility testing was performed by the method of proportions in Middlebrook 7H11 medium distributed in petri plate compartments (reference).

All 48 reported cases of isoniazid and rifampin resistance were among HIV-infected patients hospitalized in the HIV-dedicated ward from September 15, 1991, to May 1995. One patient was an HIV-infected nurse who worked on the ward from 1990 to 1994. The mean age of patients was 34.1; 81.3% were male, and 66.6% were intravenous-drug users (Table 1). Of the 47 (97.9%) who died, the mean interval from diagnosis to death was 77.6 days.

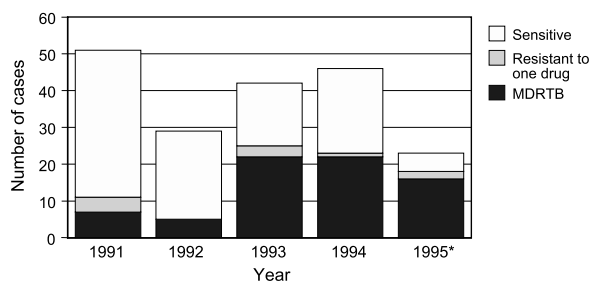
The epidemiologic curve suggests a propagated transmission pattern of MDRTB among HIV ward patients, starting in 1991 and continuing until June 1995 (Figure 1). By the first 6 months of 1995, 65% of *Mycobacterium tuberculosis* strains seen among HIV ward patients were multidrug-resistant.

Table 1. MDRTB patient characteristics

Variable	Number (n = 48)	%
Sex		
Male	39	81.3
Female	9	18.7
Mean age	34.1	(6.8) ^a
HIV status		
Infected	48	100.0
HIV risk group		
Intravenous drug users	32	66.6
Homosexual	10	20.8
Others	6	12.6
Outcome		
Death	47	95.9
Discharge	1	4.1
Mean survival after MDRTB diagnosis (in days)	77.6	(107.8) ^a

^a Standard deviation.

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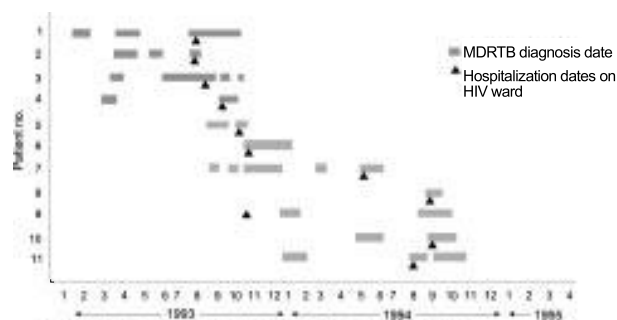
*1995 data are for first 6 months only.

Figure 1. Hospital outbreak, Madrid, Spain, 1995.

At the beginning of the outbreak, no consistent antibiogram pattern was observed among isolates. However, beginning in 1993, strains were consistently resistant to isoniazid, streptomycin, ethambutol, and rifampin (HSEr); of the 26 patients with an MDRTB diagnosis since the last trimester of 1993, 24 (92.3%) had HSEr isolates. DNA subtyping analysis was performed on 12 of these HSEr isolates that were available. Eleven of the 12 strains had the same band patterns (Figure 2). Two additional isolates with a different antibiogram pattern had different banding patterns.

Subtyping of *M. tuberculosis* strains was performed (11) by analyzing DNA located between two copies of repetitive sequence IS6110. A 10- μ l sample of the extracted DNA was amplified in a reaction mixture containing 0.5 pM of each of the four primers (Ris1, Ris2, Pntb1, and Pntb2), 200 μ M dNTPs, 50 mM Tris-HCl, 50 mM KCl (pH 8.8), 2.5 mM MgCl₂, 0.1% Triton x-100, and 0.5% Taq polymerase. The samples were denatured by incubation at 95°C for 10 min and amplified by 30 cycles of denaturation at 94°C for 1 min, primer alignment at 56°C for 2 min, and primer extension at 72°C for 1 min. The amplification products were analyzed by electrophoresis in 2% agarose gel stained with ethidium bromide and observed with an ultraviolet transilluminator.

HIV-infected patients hospitalized on the HIV-dedicated ward between September 15, 1991, and December 31, 1994, who had TB diagnosed in 1994 with a known drug-susceptibility pattern were included in a case-control study. Case patients' isolates were resistant to isoniazid, rifampin, streptomycin, and ethambutol; control patients' isolates were sensitive to the same antimicrobial drugs.



*All strains of resistance pattern HSEr (isoniazid, streptomycin, ethambutol, rifampin) had similar DNA subtyping.

Figure 2. Evolution of MDRTB strain* over time, hospital outbreak, Madrid, Spain, 1995.

A time-person line diagram was prepared for each of the case patients and control patients, including all hospitalization dates, ward and room number, potentially infectious days, and possible days exposed to infective patients. Prior admission was defined as all admissions to the HIV-dedicated ward since the MDRTB patient was diagnosed (9/15/91) until the end of the period (12/31/94). TB patients were classified as "potentially infective" from the 2 week-period before sputum or culture results were positive for *M. tuberculosis* until the time sputum results were negative or the patient died. TB-negative patients were classified as "possibly exposed" if they were hospitalized on the HIV-dedicated ward during the time a potentially infective patient was also present, beginning on September 15, 1991, until 2 weeks before TB diagnosis.

Thirty-five patients (18 with cases and 17 controls) met the established study case/control definition. Case patients and control patients were not significantly different with respect to age, sex, HIV risk factors, interval between HIV and TB diagnoses or count of CD4 lymphocytes at the time of TB diagnosis (Table 2).

Before the hospitalization during which TB was diagnosed, 76.4% of the case-patients had been hospitalized on the HIV-dedicated ward of the hospital versus 23.5% of control patients (OR = 7.8 [1.4,50.5]) (Table 3). Of the five case patients with no prior hospitalization, three were family members of previously hospitalized HIV-infected patients who had visited the HIV ward frequently during the outbreak period.

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Case patients and controls were compared with respect to possible exposure to a potentially infective wardmate beginning on 9/15/91 until 2 weeks prior to the diagnosis of TB. Case patients were more likely to have been exposed to potentially infective wardmates (72.2% with a median of 26.4 days) than control patients (41.2% with a median of 7.6 days). When we stratified possible ward exposure by days (0 days vs. 1 to 30 days vs. 30 days), we observed a dose-response effect, and the chi-square for linear trend was statistically significant (Table 3). Case patients were more likely to die during their initial hospitalization for MDRTB (94.4%) than were control patients (29.4%) during their hospitalization for TB (OR = 40.8 [3.6, 1842]) (Table 3).

A TB screening clinic visit was offered to all hospital employees after the outbreak was identified. Of the 591 active employees, 565 (95.6%) participated. Of these, 288 (51%) had not participated in previous hospital employee screening

programs conducted in 1990 and 1994. The overall prevalence of TB infection among participating employees was 450 (80%) of 565; only 115 (20%) of the current employees tested were tuberculin-negative.

Employees currently working at the hospital, who had a documented negative (< 6 mm) tuberculin test between January 1993 and June 1995 were eligible for this skin test conversion study. Many of the employees had received BCG vaccine. For those who had not received BCG vaccine, conversion was defined as an induration of 10 mm or greater with a change of at least 6 mm of induration since the last negative tuberculin test (12). For BCG vaccinees, conversion was defined as a 15-mm induration change since the last negative (< 6 mm) skin test.

Employees were defined as occupationally exposed if they worked in parts of the hospital where exposure to patients or *M. tuberculosis* was likely (the HIV-dedicated ward, HIV outpatient clinic,

radiology unit, the mycobacteriology laboratory, and the internal medicine ward). Employees were asked to quantify the cumulative number of months spent in these high-risk areas, regardless of their usual place of work, during the 30-month study period.

According to the Mantoux technique, 2 tuberculin units of purified protein derivative (PPD) tuberculin RT-23 were administered in the anterior forearm of the screened employees, and the results were read within 48 to 72 h. Of the participants, 92 (16.3%) were eligible for the conversion study. The incidence of conversion during the 30-month period was 24 of 92 (26%). Employees who had occupational exposure to high-risk areas had higher conversion rates than employees who did not have occupational exposure to high-risk areas (RR = 5.0 [2.7, 9.6]) (Table 4). The conversion had a dose-response effect, that is, the more months the person is occupationally exposed to high risk-areas, the higher the risk for conversion.

This is the first nosocomially transmitted MDRTB outbreak reported in

Table 2. Population characteristics: case control study

Variable	Case patients (%) n = 18	Control patients (%) n = 17	OR (95% CI) ^a
Mean age (yr)	34.4	35.2	<i>p</i> = 0.30 ^b
Male sex	13 (72.2)	14 (82.3)	1.8 (0.3-12.1)
IVDU	11 (61.1)	11 (64.7)	1.2 (0.2-6.7)
Interval HIV to TB diagnosis in days	1403	1293	<i>p</i> = 0.79 ^b
CD4 lymphocyte count, median	112.9	199.5	<i>p</i> = 0.30 ^b

^a OR (95% CI) = odds ratio (95% confidence intervals); Fisher's Exact Test.

^b *p* value for analysis of variance (ANOVA). IVDU = intravenous drug user.

Table 3. Variables associated with MDRTB

Variable	Case patients (%) n = 18	Control patients (%) n = 17	OR (95% CI) ^a
Prior admission to HIV ward			
Yes	13 (76.4)	5 (29.4)	6.2 (1.2-37.2)
No	5 (23.6)	12 (70.6)	
Possible ward exposure days			
None	5 (27.8)	10 (58.8)	1.0
1-30	6 (33.3)	5 (29.4)	2.4
30	7 (38.9)	2 (11.8)	7.0, <i>p</i> = 0.03 ^b
Outcome			
Death	17 (94.4)	5 (29.4)	40.8 (3.6-1842)
Discharge	1 (5.6)	12 (70.6)	

^a OR (95% CI) = odds ratio (95% confidence intervals); Fisher's Exact Test.

^b Chi-square for linear trend.

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Table 4. Employee tuberculin screening conversion study results

Variable	Convertors (%) n = 24	Nonconvertors (%) n = 68	RR (95% CI)
Occupational exposure to high-risk areas			
Yes	14 (70.0)	6 (30.0)	5.0 (2.7, 9.6)
No	10 (13.9)	62 (86.1)	
Months exposed in high-risk areas			OR ^b
0	6 (10.7)	50 (89.3)	1.0
1-6	4 (28.6)	10 (71.4)	3.3
7-36	14 (63.6)	8 (36.4)	14.6, $p < 0.01$

^a RR (95% CI) relative risk (95% confidence intervals).

^b Chi-square for linear trend.

Spain, which, with recent outbreaks in the United Kingdom (13) and Italy, is among the first in Europe. Its characteristics are similar to the other reported outbreaks on that it occurred in an HIV-dedicated ward among non-foreign-born patients who had not been treated for TB; it had a high mortality rate within 3 months of onset during which mycobacteria laboratory surveillance recognized similar antibiogram resistant patterns; and identification of MDRTB isolates was followed by DNA subtyping, which confirmed that the same strain was responsible for the outbreak. Risk factors identified include admission to the HIV-dedicated ward and more "possible exposure" days to potentially infective wardmates; additionally, skin test conversion rates among employees were directly related to working in high risk areas of the hospital. The consistency of these findings with those reported in similar outbreaks and the fact that the same isolate was cultured over an extensive period among many different patients on a hospital ward without proper room isolation techniques support the conclusion that nosocomial transmission was the leading cause of the outbreak.

CDC's recommended guidelines for hospital TB prevention and control (14) were not fully implemented in the hospital. Acid-fast bacilli room isolation techniques were not in place; moreover, no ventilation system was available to provide negative pressure to prevent bacilli from passing from the MDRTB patients' rooms to the hallway or to provide the six air interchanges per hour recommended for removing bacilli from room air. Surgical masks used in the HIV-dedicated ward during the outbreak as protective masks are not

recommended for this purpose because of filtering and facial sealing problems. Observational visits to the HIV-dedicated ward revealed that MDRTB patients without masks were walking, talking, and smoking in the halls and in the lounge next to the unprotected patients, families, and staff.

Complete follow-up of employees is an essential component of a hospital control program (14). Because 80% of the employees in this outbreak were tuberculin-positive, chest radiographs became an important component for disease screening;

yearly surveillance of the tuberculin-negative employees will help determine if the interventions in place to prevent future outbreaks have worked in this setting.

Once the case-control study findings were analyzed, a TB control committee was established. All MDRTB patients were placed in a separate area of the hospital. Hospital staff were informed about the outbreak and alerted about future possible cases and the patient management and treatment schemes. The mycobacteria laboratory expanded the antibiogram service to include all second-line antibiotics used by the hospital clinicians. Clinicians have elaborated a treatment flow chart for MDRTB patients. Masks that fulfilled the sealage and filtering criteria (15) were purchased, and mask use was aggressively implemented. An employee health clinic was also instituted, with a prophylaxis and chest X-ray follow-up program for the 410 infected employees, along with a computerized follow-up surveillance system which included all employees graded by occupational risk category. Plans were made to screen tuberculin-negative employees every 3 months to identify those who had recently seroconverted. Family, community members and wardmates of all patients whose MDRTB had been diagnosed within the previous 6 months were notified of their risk and were scheduled for follow-up evaluations. The HIV-dedicated ward will be transformed into an acid-fast bacilli isolation zone, with an exclusive ventilation system that provides 11 individual rooms, each with 12 air interchanges per hour and negative pressure relative to the hallway.

Health officials in Europe need to be updated about this emerging problem, especially in areas

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of high HIV and TB prevalence. Basic universal TB control and prevention measures (16,17) should be implemented by all general community hospitals in Spain, especially those with HIV-dedicated wards in areas where TB is prevalent. TB surveillance of health care employees is necessary to identify emerging problems as well as to protect employees, patients, and visitors.

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References

- Kent JH. The epidemiology of multidrug-resistant tuberculosis in the United States. *Med Clin North Am* 1993;77:1391-1409.
- Edlin BR, Tokars JI, Grieco MH, et al. An outbreak of multidrug-resistant tuberculosis among hospitalized patients with the acquired immunodeficiency syndrome. *N Engl J Med* 1992;326:1514-21.
- Beck-Sague C, Dooley SW, Hutton MD, et al. Hospital outbreak of multidrug-resistant *Mycobacterium tuberculosis* infections: factors in transmission to staff and HIV-infected patients. *JAMA* 1992;268:1280-6.
- Pearson ML, Jereb JA, Frieden TR, et al. Nosocomial transmission of multidrug-resistant *Mycobacterium tuberculosis*: a risk to patients and health care workers. *Ann Intern Med* 1992;117:191-6.
- Fischl MA, Uttamchandani RB, Daikos GL, et al. An outbreak of tuberculosis caused by multiple-drug resistant tubercle bacilli among patients with HIV infection. *Ann Intern Med* 1992;117:177-83.
- Dooley SW, Villarino ME, Lawrence M, et al. Nosocomial transmission of tuberculosis in a hospital unit for HIV-infected patients. *JAMA* 1992;267:2632-4.
- Centers for Disease Control. Nosocomial transmission of multidrug-resistant tuberculosis among HIV-infected persons—Florida and New York, 1988-1991. *MMWR* 1991;40:585-91.
- Ausina V, Riutort N, Viñado B, et al. Prospective study of drug-resistant tuberculosis in a Spanish urban population including patients at risk for HIV infection. *Eur J Microbiol Infect Dis* 1995;14:105-10.
- WHO-EC Collaborating Centres on AIDS. AIDS Surveillance in Europe-European Centre for the epidemiological monitoring of AIDS. Quarterly Report #45; March 1995.
- Boletín Epidemiológico de la Comunidad de Madrid 1995. Mayo #5, Vol 4. Informe: Morbilidad por Enfermedades de Declaración Obligatoria, 1994.
- Friedman CR, Stoeckle MY, Johnson WD, Riley LW. Double-repetitive-element PCR method for subtyping *M. tuberculosis* clinical isolates. *J Clin Microbiol* 1995;33:1383-4.
- Grupo de Trabajo sobre Tuberculosis. Consenso nacional para el control de la tuberculosis en España. *Med Clin (Barc)* 1992;98:24-31.
- Communicable Disease Report. Outbreak of hospital acquired multidrug resistant tuberculosis. United Kingdom PHLS Communicable Disease Surveillance Centre Weekly 1995.
- Centers for Disease Control and Prevention. Guidelines for preventing the transmission of *Mycobacterium tuberculosis* in health-care facilities, 1994. *MMWR* 1994;43 (No. RR-13).
- Lilienfeld, AM, Lilienfeld DE. Foundations of epidemiology. 2nd ed. Oxford, UK: Oxford University Press, 1980;292-5.
- Maloney SA, Pearson ML, Gordon MT, et al. Efficacy of control measures in preventing nosocomial transmission of multidrug-resistant tuberculosis to patients and health care workers. *Ann Intern Med* 1995;122:90-5.
- Wenger PN, Otten J, Breeden A, et al. Control of nosocomial transmission of multidrug-resistant *Mycobacterium tuberculosis* among healthcare workers and HIV-infected patients. *Lancet* 1995;345:235-40.

Nosocomial transmission of multidrug-resistant *Mycobacterium tuberculosis*

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Concomitant with the resurgence of tuberculosis in the United States have been increasing reports of nosocomial transmission of TB. From January 1990 through September 1992, the Centers for Disease Control (CDC) investigated eight nosocomial outbreaks of multidrug-resistant tuberculosis (MDR-TB). Over 200 patients were infected; approximately 75 % of these patients died. Risk factors for infection included human immunodeficiency virus infection or acquired immunodeficiency syndrome and recent hospitalization on the same ward as other MDR-TB patients. Restriction fragment length polymorphism (RFLP) analysis of *M. tuberculosis* isolates revealed unique strains were transmitted in each hospital. In three hospitals, health care workers (HCW) assigned to wards with MDR-TB patients were shown to be more likely to have tuberculin skin test (TST) conversions than HCW assigned to wards without MDR-TB patients. These outbreaks demonstrate the serious morbidity and mortality associated with nosocomial MDR-TB and emphasize the importance of adhering to current CDC guidelines for preventing the transmission of tuberculosis in healthcare settings, with special focus on HIV-related issues.

Introduction

Before 1990, reports of nosocomial transmission of drug-susceptible or MDR-TB were uncommon in United States hospitals. During 1953 to 1985, the number of reported patients with TB in the U.S. steadily declined and elimination of TB became a goal of the U.S. Public Health Service (PHS). However, between 1985 and 1992, the number of reported patients with TB has increased, with nearly 40,000 excessive cases over what would have been expected if reported TB had decreased at the same rate as be-

tween 1980-1984 (Jereb *et al.*, 1990). Several factors are responsible for this increase, but HIV infection and AIDS have clearly played an important role.

In addition, before 1990, MDR-TB, i.e., *M. tuberculosis* strains resistant to isoniazid (INH) and rifampin (RIF), with or without resistance to other antituberculosis agents, were uncommon in the U.S. Most MDR-TB reported was thought to result from TB patients with drug-susceptible strains who acquired drug resistance as a result of noncompliance with their therapy. Thus, primary drug resistance, i.e., the first infection with *M. tuberculosis* being with MDR strains, was very uncommon.

Most nosocomial TB reported in the U.S. between 1970 and 1991 involved ≥ 1 source-patient with active TB, who was not known to have TB and was not on therapy, or was on therapy for either a very short time (< 2 days) or had a drug-resistant strain (Hutton *et al.*, 1992). In many reports, aerosol-producing medical procedures, such as bronchoscopy, endotracheal intubation, wound manipulation, respiratory tract manipulation or autopsy, were associated with transmission.

MDR-TB outbreaks

Between 1990 and 1992, the CDC has investigated eight nosocomial outbreaks of MDR-TB (table I) (Edlin *et al.*, 1992a; Pearson *et al.*, 1992; Beck-Sague *et al.*, 1992; Kent *et al.*, 1992; Valway *et al.*, 1992; Coronado *et al.*, 1992a,b; Jereb *et al.*, 1992; Stroud *et al.*, 1992). These outbreaks have demonstrated a change in the epidemiology of nosocomial TB in health care facilities. These outbreaks have involved primary MDR-TB infection in immunocompromised patients. Outbreaks have occurred in multiple states and involved between 7 and 10 patients. All MDR-

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Table 1. Centers for Disease Control investigated nosocomial multidrug-resistant tuberculosis outbreaks, United States, 1989-1992.

Facility	Location	Time period	Total cases	Resistance pattern	% HIV infection	% Mortality	Interval, TB diagnosis to death (mean, weeks)
Hospital A	Miami	1988-1991	65	INH, RIF (EMB, ETA)	93	72	7
Hospital B	New York City	1989-1991	35	INH, SM (RIF, EMB)	100	89	16
Hospital C	New York City	1989-1992	70	INH, RIF, SM (EMB, ETA, KM, RBT)	95	77	4
Hospital D	New York City	1990-1991	29	INH, RIF (EMB, ETA)	91	83	4
Hospital E	New York State	1990-1991	7	INH, RIF, SM (EMB, ETA, KM, RBT)	14	43	4
Hospital F	New York City	1990-1991	16	INH, RIF, SM (EMB, ETA, KM, RBT)	82	82	4
Hospital I	New Jersey	1990-1992	13	INH, RIF (EMB)	100	85	4
Hospital J	New York City	1990-1992	18	INH, RIF, SM (EMB, ETA)	88	88	4

INH = isoniazid, RIF = rifampin, EMB = ethambutol, ETA = ethionamide, KM = kanamycin, SM = streptomycin, RBT = rifabutin.

TB strains have been resistant to at least INH and RIF, except for one outbreak where the predominant strain was resistant to INH and streptomycin. In addition, most strains have been resistant to from one to five other antituberculous agents. In each of the outbreaks, except for one outbreak (hospital E) that involved transfer of an infectious MDR-TB patient from a prison, the majority of infected patients had HIV infection or AIDS. In all but one outbreak (hospital E), mortality in patients exceeded 70 %. The interval from TB diagnosis to death ranged from 4-16 weeks (median 8 weeks).

Risk factors for nosocomial MDR-TB

In case-control studies, numerous risk factors for MDR-TB infection were identified (table II). These included having an HIV infection or AIDS, prior hospitalization and exposure to another infectious MDR-TB patient. MDR-TB patients did not have a prior history of TB or TB treatment and were more likely to have had prior opportunistic infections and lower CD4-T-lymphocyte counts, suggesting that the infections were likely primary infection rather than reactivation. Exposure to an acid-fast bacillus (AFB) sputum-smear and culture-positive MDR-TB patient placed patients at greater risk of acquiring MDR-TB than exposure to an AFB sputum smear-negative, culture-positive MDR-TB patient.

Other factors contributing to the outbreaks include: delayed recognition of TB in patients because of atypical presentation or low clinical suspicion; delayed initiation of effective treatment regimens; length of time required to perform and report culture and drug-susceptibility results; prolonged period of infectiousness; delayed institution, inadequate duration of, and/or inadequate facilities for AFB isolation.

In most episodes, the MDR-TB patient presented with pulmonary symptoms and fever (Coronado *et al.*, 1992b). However, because few patients had classical signs of TB, i.e., cavitory lesions or miliary patterns on chest x-ray, neither tuberculin skin tests (TSTs) nor AFB sputum smears were performed in a timely fashion. Most MDR-TB patients had abnormal chest x-rays, however, the infiltrates were often interstitial and varied in location. When cultures were obtained, there were delays in obtaining *M. tuberculosis* culture (median 7 weeks) and drug susceptibility (additional median 7 weeks) results. This contributed to delays in institution of effective antituberculosis therapy. Patients were diagnosed a median of six weeks after onset of symptoms and died a median of seven weeks after onset of symptoms. The median time from diagnosis until death was eight weeks. Thus, MDR-TB patients were often culture-positive during their entire hospitalization until death. A subsequent study has shown that with earlier diagnosis and therapy, clinical outcome can be improved (Edlin *et al.*, 1992b).

Table II. Risk factors for nosocomial multidrug-resistant *M. tuberculosis* infection, 1989-1992.

Human immunodeficiency virus infection/acquired immunodeficiency syndrome (AIDS)
Duration of AIDS
Prior opportunistic infection
Previous hospitalization
Hospitalization (exposure) on the same ward as another infectious MDR-TB patient
Exposure to an acid-fast bacillus sputum smear-positive MDR-TB patient
Proximity to infectious MDR-TB patient
Lower CD ₄ -T lymphocyte count

Because of delays in clinical suspicion of TB and delays in diagnosis, institution of AFB isolation was often delayed. In addition, many patients either did not stay in their AFB isolation rooms (patients visited lounges, walked hallways masked improperly, or went to common bathroom facilities), AFB isolation was discontinued prematurely (before clinical improvement and three negative AFB sputum smears), and/or AFB isolation facilities did not meet current CDC recommendations (i.e., air flow systems with negative pressure in relation to hallway and other rooms, six air exchanges per hour, and air exhaust directly outside). These factors contributed to nosocomial MDR-TB transmission to other patients and HCW.

Molecular epidemiologic investigations

In each of the outbreaks, infecting MDR-TB isolates were obtained and genetically typed using RFLP (Cave *et al.*, 1991; Crawford *et al.*, 1992). RFLP typing confirmed a unique common strain (which usually varied between hospitals) being transmitted in each hospital. RFLP was a more consistent marker than antimicrobial susceptibility pattern. These molecular typing data confirmed the epidemiologic data that MDR-TB was being transmitted nosocomially.

Risk of MDR-TB infection/disease in HCW

HCW also were at risk of MDR-TB infection. In comparative studies, HCW on the outbreak wards were at greater risk of TST conversion than HCW on control wards or at an AIDS outpatient clinic (Beck-Sague *et al.*, 1992). In three of the hospitals, TST conversions were identified in 24/108 (22 %), 13/39 (33 %), and 6/12 (50 %) HCW tested. At least 16 HCW have developed active MDR-TB; seven of those HCW are HIV-positive. At least five HCW have died with MDR-TB; four are known to be HIV-positive. In most of the hospitals, HCW were not wearing adequate respiratory protection i.e. partic-

ulate respirators, when they entered infectious MDR-TB patients' rooms; this included wearing no mask or wearing a mask improperly.

Infection control interventions and their efficacy

Thus, in each of these hospitals, MDR-TB outbreaks occurred when current CDC guidelines for preventing TB transmission in health care facilities were incompletely implemented (Centers for Disease Control, 1990). Follow-up investigations at several of these MDR-TB outbreak hospitals reveal varying degrees of implementation of the guidelines. At one hospital, which has implemented most of the guidelines, nosocomial MDR-TB transmission to patients and HCW has been terminated on the outbreak ward (Otten *et al.*, 1992; Wenger *et al.*, 1992). At another hospital, where the CDC guidelines have been "less fully implemented" (i.e. rapid identification, isolation in rooms even if not negative pressure), MDR-TB transmission to patients has been significantly reduced (Maloney *et al.*, 1992). A recent study by Stroud *et al.* suggests that improved clinician education to suspect TB, rapid diagnosis, and appropriate isolation of patients significantly reduces the risk of patient-to-patient MDR-TB transmission (personal communication). These data support the efficacy of the 1990 CDC guidelines and illustrate the importance of implementing these guidelines to prevent nosocomial MDR-TB transmission.

Status of U.S. hospitals to infection control programs

A recent survey of U.S. hospitals shows that; (1) MDR-TB patients were admitted to hospitals in at least 40 states; (2) HCW TST were usually applied upon employment but follow-up or repeat TST varied widely afterwards; (3) the number of AFB isolation rooms in each hospital varied widely, ranging from 0 to 99 (median 6) rooms; and (4) hospitals reported nosocomial TB transmission to patients

and/or HCW (Rudnick *et al.*, 1992). These data show that MDR-TB is widespread in many areas of the U.S. and that enhancement of HCW TST programs, AFB isolation facilities, and TB infection control practices are necessary to meet the challenge of the changing epidemiology of MDR-TB.

Recommendations

These outbreaks serve as a reminder of the importance of adequate diagnostic and infection control practices if MDR-TB outbreaks are to be terminated or prevented (table III). It is essential that clinicians maintain a high index of clinical suspicion of TB. TB can occur concomitantly with other pathogens, and thus any AFB-positive respiratory specimen should be considered *M. tuberculosis* until proven otherwise. Newer diagnostic tests, such as genetic probes, can facilitate rapid diagnosis (Cleary *et al.*, 1992). Other diagnostic tests, such as fluorescence microscopy and radiometric culture, and drug susceptibility testing can facilitate earlier diagnosis, more rapid institution of effective therapy, and early institution of AFB isolation.

Any patient with suspected or confirmed TB should be placed in AFB isolation. Effective isolation includes: negative pressure ventilation, at least

six air exchanges per hour, and air exhausted to the outside (Centers for Disease Control, 1990). To insure adequate AFB isolation, the direction of air flow should be frequently monitored. Patients in AFB isolation should remain in their rooms with the doors closed. If the patient must leave the room (medical emergency or essential procedures), the patient should wear a mask. Similarly, persons entering the AFB isolation room should wear respiratory protection. MDR-TB patients should not be removed from AFB isolation until they have both evidence of clinical improvement and the number of organisms on sequential sputum AFB smears is decreasing. When a patient is likely to be infected with drug-resistant organisms, AFB precautions should be applied until the patient is improving *and* has three successive negative AFB sputum smears.

Because of the risk of TB transmission to HCW, an active HCW TST program is essential. *All* HCW (including paid and unpaid hospital workers, medical students, attending staff, volunteers, those that have received BCG, etc.) should have baseline TST. Periodically, retest TST-negative HCW; in non-outbreak situations, TST should be conducted at least annually; where an outbreak has occurred, in high risk areas or groups, and in those with known TB contacts, TST should be conducted more frequently (≤ 6 months). In hospital A, where MDR-TB trans-

Table III. Measures necessary to prevent nosocomial tuberculosis transmission.

Early identification

- high index of suspicion
- rapid diagnostic work-up

Use rapid diagnostic techniques

- fluorescent microscopy for smears
- radiometric methods for identification and drug susceptibility testing

Prompt initiation of adequate AFB Isolation

- negative pressure rooms
- ≥ 6 air exchanges per hour
- exhaust air directly outside
- keep patient in room
- doors closed
- do not remove MDR-TB-patients from isolation until both clinical improvement *and* three successive negative AFB smears
- persons entering the room should wear respiratory protection
- appropriate follow-up of discharged patients

Prompt initiation of effective antituberculosis therapy

Monitor adequacy of therapy

- frequent acid-fast bacillus (AFB) smears and culture
-

mission was terminated, TST every 3-4 months of ward HCW was essential for evaluating the efficacy of introduced control measures (Otten *et al.*, 1992; Wenger *et al.*, 1992). All HCW with positive TST should be promptly evaluated for active disease; if active disease is ruled out, evaluate for preventive therapy (Villarino *et al.*, 1992). Of utmost importance, TST data must be collected and analysed so that high risk areas, procedures, and personnel can be identified and the efficacy of infection control practices assessed.

Conclusion

The emergence of nosocomial outbreaks of MDR-TB in U.S. hospitals is a serious public health problem requiring rapid response. The CDC and other PHS agencies have developed a PHS TB Task Force and a CDC TB Working Group to quickly initiate action to control this serious problem. A PHS TB Action Plan has been developed with a step-by-step approach to reducing TB and controlling nosocomial TB transmission. A CDC meeting of outside experts was held in October 1992 to review and assess the current 1990 CDC TB guidelines. The consensus was that the guidelines needed some revision, but that, in general, the 1990 CDC guidelines were adequate but not widely implemented in U.S. hospitals. Because of the serious morbidity and mortality to both patients and HCW resulting from nosocomial MDR-TB transmission, the current CDC guidelines should be fully implemented immediately in hospitals so that MDR-TB transmission in healthcare facilities can be prevented.

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References

- Beck-Sague, C., Dooley, S.W., Hutton, M.D., Otten, J., Breiden, A., Crawford, J.T., Pitchenik, A.E., Woodley, C., Cauthen, G. & Jarvis, W.R. (1992), Hospital outbreak of multidrug-resistant *Mycobacterium tuberculosis* infections: factors in transmission to staff and HIV-infected patients. *J. Amer. med. Ass.*, 268, 1280-1286.
- Cave, M.D., Eisenbach, K.D., McDermott, P.F., Bates, J.H. & Crawford, J.T. (1991), IS 6110: Conservation of sequence in the *Mycobacterium tuberculosis* complex and its utilization in DNA finger printing. *Mol. Cell Probes*, 5, 73-80.
- Centers for Disease Control (1990), Guidelines for preventing the transmission of tuberculosis in health-care settings, with special focus on HIV-related issues. *Mortal. Morbid. Weekly Rep.*, 39, 1-27.
- Cleary, T., Miller, N. & Gonzalez, S. (1992), Evaluation of the Gen-probe *Mycobacterium tuberculosis* direct test on patients who acquired *Mycobacterium fortuitum* during hospitalization. First World Congress on Tuberculosis, November 15-18, Rockville, MD.
- Coronado, V.G., Valway, S.E., Ihle, W., Dato, V., Finnelly, L., Woodley, C.L., Kilburn, J.O., Crawford, J.T., Pineda, M.R. & Jarvis, W.R. (1992a), Nosocomial transmission of multidrug-resistant *Mycobacterium tuberculosis* among intravenous drug users with HIV infection in an urban hospital. First World Congress on Tuberculosis, November 15-18, Rockville, MD.
- Coronado, V.G., Beck-Sague, C.M., Pearson, M.L., Pineda, M.R. & Jarvis, W.R. (1992b), Tuberculosis due to multidrug-resistant *Mycobacterium tuberculosis* among HIV-positive patients: clinical and epidemiological aspects. First World Congress on Tuberculosis, November 15-18, Rockville, MD.
- Crawford, J.T., Woodley, C.L., Butler, W.R. & Kilburn, J.O. (1992), Use of DNA fingerprinting to support investigations of outbreaks of multidrug-resistant tuberculosis. First World Congress on Tuberculosis, November 15-18, Rockville, MD.
- Edlin, B.R., Tokars, J.I., Grieco, M.H., Crawford, J.T., Williams, J., Sordillo, E.M., Ong, K.R., Kilburn, J.O., Dooley, S.W., Castro, K.G., Jarvis, W.R. & Holmberg, S. (1992a), An outbreak of multidrug-resistant tuberculosis among hospitalized patients with the acquired immunodeficiency syndrome. *New Engl. J. Med.*, 326, 1514-1521.
- Edlin, B.R., Grieco, M.H., Tokars, J.I., Attoe, L.S., Sordillo, E.M., Williams, J., Schneider, N., Gilligan, M.E. & Holmberg, S.D. (1992b), Recognition and treatment of primary multidrug-resistant tuberculosis in AIDS patients. First World Congress on Tuberculosis, November 15-18, Rockville, MD.
- Hutton, M.D., Dooley, S.W. & Cauthen, G.M. (1992), Nosocomial TB transmission: characteristics of source-patients in reported outbreaks, 1970-1991. First World Congress on Tuberculosis, November 15-18, Rockville, MD.
- Jereb, J.A., Kelly, G.D., Dooley, S.W., Cauthen, G.M. & Snider, D.E. Jr. (1991), TB morbidity in the United States: final data, 1990. *Mortal. Morbid. Weekly Rep.*, 40, 23-28.
- Jereb, J., Dooley, S., Kleven, R., Pearson, M., Frieden, T., Davis, B., Rivera, P., Sharp, V., Woodley, C., Crawford, J., Kilburn, J., Jarvis, W. & Cauthen, G. (1992), Nosocomial transmission of multidrug-resistant tuberculosis to health care workers, New York City. First World Congress on Tuberculosis, November 15-18, Rockville, MD.
- Kent, J., Valway, S. & Onorato, I. (1992), Epidemiologically linked outbreaks of multidrug-resistant tuberculosis (MDR-TB), New York State, 1990-1992. First World Congress on Tuberculosis, November 15-18, Rockville, MD.
- Maloney, S.A., Pearson, M., Gordon, M., Del Castillo, R., Boyle, J. & Jarvis, W. (1992), The efficacy of recommended infection control measures in preventing nosocomial transmission of multidrug-resistant tuberculosis. First World Congress on Tuberculosis, November 15-18, Rockville, MD.

- Otten, J., Chan, J. & Cleary, T. (1992), Successful control of an outbreak of multidrug-resistant tuberculosis in an urban teaching hospital. First World Congress on Tuberculosis, November 15-18, Rockville, MD.
- Pearson, M.L., Jered, J.A., Frieden, T.R., Crawford, J.T., Davis, B.J., Dooley, S.W. & Jarvis, W.R. (1992), Nosocomial transmission of multidrug-resistant *Mycobacterium tuberculosis*. A risk to patients and health care workers. *Ann. Intern. Med.*, 117, 191-196.
- Rudnick, J., Kroc, K., Manangan, L., Banerjee, S., Pugliese, G. & Jarvis, W. (1992), How prepared are U.S. hospitals to control nosocomial transmission of tuberculosis? First World Congress on Tuberculosis, November 15-18, Rockville, MD.
- Stroud, L.A., Coronado, V.G., Beck-Sague, C.M., Hutton, M.D., Nicholas, P., Villarreal, C., Woodley, C.L., Kilburn, J.O., Crawford, J.T., Frieden, T.R., Sinkowitz, R.L. & Jarvis, W.R. (1992), Nosocomial transmission of multidrug-resistant *Mycobacterium tuberculosis* among persons with HIV infection in an urban hospital: restriction fragment length polymorphism analysis. First World Congress on Tuberculosis, November 15-18, Rockville, MD.
- Valway, S., Richards, S., Kovacovich, J., Greifinger, R., Woodley, C. & Kilburn, J. (1992), Transmission of multidrug-resistant tuberculosis in a New York State (NYS) prison, 1991. First World Congress on Tuberculosis, November 15-18, Rockville, MD.
- Villarino, M.E., Dooley, S.W. Jr., Geiter, L.J., Castro, K.G. & Snider, D.E. Jr. (1992), Management of persons exposed to multidrug resistant tuberculosis. *Mortal. Morbid. Weekly Res.*, 41, 59-71.
- Wenger, P., Beck-Sague, C., Otten, J., Breeden, A., Orfas, D. & Jarvis, W. (1992), Efficacy of control measures in preventing nosocomial transmission of multidrug-resistant *Mycobacterium tuberculosis* among patients and health-care workers. First World Congress on Tuberculosis, November 15-18, Rockville, MD.

Multiple-drug-resistant tuberculosis: clinical and laboratory issues

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Introduction

During the past few years, tuberculosis (TB) has become a subject of concern in the United States to both healthcare workers and the public (Cowley, Leonard, and Hager, 1992). In part, this concern results from the recent appearance of *Mycobacterium tuberculosis* strains resistant to the usual first line drugs used to treat TB. This review details several factors determining the current pattern of TB in the United States, the clinical importance of multidrug-resistant TB (MDR-TB), and the increased importance that MDR-TB brings to preventing nosocomial spread of the disease. The steps needed to control TB in the hospital setting will be discussed, and the impact of these measures on the laboratory then will be highlighted.

Changes in the pattern of tuberculosis in the United States

In the United States, TB did not receive the respect it deserves during the 1980s (McGowan, 1992). There were many reasons for this. First, TB

was thought to be a disappearing disease, the subject of an elimination effort created by the Centers for Disease Control (CDC) (Centers for Disease Control, 1989). Second, TB by the 1980s had become primarily a disease of the disadvantaged — cases of TB became a rarity except in United States hospitals serving the homeless and the helpless. As these hospitals and their patients tend to be ignored by the health authorities and the public, TB was lost to medical attention, especially in comparison to new problem infections like acquired immunodeficiency syndrome (AIDS). Third, virtually all TB isolates were susceptible to the two major drugs used for treatment, isoniazid and rifampin. The tuberculocidal action of these drugs in combination made treatment shorter and easier than ever before. When resistance to these drugs was found in occasional strains, these usually emerged from initially susceptible strains in patients who were non-compliant with therapy, or were found in patients with infections acquired in countries other than the United States. Thus, the threat of TB seemed diminished. As a result, during this period, TB control programs at the federal, state, and local levels were cut back or eliminated (Glassroth, 1992; Bloom and Murray, 1992).



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Evaluation of Infection Control Measures in Preventing the Nosocomial Transmission of Multidrug-Resistant Mycobacterium tuberculosis in a New York City Hospital

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EVALUATION OF INFECTION CONTROL MEASURES IN PREVENTING THE NOSOCOMIAL TRANSMISSION OF MULTIDRUG-RESISTANT MYCOBACTERIUM TUBERCULOSIS IN A NEW YORK CITY HOSPITAL

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ABSTRACT

OBJECTIVE: To evaluate the efficacy of Centers for Disease Control and Prevention (CDC)-recommended infection control measures implemented in response to an outbreak of multidrug-resistant (MDR) tuberculosis (TB).

DESIGN: Retrospective cohort studies of acquired immunodeficiency syndrome (AIDS) patients and healthcare workers. The study period (January 1989 through September 1992) was divided into period I, before changes in infection control; period II, after aggressive use of administrative controls (eg, rapid placement of TB patients or suspected TB patients in single-patient rooms); and period III, while engineering changes were made (eg, improving ventilation in TB isolation rooms).

SETTING: A New York City hospital that was the site of one of the first reported outbreaks of MDR-TB among AIDS patients in the United States.

PARTICIPANTS: All AIDS patients admitted during periods I and II. Healthcare workers on nine inpatient units with TB patients and six without TB patients.

RESULTS: The epidemic (38 patients) waned during period II and only one MDR-TB patient presented during period III. The MDR-TB attack rate among AIDS patients hospitalized on the same ward on the same days as an infectious MDR-TB patient was 8.8% (19 of 216) during period I, decreasing to 2.6% (5 of 193; $P=0.01$) during period II. In a small group of healthcare workers with tuberculin skin test data, conversions during periods II through III were higher on wards with than without TB patients (5 of 29 versus 0 of 15; $P=0.15$), although the difference was not statistically significant.

CONCLUSIONS: Transmission of MDR-TB among AIDS patients decreased markedly after enforcement of readily implementable administrative measures, ending the outbreak. However, tuberculin skin-test conversions among healthcare workers may not have been prevented by these measures. CDC guidelines for prevention of nosocomial transmission of TB should be implemented fully at all US hospitals (*Infect Control Hosp Epidemiol* 1995;16:141-147).

INTRODUCTION

Nosocomial transmission of tuberculosis (TB) to healthcare workers (HCWs) is a well-documented risk, usually associated with highly infectious patients with unsuspected disease.^{1,2} In 1989, nosocomial transmission of drug-sensitive TB to human immunodeficiency virus (HIV)-infected patients was reported in

Italy³ and investigated by the Centers for Disease Control and Prevention (CDC) in Puerto Rico.⁴ In 1990, Jackson Memorial Hospital in Miami and Roosevelt Hospital in New York City reported to the CDC outbreaks of multidrug-resistant (MDR) tuberculosis (TB). Nosocomial transmission was suspected but confirmed only after completion of detailed epidemiol-

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ologic and laboratory studies.^{5,6} Subsequently, the CDC documented nosocomial transmission of MDR-TB at six additional US hospitals and a New York state prison.⁷⁻¹³ These outbreaks were associated with incomplete implementation of CDC TB infection control guidelines.¹⁴⁻¹⁶

Many TB infection control measures are of unproven efficacy. In the wake of recent nosocomial outbreaks, the adequacy of CDC TB infection control guidelines has been questioned. An important component of the National Action Plan to Combat MDR-TB, published in 1992, is an assessment of TB infection control strategies.¹⁷ Data on the efficacy of such strategies has been used in the revision of CDC TB infection control guidelines.¹⁸

Our initial report described the epidemic of MDR-TB among acquired immunodeficiency syndrome (AIDS) patients at Roosevelt Hospital⁶ during an era when CDC-recommended TB infection control guidelines were poorly implemented at many US hospitals. Nosocomial transmission on inpatient-care units was implicated strongly and explained 13 of 18 outbreak patients; the remaining five patients may have acquired disease in other areas of the hospital (eg, outpatient clinics, radiology department) or community settings. Evaluation of patient-to-HCW transmission was hampered by insufficient tuberculin skin-test data.¹⁹ The objectives of our currently reported study were to assess changes in infection control policy and procedures made in response to the outbreak and to evaluate the impact that these changes had on transmission of MDR-TB from patient to patient and from patient to HCW.

METHODS

To ascertain changes in infection control measures, in September 1992 we interviewed infection control personnel, reviewed hospital isolation policies and practices, and inspected hospital facilities. A smoke dispenser was used to determine the direction of airflow in rooms used for TB isolation. On the basis of infection control precautions used, the study period (January 1989 to September 1992) was divided into three 15-month intervals: period I (January 1989 to March 1990), period II (April 1990 to June 1991), and period III (July 1991 to September 1992).

Case-Patients

To facilitate comparison, we used the definitions and methodology employed in our previous study⁶ whenever possible. A case-patient was defined as any patient meeting the 1987 CDC AIDS case definition²⁰ who had a diagnosis of active TB at Roosevelt Hospital during the study period, and whose *Mycobacterium tuberculosis* isolate was resistant to at least isoniazid

and streptomycin (MDR-TB). The date of diagnosis was defined as the date of collection of the first specimen culture positive for MDR-TB. Hospital mycobacteriology and infection control records were reviewed to identify case-patients; medical records were reviewed to obtain demographic, clinical, and microbiologic data. Case-patients were considered to be infectious for 15 days before and after having a positive acid-fast bacillus (AFB) smear from sputum or bronchoalveolar lavage fluid.

Cohort Study Among AIDS Patients

A cohort study was performed among all AIDS patients identified in the hospital's AIDS center program data base who were admitted during periods I or II. AIDS patients who had TB at the time of first admission, or who developed TB not meeting the case definition, were excluded. The risk of same-ward exposure (hospitalization on the same ward on the same days as an infectious case-patient) was compared for periods I and II. Days of same-ward exposure were determined from a hospital computer data base with information on ward and room assignments. For case-patients, same-ward exposures <14 days before the date of MDR-TB diagnosis were excluded. A small number of computer-identified same-ward exposures of 1-day duration were excluded because comparisons with hospital charts showed that such exposures often had not occurred (ie, they were due to errors in the hospital computer data base); however, these comparisons proved the data base to be reliable for exposures of ≥ 2 days.

Laboratory Studies

Case-patient *M tuberculosis* isolates were tested by the hospital laboratory for resistance to at least isoniazid, rifampin, streptomycin, and ethambutol. At the CDC, antimicrobial resistance testing was repeated, and restriction fragment length polymorphism (RFLP) analysis was performed on available case-patient *M tuberculosis* isolates.^{6,21}

TB Infection Among Healthcare Workers

We reviewed hospital employee health records to obtain demographic, clinical, and tuberculin skin-test information on HCWs. Skin tests were performed using the Mantoux technique (intradermal injection of 0.1 mL of intermediate-strength purified protein derivative). Employee health personnel or the authors performed and read all skin tests. Tuberculin skin-test conversion (defined for this study as ≥ 10 mm increase in induration) rates among healthcare workers during periods II and III were compared on nine units with and six units without TB patients. To exclude reactivity due to TB exposure during period I, only workers

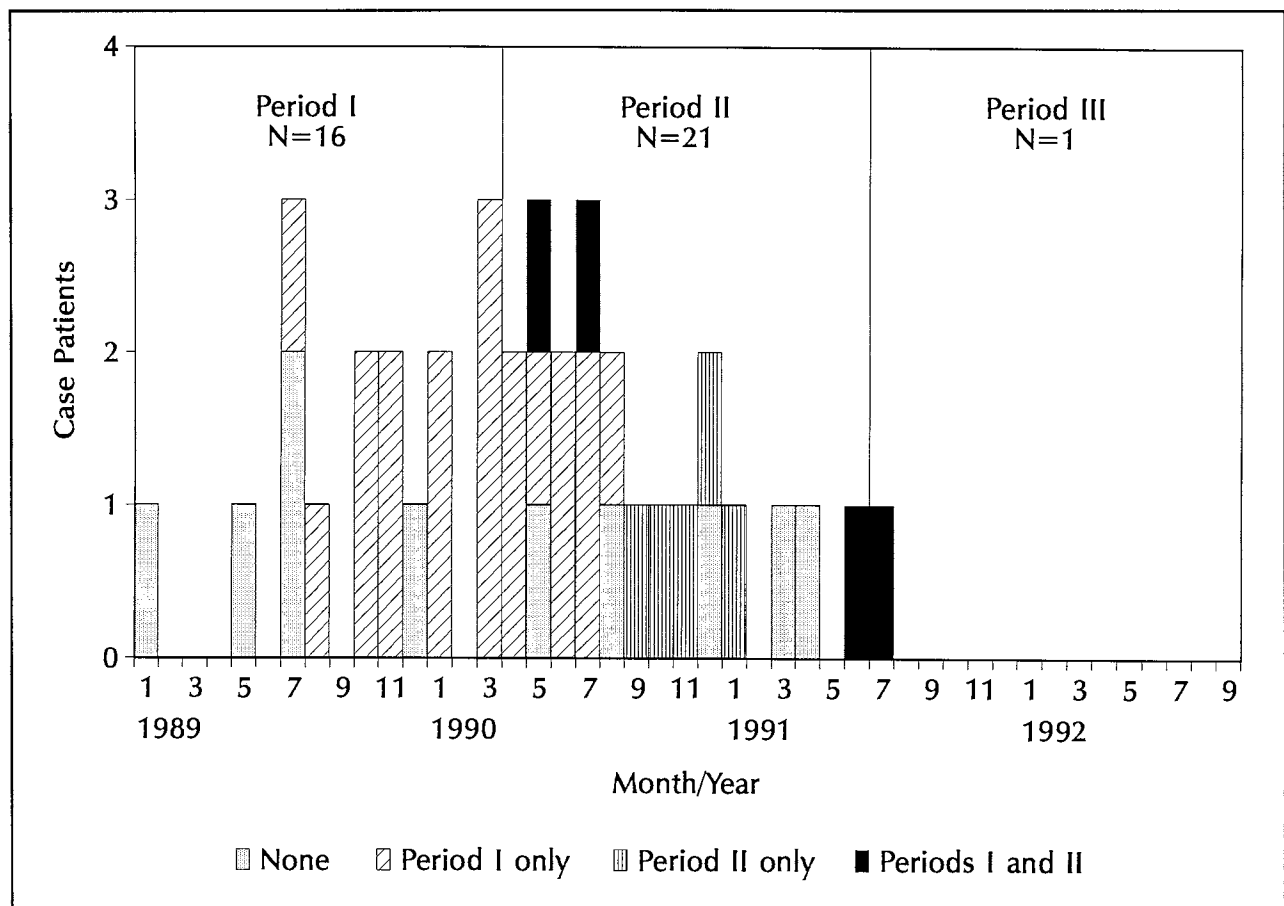


TABLE 1

COMPARISON OF THE CHARACTERISTICS OF CASE PATIENTS BY TIME PERIOD OF MDR-TB DIAGNOSIS, ROOSEVELT HOSPITAL, JANUARY 1989 THROUGH SEPTEMBER 1992

Characteristic	Period I (N = 16)	Periods II-III (N = 22)	P Value
Categorical variables, number (%)			
Male	15 (94)	21 (95)	1.0
Race/ethnicity			
White	9 (56)	8 (36)	0.2*
Black	3 (19)	10 (45)	
Hispanic	3 (19)	4 (18)	
Other	1 (6)	0 (0)	
Previous Roosevelt Hospital admission	13 (81)	19 (86)	0.7
Infectious	11 (69)	16 (73)	1.0
Placed in TB isolation on admission†	0 (0)	7 (44)	0.02
Died during hospitalization	6 (38)	8 (36)	0.8
Continuous variables, median (range)			
Age	33 (28 to 45)	38 (24 to 66)	0.06
Days hospitalized while infectious†	37 (13 to 91)	32 (14 to 135)	1.0
Days from admission to TB isolation†	6 (2 to 20)	2 (0 to 32)	0.06
Days from same-ward exposure to MDR-TB diagnosis‡	67 (29 to 102)	106 (40 to 592)	<0.001
No. of drugs in initial regimen§	1.5 (0 to 4)	2.0 (0 to 4)	0.2

* Black versus all other race/ethnicity.

† Among infectious case-patients (N = 11 for period I, N = 16 for periods II through III).

‡ Among case patients with same-ward exposure (N = 11 for period I, N = 17 for periods II through III).

§ Antituberculous drugs begun within 2 weeks of diagnosis, excluding those to which the isolate was resistant in vivo.

suspected TB often exceeded the number that had undergone these modifications. Isolation chambers were used for sputum induction and aerosolized pentamidine therapy, and dust-mist respirators (3M no. 8715, Minneapolis, MN) were used by HCWs during such procedures. Surgical masks (Technol. no. 47080-070, Fort Worth, TX) were used for routine care of patients on TB isolation precautions.

During the study period, 46 patients had TB resistant to isoniazid and streptomycin; 38 (83%) also had AIDS and, therefore, met the case definition (Figure). The proportion of total TB patients meeting the case definition was similar during periods I (16 [16.3%] of 98) and II (21 [17.4%] of 121; $P = 1.0$), but decreased significantly during period III (1 [1.3%] of 76; $P < 0.001$ compared with periods I and II combined).

Compared with case-patients who had MDR-TB diagnosed in period I, period II and III case-patients were older and more likely to be black, but these differences were not statistically significant (Table 1). Also, for period I versus periods II and III, the proportions of case-patients that were infectious were similar. However, placement of infectious patients in TB isolation on the day of admission rose significantly from 0% to 44%, and the median time from admission to TB isolation decreased from 6 to 2 days (Table 1).

Use of antituberculosis therapy and mortality did not differ significantly during the two intervals (Table 1).

The Risk of Nosocomial Transmission to AIDS Patients

The cohort of 1,356 AIDS patients admitted during periods I or II included 32 case-patients (six case-patients were admitted after diagnosis of MDR-TB and, therefore, were not included in the cohort study). Case-patients were similar to other cohort patients in numbers of days hospitalized during periods I and II (median, 33.5 versus 28.0, respectively; $P = 0.6$).

The MDR-TB attack rate was 0.5% (4 of 863) for AIDS patients without same-ward exposure, 8.8% (19 of 216) for those with period I exposures only, 2.6% (5 of 193) for those with period II exposures only, and 4.8% (4 of 84) for those with exposures in both periods I and II. The one case-patient presenting in period III had no same-ward exposures during period III.

Among the 216 AIDS patients with same-ward exposure during period I only, the attack rate decreased as exposure distance (ie, number of rooms from the infectious patient) increased, but did not show a progressive increase as the total days of exposure increased (Table 2). Most exposures

TABLE 2

RISK OF MDR-TB AMONG 409* AIDS PATIENTS WITH SAME-WARD EXPOSURE TO AN INFECTIOUS CASE-PATIENT DURING PERIODS I OR II, ROOSEVELT HOSPITAL, JANUARY 1989 THROUGH JUNE 1991

Type of Same-Ward Exposure	Case Patients/Total (Attack Rate)	
	Exposure During Period I	Exposure During Period II
Any exposure	19/216 (8.8)†	5/193 (2.6)†
Exposure distance		
Same room	4/10 (40.0)†	0/6 (0)
1 room	8/53 (15.1)†	1/49 (2.0)
2 to 3 rooms	7/91 (7.7)†	2/59 (3.4)
4 to 5 rooms	10/93 (10.8)†	1/46 (2.2)
≥6 rooms	7/132 (5.3)†	2/120 (1.7)
Total days exposed		
2 to 5	4/47 (8.5)†	0/44 (0)
6 to 10	5/48 (10.4)†	4/56 (7.1)†
11 to 20	4/55 (7.2)†	0/55 (0)
>20	6/66 (9.1)†	1/38 (2.6)
Ward where exposed		
A	10/79 (12.7)†	4/69 (5.8)†
B	9/126 (7.1)†	1/70 (1.4)
Others	1/38 (2.6)	0/83 (0)
Infectious patient exposed to‡		
A	9/85 (10.6)†	0/0 –
B	5/50 (10.0)†	0/0 –
C	5/36 (13.9)†	0/0 –
D	4/59 (6.8)†	0/0 –
E	4/32 (12.5)†	0/0 –
F	0/0 –	5/58 (8.6)†
G	0/0 –	4/16 (25.0)†

* 84 patients (four of whom were case-patients) with same-ward exposure during both periods I and II are not tabulated.

† $P < 0.05$ compared with the attack rate (4/863 [0.5%]) among those without exposure in either period.

‡ Data tabulated only for infectious patients exposing ≥4 case patients.

occurred on wards A and B. Of 27 infectious MDR-TB patients, five exposed ≥4 case-patients during period I (Table 2, patients A through E).

Although approximately equal numbers of AIDS patients had same-ward exposures in periods I and II, the MDR-TB attack rate was significantly lower during period II (19 of 216 versus 5 of 193; $P = 0.01$). Among 193 AIDS patients exposed during period II only, attack rates were not related to exposure distance or to total days exposed, but were associated highly with exposure to patients F and G (Table 2). Of five case-patients exposed during period II only, four were exposed to both patients F and G during July 1990, and the fifth was exposed to patient F during June 1990.

TABLE 3

LOGISTIC REGRESSION MODEL: EFFECT OF SAME-WARD EXPOSURE ON RISK OF MDR-TB AMONG 1,356 AIDS PATIENTS ADMITTED DURING PERIODS I AND II, ROOSEVELT HOSPITAL, JANUARY 1989 THROUGH JUNE 1991

Factor	Odds Ratio	P Value
No exposure	1.0	–
Period I exposures		
Exposure distance		
Same room	15.3	<0.001
1 room	3.9	0.01
2 to 3 rooms	1.1	0.9
4 to 5 rooms	1.5	0.5
≥6 rooms	0.2	0.01
Patient A	6.2	0.01
Patient C	10.9	<0.001
Period II exposures		
Patient G	40.0	<0.001
Other patients	0.7	0.4

A logistic regression model was used to assess the independent importance of exposure distance and exposure to specific infectious patients. To assess the importance of exposure duration, each variable was evaluated both as a dichotomous variable coding for the presence or absence of the exposure and a continuous variable coding for the number of days of such exposure; however, the continuous variables were less predictive of risk, and none were incorporated into the model (Table 3). During period I, the risk of MDR-TB was related independently to exposure distance and exposure to patients A and C; during period II, risk was related only to exposure to patient G. Interaction terms between patients (A and C) and exposure distance (same room or one room away) were not statistically significant and were not incorporated into the model.

A separate analysis was performed to evaluate the importance of exposure to case-patients who were culture-positive but smear-negative from pulmonary specimens. Forty-six AIDS patients in the cohort were hospitalized on the same ward at the same time as such patients; only one of the 46 (who also had exposure to smear-positive case-patients) contracted MDR-TB. We also explored the possibility of transmission from eight patients with isoniazid-streptomycin-resistant TB but not meeting the case definition because they did not have AIDS; the MDR-TB attack rate was 0 of 120 after same-ward exposure to such patients.

Laboratory Results

Among the 38 case-patient *M tuberculosis* isolates (all were resistant to isoniazid and streptomycin by

definition), 26 (68%) were rifampin resistant and 15 (39%) were ethambutol resistant; of 18 tested, 2 (11%) were amikacin resistant; of 19 tested, none were ciprofloxacin resistant.

Of 35 *M. tuberculosis* isolates available for RFLP typing, 32 (91%) had an identical pattern (outbreak pattern), two (6%) shared a unique pattern identified during a nosocomial outbreak at another New York City hospital, and one (3%) had a distinct pattern. Of the 32 patients with outbreak pattern isolates, three also had a second isolate collected on a different occasion with a different RFLP pattern. When only RFLP-typed isolates were considered, among 26 from patients with same-ward exposure, all had the outbreak pattern; among nine from patients without same-ward exposure, six had the outbreak pattern ($P=0.01$). All five case-patients with same-ward exposures only during period II had an isolate with the RFLP outbreak pattern.

TB Infection Among Healthcare Workers

Although most HCWs had at least one tuberculin skin test performed during periods II and III, paired (baseline and follow-up) tuberculin skin tests were available for only 29 (16%) of 181 HCWs on nine wards with TB patients and 15 (14%) of 110 workers on six wards without TB patients. Most workers with paired tests had a baseline test in period II and a follow-up test in period III; therefore, it was not possible to calculate separate conversion rates for the two periods. During periods II and III, the HCW tuberculin skin-test conversion rate was higher on the TB-care wards than on other wards, although the difference was not statistically significant (5 of 29 versus 0 of 15; $P=0.15$).

None of the HCWs with skin-test conversion had evidence of active disease. However, four other HCWs developed isoniazid-streptomycin-resistant TB; of three isolates tested by RFLP, all had the Roosevelt Hospital outbreak strain. All four worked during period I, and two also worked during period II. Two were HIV positive, one was HIV negative, and one was not tested for HIV but had a normal CD4+ lymphocyte count. No active TB was identified among those who worked only during periods II and III.

DISCUSSION

Our initial report documented nosocomial MDR-TB transmission among AIDS patients.⁶ Continued surveillance revealed a decline in the number of case-patients, forming a typical "epidemic curve." The usual reasons for such a pattern (ie, the epidemic having been caused by a point source or ended because of exhaustion of susceptibles) do not apply to this outbreak: our investigation suggested transmis-

sion from several source patients and documented continuing same-ward exposure of susceptible AIDS patients. Although reduced transmission in the community and in other New York City hospitals may have played a role, most of the decline probably was due to improvements in infection control at Roosevelt Hospital.

In response to the outbreak, administrative infection control precautions were stressed during period II. Patient-to-patient MDR-TB transmission declined, and only one case-patient presented during period III. This result documents the efficacy of early identification, isolation, and treatment of infectious TB patients. However, MDR-TB was transmitted to at least five patients during period II, after administrative measures were stressed but before environmental changes were made. Transmission probably was from a particularly infectious patient; patient F exposed all five case-patients, but patient G (who exposed 4 of 5) was associated more strongly statistically. Regardless of the source patient, this continued nosocomial transmission during period II underscores the importance of full implementation of CDC guidelines.

The last case-patient was diagnosed months before installation of exhaust fans to improve ventilation in TB isolation rooms. However, before installation of these fans, most rooms had air exhausted directly to the outside; although this feature did not prevent the outbreak, it may have contributed to ending it.

During period I, risk of acquiring MDR-TB was independently conferred by same-ward exposures at short distances to any infectious case-patient, and exposures at any distance to two specific patients (A or C). During period II, AIDS patients continued to be hospitalized in proximity to infectious MDR-TB patients, but attack rates after such exposure were reduced substantially. In addition to the protection afforded by earlier placement of infectious patients in TB isolation rooms, period II case-patients may have been less infectious on average, in part due to earlier antimycobacterial treatment.

These findings are in accord with those of two other CDC follow-up studies at hospitals that have experienced MDR-TB outbreaks.^{22,23} Both studies showed that use of CDC-recommended infection control measures resulted in termination of the outbreaks. At neither of these two hospitals were UV lamps installed. At Roosevelt Hospital, installation of UV lamps began during the month of diagnosis of the last case-patient; therefore, we are unable to assess whether UV lamps were protective.

Ten of 38 MDR-TB patients could not be explained by documented same-ward exposures, six had no Roosevelt Hospital admissions prior to diagnosis, and four had previous admissions but no same-

ward exposures. The results of RFLP typing suggested that two patients had acquired MDR-TB at another New York City hospital. The mode of acquisition for the other eight (six of whom had isolates with the RFLP outbreak pattern on at least one occasion) is uncertain. We were unable to evaluate the possibility of acquisition in the community or in areas of the hospital other than patient-care wards.

The rate of tuberculin skin-test conversion on TB-care wards during periods II and III was high, but data were not available on a sufficient number of workers to evaluate risk adequately. The minority with both a baseline and follow-up skin test may not have been representative of other workers. Because HCWs must enter TB isolation rooms routinely and work in proximity to infectious patients, the combination of administrative controls, engineering controls, and personal protective equipment (eg, respirators) may be needed to safeguard this group.

We conclude that, at Roosevelt Hospital, inexpensive and readily implementable administrative measures, such as rapid identification and isolation of known and suspected TB patients, greatly reduced patient-to-patient transmission of MDR-TB and ended the outbreak. Although active disease did not occur among healthcare workers who worked only during periods II and III, tuberculin skin-test conversions among workers may not have been prevented by these administrative measures. It is possible that earlier complete implementation of CDC guidelines, especially use of negative-pressure TB isolation rooms and provision of particulate respirators to workers, would have reduced nosocomial transmission further. Full implementation of CDC guidelines^{16,18} at hospitals caring for TB patients is recommended for maximum protection of both patients and HCWs.

REFERENCES

- Catanzaro A. Nosocomial tuberculosis. *Am Rev Respir Dis* 1982;125:559-562.
- Haley CE, McDonald RC, Rossi L, Jones J WD, Haley RW, Luby JP. Tuberculosis epidemic among hospital personnel. *Infect Control Hosp Epidemiol* 1989;10:204-210.
- Di Perri G, Cruciani M, Danzi MC, et al. Nosocomial epidemic of active tuberculosis among HIV-infected patients. *Lancet* 1989;2:1502-1504.
- Dooley SW, Villarino ME, Lawrence M, et al. Nosocomial transmission of tuberculosis in a hospital unit for HIV-infected patients. *JAMA* 1992;267:2632-2634.
- Beck-Sague C, Dooley SW, Hutton MD, et al. Hospital outbreak of multidrug-resistant *Mycobacterium tuberculosis* infections: factors in transmission to staff and HIV-infected patients. *JAMA* 1992;268:1280-1286.
- Edlin BR, Tokars JI, Grieco MH, et al. An outbreak of multidrug-resistant tuberculosis among hospitalized patients with the acquired immunodeficiency syndrome. *N Engl J Med* 1992;326:1514-1521.
- Jereb J, Dooley S, Klevens R, et al. Nosocomial transmission of multidrug-resistant tuberculosis to healthcare workers, New York City. In: *World Congress on Tuberculosis Program and Abstracts*; November 16-19, 1992; Bethesda, Maryland. Abstract 51A.
- Pearson ML, Jereb JA, Frieden TR, et al. Nosocomial transmission of multidrug-resistant *Mycobacterium tuberculosis*: a risk to patients and healthcare workers. *Ann Intern Med* 1992;117:191-196.
- Ikeda RM, Birkhead G, DiFerdinando G Jr, Bornstein D, Morse D. Nosocomial transmission of multidrug-resistant tuberculosis, New York. In: *Abstracts of the Epidemic Intelligence Service Conference, Atlanta, April 6-10, 1992*. Washington, DC: US Department of Health and Human Services; 1992:29.
- Coronado VG, Beck-Sague CM, Hutton MD, et al. Transmission of multidrug-resistant *Mycobacterium tuberculosis* among persons with human immunodeficiency virus infection in an urban hospital: epidemiologic and restriction fragment length polymorphism analysis. *J Infect Dis* 1993;168:1052-1055.
- Valway S, Papania M, Richards J, et al. Multidrug resistant tuberculosis (MDR-TB) in New York State (NYS) correctional facilities, 1990-1991. Presented at the World Congress on Tuberculosis; November 16-19, 1992; Bethesda, Maryland. Abstract 54B.
- Coronado VG, Valway S, Finelli L, et al. Nosocomial transmission of multidrug-resistant *Mycobacterium tuberculosis* among intravenous drug users with human immunodeficiency virus infection. Presented at the Third Annual Meeting of The Society for Hospital Epidemiology of America; April 18-20, 1993; Chicago, Illinois. Abstract S50.
- Centers for Disease Control and Prevention. Outbreak of multidrug-resistant tuberculosis at a hospital—New York City, 1991. *MMWR* 1993;42:427-434.
- Centers for Disease Control and Prevention. *Guidelines for Prevention of TB Transmission in Hospitals*. Atlanta, GA: US Department of Health and Human Services, Public Health Service; 1982; DHHS publication no. (CDC) 82-8371.
- Garner JS, Simmons BP. Guideline for isolation precautions in hospitals. *Infect Control* 1983;4:245-325.
- Centers for Disease Control and Prevention. Guidelines for preventing the transmission of tuberculosis in health-care settings, with special focus on HIV-related issues. *MMWR* 1990;39(RR-17).
- Centers for Disease Control and Prevention. National action plan to combat multidrug-resistant tuberculosis. *MMWR* 1992;41(RR-11):1-48.
- Centers for Disease Control and Prevention. Guidelines for preventing the transmission of *Mycobacterium tuberculosis* in health-care facilities—1994. *MMWR* 1994;43(RR-13).
- Tokars JI, Jarvis WR, Edlin BR, et al. Tuberculin skin testing of hospital employees during an outbreak of multidrug-resistant tuberculosis in HIV-infected patients. *Infect Control Hosp Epidemiol* 1992;509-510.
- Centers for Disease Control and Prevention. Revision of the CDC surveillance case definition for acquired immunodeficiency syndrome. *MMWR* 1987;36:3S-14S.
- Cave MD, Eisenach KD, McDermott PF, Bates JH, Crawford JT. IS6110: conservation of sequence in the *Mycobacterium tuberculosis* complex and its utilization in DNA fingerprinting. *Molecular and Cellular Probes* 1991;5:73-80.
- Wenger PN, Otten J, Breeden A, Orfas D, Beck-Sague CM, Jarvis WR. Control of nosocomial transmission of multidrug resistant *Mycobacterium tuberculosis* among health care workers and HIV-infected patients. *Lancet* 1995;345:235-240.
- Maloney SA, Pearson ML, Gordon MT, Del Castillo R, Boyle JF, Jarvis WR. Efficacy of control measures in preventing nosocomial transmission of multidrug-resistant tuberculosis to patients and health care workers. *Ann Intern Med* 1995;122:90-95.

Efficacy of Control Measures in Preventing Nosocomial Transmission of Multidrug-Resistant Tuberculosis to Patients and Health Care Workers

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■ **Objective:** To assess the efficacy of control measures in decreasing nosocomial transmission of multidrug-resistant tuberculosis.

■ **Design:** Retrospective cohort study.

■ **Setting:** A teaching hospital in New York City.

■ **Population:** 40 patients hospitalized with multidrug-resistant tuberculosis (case-patients) and health care workers receiving tuberculin skin testing.

■ **Interventions:** Centers for Disease Control and Prevention (CDC) 1990 guidelines for preventing transmission of tuberculosis, including 1) prompt isolation and treatment of patients with tuberculosis; 2) rapid diagnostic techniques for processing *Mycobacterium tuberculosis* specimens; 3) negative-pressure isolation rooms; and 4) molded surgical masks for health care workers.

■ **Measurements:** Proportion of case-patients with nosocomially acquired tuberculosis and rate of tuberculin skin test conversion among health care workers before and after implementation of control measures.

■ **Results:** The proportion of patients with multidrug-resistant strains of *M. tuberculosis* decreased after the interventions (10 of 70 [14%] compared with 30 of 95 [32%] patients before the intervention; relative risk [RR], 0.5; 95% CI, 0.2 to 0.9). Before onset of multidrug-resistant tuberculosis, case-patients in the intervention period were as likely to be hospitalized on high-risk wards containing patients with tuberculosis (4 of 10 compared with 17 of 30 patients; RR, 0.7; $P = 0.5$) but were less likely to be exposed to another case-patient with tuberculosis (1 of 10 compared with 20 of 30 patients; RR, 0.2; $P = 0.003$). Tuberculin skin test conversion rates for health care workers assigned to wards housing patients with tuberculosis were lower in the intervention period than in the preintervention period (4 of 78 [5%] compared with 15 of 90 [17%] conversions; $P = 0.02$), decreasing to levels observed for workers assigned to other wards (4 of 78 [5%] compared with 9 of 228 [4%] conversions; $P = 0.7$).

■ **Conclusions:** Implementing control measures reduced nosocomial transmission of multidrug-resistant strains to patients and health care workers.

Nosocomial transmission of *Mycobacterium tuberculosis*, particularly transmission of multidrug-resistant strains, to patients and health care workers is a major public health problem (1–12). From 1990 through 1992, the Centers for Disease Control and Prevention (CDC) investigated eight outbreaks of multidrug-resistant tuberculosis in U.S. hospitals (1–6; CDC, unpublished data). More than 300 patients with multidrug-resistant tuberculosis were identified during these investigations; most (87%) were infected with human immunodeficiency virus (HIV). Their clinical course was characterized by rapid progression from infection to active tuberculosis and their mortality rate was high (9). Additionally, more than 100 health care workers at hospitals where outbreaks of multidrug-resistant tuberculosis had occurred had conversion of their tuberculin skin tests, suggesting recently acquired *M. tuberculosis* infection. At least 17 of these newly infected health care workers developed active multidrug-resistant *M. tuberculosis*, and at least 7 of them died with multidrug-resistant tuberculosis (10).

Because of the explosive and fatal nature of these recent nosocomial outbreaks of multidrug-resistant tuberculosis, questions have been raised about the most effective interventions and control measures necessary to prevent institutional transmission of tuberculosis (13–15). We evaluated the efficacy of control measures for decreasing the transmission of these multidrug-resistant *M. tuberculosis* strains in one of the hospitals that had had an outbreak.

Methods

In May 1991, we investigated an outbreak of multidrug-resistant tuberculosis at Cabrini Medical Center, a teaching hospital in New York City. In that investigation, epidemiologic and laboratory data showed the occurrence of nosocomial transmission of multidrug-resistant tuberculosis to patients and health care workers (5). Risk factors for acquisition of multidrug-resistant tuberculosis by patients included age, HIV seropositivity, and hospital admission to Cabrini Medical Center within 7 months before onset of multidrug-resistant tuberculosis. Additionally, health care workers assigned to the medical or HIV wards (primary wards housing patients with tuberculosis) were identified as being at increased risk for tuberculin skin test conversion. Conditions facilitating tuberculosis transmission included delayed identification, isolation, or treatment of patients with infectious tuberculosis; lapses in tuberculosis isolation practices; and inadequate isolation facilities for patients with tuberculosis. In response to the outbreak, control measures similar to those recommended in the CDC's 1990 tuberculosis guidelines were instituted to prevent further nosocomial transmission of tuberculosis (16).

Control Measures

Numerous measures were introduced to decrease transmission of multidrug-resistant tuberculosis, including source controls, en-

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Table 1. Infection Control Measures*

Control Measures	Preintervention Period	Intervention Period
Source control		
Isolation or treatment practices, %		
Acid-fast bacilli isolation on admission	40	90†
Receiving adequate therapy	43	90†
Laboratory diagnostics		
Duration		
Acid-fast bacilli smears, h	NA	4 to 8
Species identification, median (range), wk	9 (2 to 16)	2 (1 to 5)
Drug susceptibility, median (range), wk	6 (3 to 15)	3 (0 to 7)
Environmental measures		
Ventilation		
Acid-fast bacilli rooms with negative pressure, n/n (%)	0/10 (0)	16/27 (67)†
Chambers for cough-inducing procedures‡	No	Yes
Respiratory protection for health care workers	Nonmolded surgical masks	Molded surgical masks§

* NA = not available

† $P \leq 0.01$ when compared with preintervention period.

‡ Cough-inducing procedures = sputum induction or aerosolized pentamidine administration.

§ 3M 1800+ Aseptex, 3M Inc., St. Paul, Minnesota.

Environmental controls, and respiratory protection for health care workers (Table 1). Source control measures included improved isolation precautions and expanded treatment regimens for patients with suspected or confirmed tuberculosis and included routine use of acid-fast bacilli smears to determine length of isolation and to establish treatment efficacy. To expedite the identification of patients with infectious tuberculosis and the determination of the antimicrobial susceptibility of *M. tuberculosis* isolates, laboratory procedures were also modified. Thus, personnel and workday hours devoted to processing of mycobacterial isolates were expanded; a hospital-wide computerized database of patients with tuberculosis was developed; a gene probe was introduced; and the reporting of acid-fast bacilli smear results to requesting physicians was standardized.

Environmental modifications included installing exhaust fans in isolation rooms to increase the number of acid-fast bacilli isolation rooms with negative pressure and included using portable Aeroguard (HR Incorporated, Bellevue, Washington) chambers to do cough-inducing procedures, such as sputum induction or aerosolized pentamidine administration. Finally, to further decrease the risk for occupational acquisition of tuberculosis, the respiratory protection worn by health care workers was changed from nonmolded to molded surgical masks (3M 1800+ Aseptex, 3M Incorporated, St. Paul, Minnesota).

To assess compliance with these control measures, we examined the hospital's isolation facilities, reviewed patient charts for documentation of initiation and discontinuation of acid-fast bacilli isolation precautions, interviewed infection control and laboratory personnel, observed isolation practices on hospital wards containing patients with tuberculosis, and evaluated the ventilation system in acid-fast bacilli isolation rooms by testing air-flow direction using smoke tubes.

Epidemiologic Studies

A case-patient was defined as any Cabrini Medical Center patient whose *M. tuberculosis* isolate was resistant to at least isoniazid and rifampin and as any patient whose clinical course was consistent with active tuberculosis during the study period (1 January 1990 to 11 August 1992). Case-patients and all other patients with tuberculosis were identified by reviewing Cabrini Medical Center laboratory and infection control records during the study period. Medical records of all potential case-patients were reviewed to verify a clinical course consistent with tuberculosis.

To determine whether a decrease had occurred in the incidence of multidrug-resistant tuberculosis after the institution of control measures, we compared the proportion of patients with tuberculosis who had multidrug-resistant strains before (preintervention period) and after (intervention period) the implementation of control measures. The preintervention period (January 1990 to June 1991) was defined as the time from the onset of the

outbreak until the formal institution of recommended control measures; the intervention period (July 1991 to 11 August 1992) was defined as the time during and after the institution of recommended control measures until our follow-up study.

Patient-to-Patient Transmission

To investigate possible patient-to-patient transmission of multidrug-resistant tuberculosis, we evaluated case-patient medical records to determine if case-patients had been hospitalized at Cabrini Medical Center within 7 months before onset of tuberculosis. For those case-patients who had been previously hospitalized, we determined whether they had been hospitalized on the same ward at the same time or whether they had a documented nosocomial exposure to another patient with culture-confirmed multidrug-resistant tuberculosis during a previous hospitalization. Data collected included age, sex, race, HIV serologic status, previous opportunistic infections, dates and results of acid-fast bacilli smears and mycobacterial cultures, *M. tuberculosis* antimicrobial susceptibilities, dates of admission and discharge, hospital room assignments, dates of isolation for tuberculosis, nursing documentation of proper application of isolation precautions, antituberculous medications prescribed, clinical course, and outcome.

Patient-to-Health Care Worker Transmission

To evaluate whether the risk for transmission of multidrug-resistant tuberculosis from patients to health care workers had been reduced, we compared conversion rates of tuberculin skin tests in health care workers during the preintervention and intervention periods. During both periods, the tuberculin skin testing program at Cabrini Medical Center required annual testing of all hospital employees and additional testing of health care workers after a known tuberculosis exposure. A tuberculin skin test conversion was defined as induration of 10 mm or more to purified protein derivative in a Cabrini Medical Center employee with a documented tuberculin skin test result that was negative within the previous 24 months. Employees without negative skin test results at baseline were excluded from our analyses. Conversion rates were compared by period, by job category (frequent direct patient contact compared with infrequent or no direct patient contact), and by ward assignment (primary wards housing patients with tuberculosis [medical and HIV wards] compared with wards infrequently housing patients with tuberculosis).

Health care workers with direct patient contact included physicians, nurses, nursing aides, respiratory therapists, and social workers; workers without direct patient contact included administrative staff, clerks, dietitians, housekeepers, engineers, and laboratory personnel. Health care workers with tuberculin skin-test conversions or active tuberculosis or both were identified by reviewing employee health and infection control records during

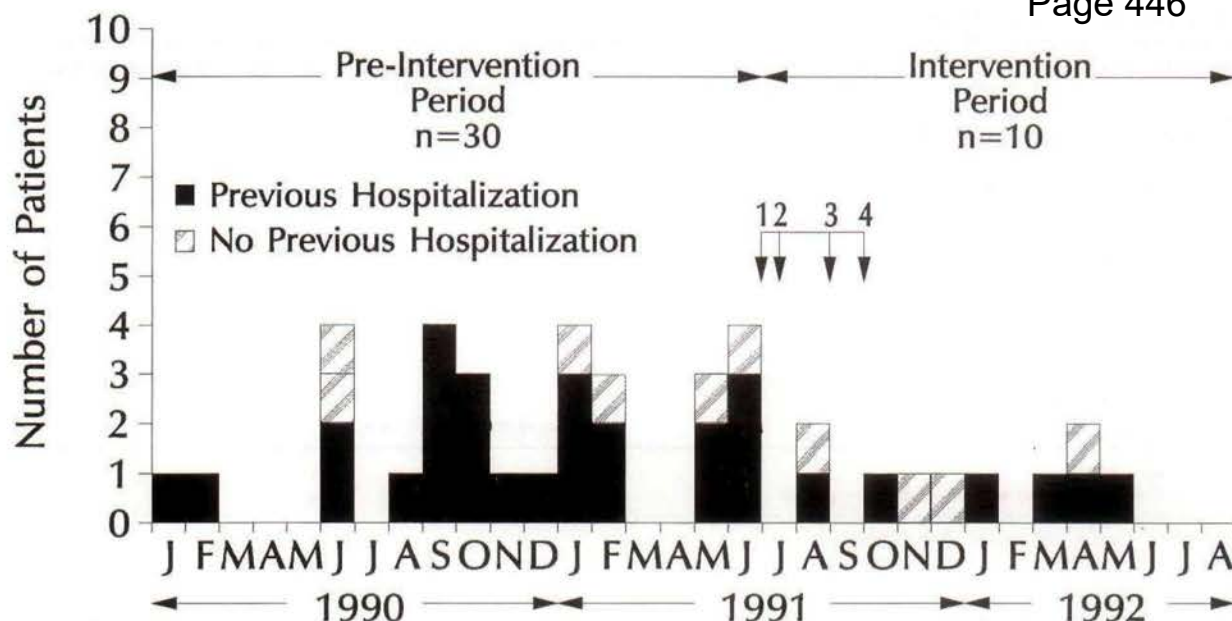


Figure 1. Distribution of patients with multidrug-resistant tuberculosis by date of first positive culture. The numbers 1 to 4 with arrows indicate the dates of introduction of 1) improved patient isolation, expanded criteria for isolation of patients (June to July 1991), and molded surgical masks (July 1991); 2) improved laboratory services (15 July 1991); 3) acid-fast bacilli isolation rooms on wards with negative pressure systems (September 1991); and 4) negative-pressure chambers for aerosolized pentamidine administration and sputum induction (October 1991). The months are abbreviated using the first letter of the month.

the study period. Data collected included age, sex, race, history of bacille Calmette-Guérin (BCG) vaccination or tuberculosis exposure or both, country of origin, job title, duration of employment, and work location at time of tuberculin skin-test conversion.

Statistical Analysis

Data were collected on standardized forms, entered into Epi Info Version 5.01b software, and analyzed (17). Categorical variables were compared by the Fisher exact or chi-square test, and relative risks (RRs) were calculated. Continuous variables were compared by the Student *t*-test or the Kruskal-Wallis rank-sum test.

Results

Case-Patients

Forty patients met the case definition (Figure 1). Case-patients in the preintervention and intervention periods were similar in age, race, sex, HIV serologic status, and diagnosis of AIDS (data not shown). However, case-patient mortality decreased in the intervention compared with the preintervention period (4 of 10 [40%] compared with 25 of 30 [83%] deaths; $P = 0.01$). Further, in the preintervention period, 20 of 25 (80%) case-patient deaths were attributed to tuberculosis, whereas in the intervention period, only 1 of 4 deaths was attributed to tuberculosis (the 3 remaining case-patient deaths occurring in the intervention period were attributed to complications of AIDS [$n = 2$] and to suicide [$n = 1$]).

The proportion of patients with multidrug-resistant *M. tuberculosis* infection decreased in the intervention compared with the preintervention period (10 of 70 [14%] compared with 30 of 95 [32%] patients; RR, 0.5 [95% CI, 0.2 to 0.9; $P = 0.02$]). Because hospitalization at Cabrini Medical Center within 7 months before onset of tuber-

culosis, particularly on the HIV ward, was identified as a risk factor for development of multidrug-resistant tuberculosis, we next examined the location and duration of hospitalization for case-patients before onset of tuberculosis. A similar number of case-patients in the intervention and preintervention periods had a history of previous hospitalization at Cabrini Medical Center (6 of 10 compared with 24 of 30 patients; RR, 0.8; $P = 0.2$) (Figure 1). Further, case-patients in the intervention and preintervention periods were equally likely to have been admitted to the HIV ward (4 of 10 compared with 17 of 30 patients; RR, 0.7; $P = 0.5$) and were hospitalized for a similar number of days (median, 5 compared with 15 days; $P = 0.2$) before onset of tuberculosis. However, case-patients diagnosed during the intervention period were less likely than those diagnosed during the preintervention period to have had an identified nosocomial exposure to another case-patient during a previous hospitalization (1 of 10 compared with 20 of 30 patients; RR, 0.2; $P = 0.003$).

The one identified exposure of a case-patient to a patient with multidrug-resistant tuberculosis during the intervention period occurred approximately 6 months after the implementation of control measures. The putative source-patient was not isolated at the time of admission, and when finally isolated, the patient was intermittently noncompliant with isolation precautions (walking in hallways without a mask). Of the remaining 5 case-patients in the intervention period with previous hospitalizations, 1 was the partner and housemate of a case-patient, 1 had a history of tuberculosis and poor compliance with medications, 1 had a prolonged hospitalization that included preintervention and intervention periods and had been hospitalized on the same ward as a case-patient during

the preintervention segment of the hospitalization, and 2 had no identified source of exposure.

Health Care Workers

Of 1567 tuberculin skin tests administered to health care workers with previously negative skin test results, we identified 48 (3.0%) skin-test conversions. Overall, tuberculin skin-test conversion rates during the preintervention and intervention periods were similar (26 of 840 [3.1%] compared with 22 of 727 [3.0%] conversions; $P=0.9$).

Health care workers who had tuberculin skin-test conversions had a median age of 34 years (range, 23 to 58 years), 34 (71%) were women, 12 (25%) were black, and approximately half (56%) were born in the United States. Only 4 (8%) were known to have received BCG vaccination; none had a known history of tuberculosis. Before tuberculin skin test conversion, these health care workers had been in their current positions a median of 5.0 years (range, 0 to 21 years), and most workers (36 of 48 [75%]) had direct patient care responsibilities.

Health care workers with tuberculin skin-test conversions during the preintervention or intervention periods were similar in age, sex, race, and BCG vaccination status. However, health care workers with tuberculin skin test conversions during the preintervention period were more likely than those with conversions during the intervention period to be assigned to the medical or HIV wards (primary wards housing patients with tuberculosis) (Table 2).

Because overall conversion rates for tuberculin skin tests were similar for the two time periods, we next examined conversion rates by job category and ward location. During the preintervention period, health care workers with direct patient contact had higher skin-test conversion rates than did health care workers without direct patient contact (22 of 342 [6.4%] compared with 4

Table 2. Characteristics of Health Care Workers with Tuberculin Skin Test Conversions*

Characteristic	Preintervention Period (n = 26)	Intervention Period (n = 22)	P Value
Median age, y	34	34.5	0.9
Female sex, n (%)	19 (73)	15 (68)	0.7
Race or ethnicity, n (%)			
Black	8 (21)	4 (18)	0.5
White	7 (27)	5 (23)	
Hispanic	8 (31)	7 (32)	
Asian	3 (11)	6 (27)	
History of BCG vaccination, n(%)	3 (11)	1 (4)	0.6
Assignment to medical or HIV wards, n (%)	15 (58)	4 (18)	0.006

* BCG = bacille Calmette-Guérin; HIV = human immunodeficiency virus.

of 409 [1.0%] conversions; RR, 6.6; $P < 0.001$). During the intervention period, skin test conversion rates among health care workers with and without direct patient contact were similar (14 of 296 [4.7%] compared with 8 of 354 [2.3%]; RR, 2.1; $P=0.08$) (Figure 2).

When we compared tuberculin skin-test conversion rates for specific wards, a change in the risk for conversion also occurred between the preintervention and intervention periods (Table 3). Before the institution of control measures, conversion rates in health care workers assigned to primary wards housing patients with tuberculosis were higher than those in workers assigned to other wards; however, in the intervention period, conversion rates among workers assigned to wards housing patients with tuberculosis decreased to levels seen in workers assigned to other hospital wards. In contrast, conversion rates for tuberculin skin tests among health care workers

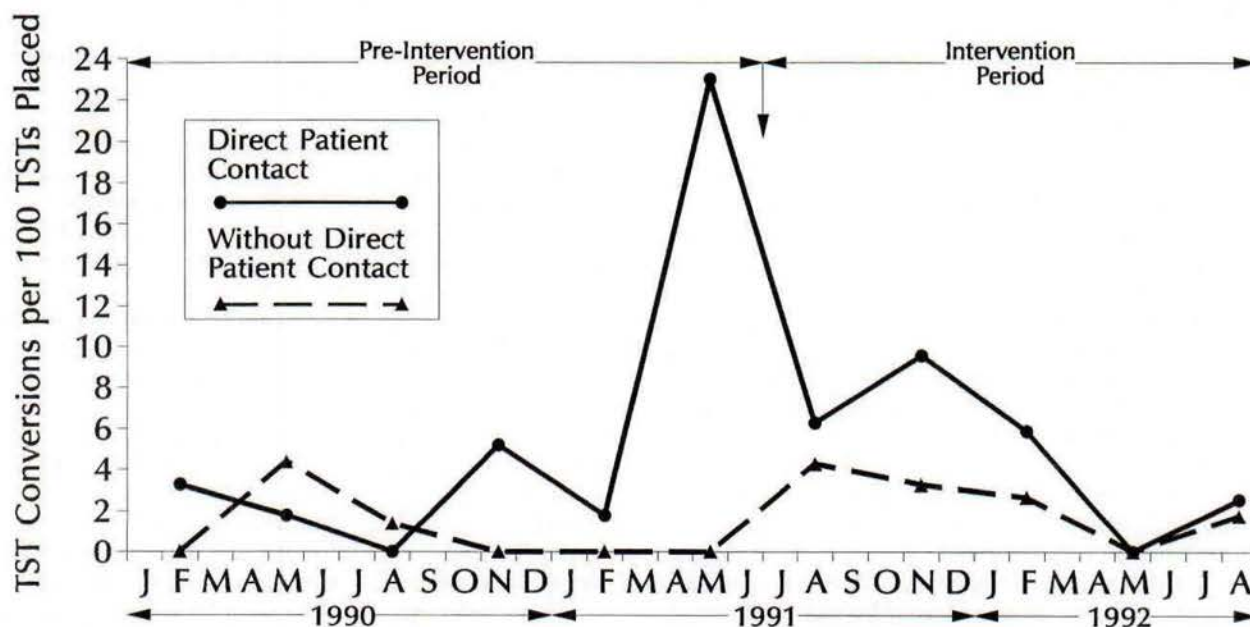


Figure 2. Tuberculin skin test conversion rates in health care workers with and without direct patient contact. Health care workers with direct patient contact included physicians, nurses, nurses' aides, respiratory therapists, and social workers. Health care workers without direct patient contact included administrative staff, clerks, dieticians, housekeeping personnel, engineers, and laboratory personnel. TST = tuberculin skin test.

Table 3. Ward-specific Tuberculin Skin Test Conversion Rates in Health Care Workers*

Variable	Preintervention Period	Intervention Period	Relative Risk	P Value
Primary wards housing patients with tuberculosis (medical and HIV), n/n (%)	15/90 (16.7)	4/78 (5.1)	3.2	0.02
Other wards, n/n (%)	7/254 (2.8)	9/228 (4.0)	0.7	0.5
Relative risk	6.0	1.3		
P value	<0.001	0.7		

* HIV = human immunodeficiency virus.

assigned to other wards infrequently housing patients with tuberculosis were similar during the two time periods (Table 3).

Active tuberculosis developed in two health care workers. The first had cutaneous anergy and contracted active tuberculosis after an exposure during the preintervention period. This health care worker (a housekeeper) was HIV seropositive, had an *M. tuberculosis* isolate that matched the restriction fragment length polymorphism pattern for the hospital's epidemic strain of tuberculosis, was treated with a multidrug regimen for tuberculosis, and died of tuberculosis. The second health care worker had a documented skin-test conversion and contracted active tuberculosis during the intervention period. This health care worker, a physician with unknown HIV serologic status, had an upper lobe infiltrate on chest radiograph; no *M. tuberculosis* isolate was available. This health care worker was treated with isoniazid, rifampin, and pyrazinamide and survived.

Discussion

Recent reports of outbreaks of multidrug-resistant tuberculosis have documented the risk for nosocomial transmission of multidrug-resistant tuberculosis to patients and workers in medical facilities (1–10). At one hospital that had had an outbreak, Cabrini Medical Center, transmission of multidrug-resistant tuberculosis occurred at a time when the CDC guidelines were not being fully implemented (5). In response to the outbreak, various control measures were instituted to decrease transmission of tuberculosis.

Our data suggest that after the introduction of these control measures, the risk for nosocomial transmission of multidrug-resistant tuberculosis from patient to patient decreased. Decreases occurred in the proportion of patients with tuberculosis who had multidrug-resistant *M. tuberculosis* isolates and in the number of case-patients who might have acquired their disease nosocomially despite the similar placement of case-patients on wards housing patients with tuberculosis and despite a similar duration of hospitalization before onset of tuberculosis. At Cabrini Medical Center, the implementation of these control measures was supported by expanded staffing of the mycobacteriology laboratory and by the introduction of a standardized reporting system. Moreover, modifications such as rapid identification and treatment of case-patients with an expanded drug regimen were probably responsible for the reduction in mortality associated with multidrug-resistant tuberculosis seen in the intervention period, despite the similar demographic characteristics of

case-patients and the similar severity of underlying disease.

Our results also suggest that the introduced control measures were effective in reducing transmission of multidrug-resistant tuberculosis from patients to health care workers. After control measures were introduced, health care workers with and without frequent direct patient contact had similar rates of tuberculin skin-test conversion. More importantly, the skin-test conversion rate among workers assigned to primary wards housing patients with tuberculosis decreased by 70%, returning to a rate similar to that of health care workers assigned to other hospital wards. The observed decreases in skin-test conversion rates could not be attributed to other differences (for example, age, race, or BCG vaccination status) between workers, factors that may confound conversion rates (18, 19). These data suggest that the combination of source and environmental controls together with the use of molded surgical masks were all effective in reducing tuberculin skin-test conversion rates among health care workers at this hospital. At present, the efficacy of these molded surgical masks is unknown, and the contribution of their use to the reduction in risk for tuberculin skin-test conversion remains unclear. Recently, however, other models of molded surgical masks have been shown to filter mycobacterial organisms with more than 95% efficiency (20).

Tuberculin skin-testing programs serve two important functions in health care settings: 1) monitoring tuberculosis transmission among health care workers and 2) targeting health care workers who need prophylactic therapy or treatment of active tuberculosis. Therefore, all workers who might have had contact with infectious patients who have tuberculosis should be included in an annual tuberculin skin testing program. As our data show, hospital-wide conversion rates for tuberculin skin tests may be insensitive in determining tuberculosis transmission within an institution. Instead, calculation of job- and ward-specific (for example, nursing and bronchoscopy personnel, HIV ward) conversion rates for tuberculin skin tests may be a superior means of identifying high-risk groups for whom more frequent skin testing and adequate respiratory protection should be targeted.

Although our findings strongly suggest that nosocomial transmission was reduced as a result of the introduced control measures, our study had inherent limitations. First, results of acid-fast bacilli smears were not available throughout the entire study period, making it difficult to systematically assess the infectiousness of case-patients on the basis of smear-positivity data. Second, we used the tuberculin skin test, not the person, as the unit of analysis

for our evaluation of skin-test data because health care worker-specific data for all tests were not available for analysis. However, because tuberculin skin testing was done annually and because each period (preintervention and intervention) was between 12 and 18 months in duration, the test unit is probably also a good approximation of the number of health care workers tested. We were also unable to assess potential community acquisition of tuberculosis among health care workers and how such transmission may have affected conversion rates of tuberculin skin tests. However, no clustering of conversions was noted by residence zip code and, in the absence of multiple, concurrent community outbreaks of multidrug-resistant tuberculosis, the rate of community acquisition should have been constant. Therefore, it is unlikely that community transmission of tuberculosis substantially affected the differences seen in skin-test conversion rates during the two periods. Third, it could not be determined with absolute accuracy whether some skin-test conversions occurred in the preintervention or the intervention period unless an occupational exposure was identified. However, the substantial reduction in skin test conversion rates among health care workers after the introduction of control measures provides strong evidence for a decreased risk for occupationally acquired tuberculosis infection. Fourth, because the implementation of control measures was associated with a decrease in the number of case-patients, the effectiveness of these control measures in the presence of a high concentration of infectious patients with multidrug-resistant tuberculosis during a prolonged period could not be fully evaluated. Finally, because several interventions were instituted simultaneously or consecutively, we were unable to determine the independent importance of any single control measure in decreasing nosocomial transmission of multidrug-resistant tuberculosis.

Nosocomial outbreaks of multidrug-resistant tuberculosis have been associated with significant morbidity and mortality among patients and health care workers (1-8). Our data show that full implementation of a multifaceted approach, similar to that described in the CDC 1990 guidelines (16), can effectively reduce the risk for transmission of multidrug-resistant tuberculosis in health care settings and can reduce morbidity and mortality in affected patients. To reduce the risk for nosocomial transmission of tuberculosis to patients and health care workers, similar infection control programs should be implemented at all U.S. hospitals caring for patients with tuberculosis.

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References

- Centers for Disease Control. Nosocomial transmission of multidrug-resistant tuberculosis to health-care workers and HIV-infected patients in an urban hospital-Florida. MMWR Morb Mortal Wkly Rep. 1990; 39:718-22.
- Centers for Disease Control. Nosocomial transmission of multidrug-resistant tuberculosis among HIV-infected persons-Florida and New York, 1988-1991. MMWR Morb Mortal Wkly Rep. 1991;40:585-91.
- Beck-Sague C, Dooley SW, Hutton MD, Otten J, Breeden A, Crawford JT, et al. Hospital outbreak of multidrug-resistant *Mycobacterium tuberculosis* infections. Factors in transmission to staff and HIV-infected patients. JAMA. 1992;268:1280-6.
- Edlin BR, Tokars JI, Grieco MH, Crawford JT, Williams J, Sordillo EM, et al. An outbreak of multidrug-resistant tuberculosis among hospitalized patients with the acquired immunodeficiency syndrome. N Engl J Med. 1992;326:1514-21.
- Pearson ML, Jereb JA, Frieden TR, Crawford JT, Davis BJ, Dooley SW, et al. Nosocomial transmission of multidrug-resistant *Mycobacterium tuberculosis*. A risk to patients and health care workers. Ann Intern Med. 1992;117:191-6.
- Coronado VG, Beck-Sague CM, Hutton MD, Davis BJ, Nicholas P, Villareal C, et al. Transmission of multidrug-resistant *Mycobacterium tuberculosis* among persons with human immunodeficiency virus infection in an urban hospital: epidemiologic and restriction fragment length polymorphism analysis. J Infect Dis. 1993;168:1052-5.
- Fischi MA, Uttamchandani RB, Daikos GL, Poblete RB, Moreno JN, Reyes RR, et al. An outbreak of tuberculosis caused by multiple-drug-resistant tubercle bacilli among patients with HIV infection. Ann Intern Med. 1992;117:177-83.
- Pitchenik AE, Burr J, Laufer M, Miller G, Cacciatore R, Bigler WJ, et al. Outbreaks of drug-resistant tuberculosis at AIDS centre [Letter]. Lancet. 1990;336:440-1.
- Dooley SW, Jarvis WR, Martone MJ, Snider DE Jr. Multidrug-resistant tuberculosis [Editorial]. Ann Intern Med. 1992;117:257-9.
- Valway SE, Pearson ML, Ikeda R, Edlin BR. HIV infected healthcare workers with multidrug resistant tuberculosis (MDR-TB), 1990-1992. In: Programs and Abstracts of the Thirty-third Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC). New Orleans, Louisiana; 1993:231.
- Haley CE, McDonald RC, Rossi L, Jones WD Jr, Haley RW, Luby JP. Tuberculosis epidemic among hospital personnel. Infect Control Hosp Epidemiol. 1989;10:204-10.
- Ramirez JA, Anderson P, Herp S, Raff MJ. Increased rate of tuberculin skin test conversion among workers at a university hospital. Infect Control Hosp Epidemiol. 1992;13:579-81.
- Iseman MD. A leap of faith. What can we do to curtail intrahospital transmission of tuberculosis? Ann Intern Med. 1992;117:251-3.
- Nolan CM. Human immunodeficiency syndrome-associated tuberculosis: a review with an emphasis on infection control issues. Am J Infect Control. 1992;20:30-4.
- Hutton MD, Polder JA. Guidelines for preventing tuberculosis transmission in health care settings: what's new? Am J Infect Control. 1992;20:24-6.
- Dooley SW Jr, Castro KG, Hutton MD, Mullan RJ, Polder JA, Snider DE Jr. Guidelines for preventing the transmission of tuberculosis in health-care settings, with special focus on HIV-related issues. MMWR Morb Mortal Wkly Rep. 1990;39(RR-17):1-29.
- Dean AG, Dean JA, Burton JH, Dicker RC. Epi Info, Version 5.01b. A word processing, database and statistics program for epidemiology on microcomputers. Atlanta: Centers for Disease Control; 1991.
- Pugliese G. Screening for tuberculosis infection: an update. Am J Infect Control. 1992;20:37-40.
- Snider DE Jr. Bacille Calmette-Guerin vaccinations and tuberculin skin tests. JAMA. 1985;253:3438-9.
- Chen SK, Vesley D, Brosseau LM, Vincent JH. Evaluation of single-use masks and respirators for protection of health care workers against mycobacterial aerosols. Am J Infect Control. 1994;22:65-74.

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MAJOR ARTICLE

The Influence of High-Efficiency Particulate Air Filtration on Mortality and Fungal Infection among Highly Immunosuppressed Patients: A Systematic Review

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Background. Patients with hematological malignancies who are treated with intensive chemotherapy or who receive bone marrow transplants are exposed to an increased risk of developing nosocomial fungal infections. The aim of this systematic review was to compare the effectiveness of high-efficiency particulate air (HEPA) filtration with that of non-HEPA filtration in decreasing the rates of mortality and fungal infection among patients with diagnosed hematological malignancies and neutropenia or among patients with bone marrow transplants.

Methods. Articles identified in a Medline search, guidelines, and books, as well as the bibliographies of review articles, monographs, and the articles identified by Medline, were researched. Randomized trials and observational studies comparing HEPA filtration with conventional room ventilation were selected for inclusion in the present review.

Results. Sixteen trials (9 with death as an outcome and 10 with fungal infection as an outcome) that compared HEPA filtration with non-HEPA filtration were selected for meta-analyses. We discovered no significant advantages of HEPA filtration in the prevention of death among patients with hematological malignancies with severe neutropenia in randomized controlled trials (RCTs; relative risk [RR], 0.86 [95% confidence interval {CI}, 0.65–1.14]) and in studies of a lower standard (non-RCTs; RR, 0.87 [95% CI, 0.60–1.25]).

Conclusions. The placement in protected areas of patients with hematological malignancies with severe neutropenia or patients with bone marrow transplants appears to be beneficial, but no definitive conclusion could be drawn from the data available.

Fungal infections are a major complication of severe neutropenia brought on by the treatment of hematological malignancies [1], and they are associated with high mortality rates [2, 3]. High environmental *Aspergillus* spore counts constitute a major risk for infection after inhalation of the spores [4, 5]. Therefore, patients with acute lymphocytic leukemia, acute nonlymphocytic leukemia, aplastic anemia, or cancer who are being

treated with chemotherapy or are receiving bone marrow transplants (BMTs), thereby developing severe neutropenia, are often placed in rooms with high-efficiency particulate air (HEPA) filtration, with or without laminar airflow (LAF) [6]. HEPA filtration leads to a significant decrease in the number of microorganisms in the air, whereas LAF increases air change in the cleanest zone, which is why both measures are frequently combined. Krüger et al. [6], in a survey of various practices of infectious disease prevention and management during hematopoietic stem cell transplantation, found that only 16.5% of the patients receiving autologous BMTs and 5.3% of the patients receiving allogeneic BMTs did not receive special accommodation.

To be highly protected, patients are confined to a room, and persons who enter the room have to wear masks and gowns. This may be why there were some studies that reported a high frequency of mental dis-

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turbance among patients with BMTs during the course of their isolation [7, 8].

In 4 guidelines from the Centers for Disease Control and Prevention (CDC), the installation of HEPA filters according to category BIII or IB is recommended [9–12]. However, the guidelines refer to only a small number of studies and, in part, only to outbreaks. There are more studies that examine the influence of protective environment on fungal infection and mortality than are mentioned in the recommendations.

There has been a trend toward relaxing the degree of patient isolation, in the absence of definitive data to support its use [13]. Because the protective environment regimen is expensive and is a burden on patients, and because there is still no systematic review of HEPA filtration available, we conducted a systematic review to investigate whether HEPA filtration reduces the risk of death and fungal infection for patients with hematological malignancies who have severe neutropenia or for patients with bone marrow transplants.

METHODS

Literature search. The type of literature that we selected for the present review included literature on randomized trials, cohort studies, case-control studies, and nonrandomized controlled trials (non-RCTs). In these trials and studies, the effectiveness of HEPA filtration, with or without LAF, was compared with that of standard ventilation of patient hospital rooms with no air filtration, with regard to identification of decreasing rates of death and fungal infection among patients with hematological malignancies who have neutropenia due to their illness or its treatment (i.e., chemotherapy or BMTs [no stem cell transplantation]) or among patients without cancer who have BMTs (no stem cell transplantation) for other reasons. Every study included both an intervention group of patients who were treated in rooms with HEPA filtration with or without LAF and a control group of patients who were treated in patient hospital rooms with standard ventilation. Each study had to have at least 1 type of outcome enabling measurement of mortality or fungal infection.

A Medline search of the literature published from 1 January 1966 through 30 June 2005 was performed. One or more of the following search terms were used: “LAF,” “laminar airflow,” “HEPA,” “high-efficiency particulate,” and “protect* environment” (where “*” denoted a wild card). The term or terms were then combined with ≥ 1 of the following search terms: “BMT,” “marrow transplant*” (where “*” denoted a wild card), and “chemotherapy.” In addition, we searched for guidelines [9–12], related sections of books [14–16], and bibliographies of review articles, monographs, and articles identified in our initial search of the literature. We also established personal contact with experts in the field.

Literature selection. All the references that were identified

were initially selected on the basis of their titles and/or abstracts. Full reports from potentially relevant publications were obtained and checked for eligibility for inclusion in the review. Decisions about whether to include trials were based on the completeness of the trials. Only randomized controlled trials (RCTs), non-RCTs, cohort studies, and case-control studies were considered. Because of differences in study design, RCTs were analyzed separately, and the results of observational studies and non-RCTs were dealt with in other analyses [17, 18]. In some of the studies, additional prevention measures were investigated, because these studies were 3- and 4-arm studies. Studies were only considered for inclusion if the HEPA (intervention) and non-HEPA (control) groups had similar additional intervention measures.

On the basis of outcome and study design, the studies that were identified were categorized into 4 groups, as follows: (1) RCTs with death due to all causes as an outcome; (2) RCTs with fungal infection (invasive aspergillosis and non-*Candida* fungal infection) as an outcome; (3) non-RCTs with death due to all causes as an outcome; and (4) non-RCTs with fungal infection as an outcome. Because of the 2 different outcomes assessed, it was decided to perform 2 meta-analyses for each study design. If a study assessed both outcomes, then it was included in 2 meta-analyses.

Data collection and analysis. Two investigators assessed the methodology used in each trial individually and then extracted the information required. Differences in the data extracted were resolved together by the investigators. From each study, we extracted source details (authors, country and city where the study was performed, and year of publication), study information (design and outcome[s] assessed), patient information (number of patients evaluated, diagnosis received, therapy received, and age), intervention (type of protected area and additional intervention used), duration of follow-up, time in the protected area, and outcome (fungal infection and/or death).

The random-effects method was used to derive a summary estimate, as implemented in Stata software (version 7.0; Stata) [19]. Protective effects (with 95% confidence intervals [CIs] and heterogeneity testing) were calculated.

RESULTS

Literature search. Figure 1 shows the route of identification of relevant articles. Of a preliminary total of 923 articles identified by a Medline search and an additional 25 articles identified by a hand search, only 64 were retained after the titles and abstracts were read, and then only 16 were retained after the full articles were evaluated. Although the 923 articles were identified through an extensive search strategy, the majority of articles focused on topics other than air filtration and patients with neutropenia. The 48 studies that were excluded were mainly

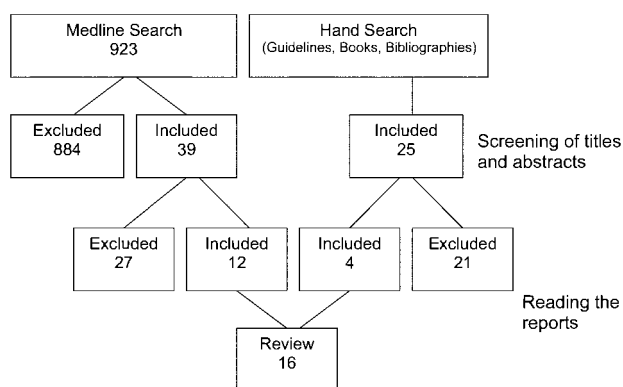


Figure 1. Route of references collected from Medline, guidelines, books, and bibliographies

nonsystematic reviews, descriptions of outbreaks, and studies that dealt with the problem on a technical level. Appropriate numerical data or figures were missing from some studies.

An advantage for the use of air filtration was suggested by one study that did address our question and criteria but did not contain valid data [20]. The other study of a similar nature suggested no advantage [21].

There are 2 additional important reasons for the exclusion of preselected articles. First, some studies that examine the influence of air filtration on fungal infection and death among immunosuppressed patients contain contradictions between the text and a figure [20] or a figure and a table (see [21] for a contradiction regarding death as an outcome). Because the studies in question were older, we decided not to ask their authors for clarification, and we therefore did not consider the studies for inclusion in the review. Second, 2 research centers (Seattle and Houston) in the United States were the main sources of the discussion of the use of air filtration for immunosuppressed patients in the 1970s and 1980s. There were 5 studies (31%) from Seattle alone in our meta-analyses. However, because there were patients who were included in >1 study, one study was of no use in the meta-analysis (i.e., the patients in the study of Freireich et al. [22] were a subgroup of the patients in the study of Rodriguez et al. [23], and, therefore, the study of Freireich et al. [22] was excluded). Another study was only partially useful, because the patients who had aplastic anemia diagnosed in the study of Buckner et al. [24] were a subgroup of the patients in the study of Storb et al. [25].

Literature selection. Six RCTs [24–29] and 3 non-RCTs [23, 30, 31] were considered for 2 meta-analyses with death as the outcome. The meta-analyses included 774 and 231 patients, respectively. Four RCTs [21, 24, 27, 32] and 6 non-RCTs [23, 33–37] were suitable for 2 meta-analyses with fungal infection as the outcome; the meta-analyses included 238 and 759 patients, respectively. Three of the studies [23, 24, 27] included both death and fungal infection as outcomes.

Table 1, which presents data from RCTs, and table 2, which presents data from non-RCTs, provide an overview of the basic features of the included studies that were heterogeneous with regard to various parameters. The publication dates of the studies span 28 years (from 1973 to 2001). The participants in the trials were patients with different kinds of acute leukemia and aplastic anemia, as well as patients who had received an unspecified BMT. In the trials, patient treatment consisted of chemotherapy (6 trials [37.5%]) [21, 23, 26, 27, 32, 37] and allogeneic and autologous BMT (9 trials [56.3%]) [24, 25, 28–31, 33–35]. In one trial, patient treatment consisted of both chemotherapy and allogeneic and autologous BMT [36]. Follow-up duration and additional measures differed partially. Time in a protected area was mentioned in only 6 studies (37.5%) [21, 24, 25, 27, 32, 33]. In 5 of these 6 studies, the time in a protected area was 50 days; in the other study [32], this time was 29 days. One study investigated mainly children [31], whereas the other studies investigated mainly adults. In the study of Rhame et al. [34], the protected area was established through in-room HEPA units, and, in the study of Oren et al. [37], the protected area was established through the use of HEPA filtration without LAF. All other protected areas were provided with HEPA filtration with LAF. In no study was the sample size calculated.

In the study of Rodriguez et al. [23], patients were only randomized to a protected environment when a unit was available. If all the units were occupied, patients were treated in rooms without HEPA filtration. Because of this severe methodological flaw in randomization, this study was considered to be a non-RCT. Some of the patients included in the study of Navari et al. [33] were not randomized. This study was also counted as a non-RCT. Of the remaining 6 non-RCTs, 5 were cohort studies, and the study of Schmeiser et al. [30] was an interventional trial.

In some studies, only subgroups of patients were considered for the meta-analyses, because comparison of protected and nonprotected areas was possible only for the subgroups considered (table 1 and table 2). In the study of Yates et al. [26], information about death as an outcome in relation to a protected environment was available solely for 1 subgroup of the patients included. These data were used in the meta-analysis. In the study of Buckner et al. [24], which had death as an outcome, only patients with acute leukemia were considered for inclusion, because the more extensive study of Storb et al. [25] included patients with aplastic anemia.

Data analysis. Table 3 shows results of the single trials and the pooled relative risks (RRs) for studies with death as the outcome. The mortality rates in the 9 studies varied between 8% and 86%. Five of 9 studies suggested a decrease in the mortality rate. Four of 6 RCTs showed some advantage associated with the use of HEPA filtration with LAF (pooled RR, 0.86 [95% CI, 0.65–1.14]).

Table 1. Characteristics of 8 randomized controlled trials included in the meta-analyses.

Authors, year of publication [reference]	Location	Outcome	Clinical condition(s) of participants	Therapy received	Portion of participants considered ^a	Follow-up duration	Additional therapy received
Levine et al., 1973 [27]	Bethesda, MD	Fungal infection and death	Acute leukemia	Chemotherapy	Patients in 2 of 3 study arms	50 days	Topical or official antiseptics and antibiotics
Yates et al., 1973 [26]	Buffalo, NY	Death	Acute myeloid leukemia	Chemotherapy	A portion of the patients evaluated	Not mentioned	Partial gut sterilization
Schimpff et al., 1975 [21]	Baltimore, MD	Fungal infection	Acute myeloid leukemia	Chemotherapy	Patients in 2 of 3 study arms	120 days	Oral nonabsorbable antibiotics
Buckner et al., 1978 [24] ^b	Seattle, WA	Fungal infection and death	Aplastic anemia plus acute leukemia; acute leukemia only	BMT	For fungal infection as the outcome, all participants; for death as the outcome, a portion of the participants	6 months to 4 years	Oral nonabsorbable antibiotics ^c
Lohner et al., 1979 [32]	Brussels, Belgium	Fungal infection	Acute leukemia, agranulocytosis, lymphosarcoma	Chemotherapy	All	Not mentioned	Oral nonabsorbable antibiotics
Storb et al., 1983 [25]	Seattle, WA	Death	Aplastic anemia	BMT	All	16 months to 11 years	Oral nonabsorbable antibiotics ^c
Petersen et al., 1987 [29]	Seattle, WA	Death	All diseases that make BMT necessary	BMT	All	100 days	Prophylactic systemic antibiotics
Petersen et al., 1988 [28]	Seattle, WA	Death	All diseases that make BMT necessary	BMT	Patients in 2 of 4 study arms	30 days	Prophylactic systemic antibiotics or nonabsorbable antibiotics

NOTE. BMT, bone marrow transplantation.
^a For inclusion in the meta-analyses.
^b When death was the study outcome, we considered only patients with acute leukemia, because the other patients were included in the study of Storb et al. [25], which was published 5 years after the study of Buckner et al. [24].
^c Received only by patients in the intervention group.

Table 2. Characteristic of 8 nonrandomized controlled trials included in the meta-analyses.

Authors, year of publication [reference]	Location	Outcome	Clinical condition(s) of participants	Therapy received	Portion of study participants considered ^a	Follow-up duration	Additional therapy received
Rodriguez et al., 1978 [23] ^b	Houston, TX	Fungal infection and death	Acute leukemia	Chemotherapy	All	10 months to 4 years	Oral antibiotics and systemic antibiotics
Navari et al., 1984 [33] ^c	Seattle, WA	Fungal infection	Aplastic anemia	BMT	Patients in 2 of 3 study arms	100 days	None
Rhame et al., 1984 [34]	Minneapolis, MN	Fungal infection	All diseases that make BMT necessary	BMT	All	Not mentioned	Oral nonabsorbable antibiotics ^d
Sherertz et al., 1987 [35]	Gainesville, FL	Fungal infection	All diseases that make BMT necessary	BMT	All	>50 days	None
Schmeiser et al., 1988 [30] ^e	Ulm, Germany	Death	All diseases that make BMT necessary	BMT	All	Not mentioned	Total decontamination
Gamillscheg et al., 1991 [31]	Graz, Austria	Death	Aplastic and sideroblastic anemia; hematological and solid malignancies	BMT	All	10 months to 12 years	Total decontamination
Withington et al., 1998 [36]	Christchurch, New Zealand	Fungal infection	All diseases that make BMT necessary	BMT and chemotherapy	Patients from 2 of 3 study periods	Not mentioned	Prophylactic intranasal amphotericin (selective)
Oren et al., 2001 [37]	Haifa, Israel	Fungal infection	AML and ALL	Chemotherapy	Patients in 2 of 3 study arms from 1 of 3 periods	Not mentioned	None

NOTE. ALL, acute lymphatic leukemia; AML, acute myeloid leukemia; BMT, bone marrow transplantation.

^a For inclusion in the meta-analyses.

^b Patients were only randomized to be placed in a protected environment when a unit was available. If all units were occupied, patients were placed in hospital rooms with standard ventilation. Hence, this study was counted as a nonrandomized controlled trial.

^c Some of the patients who were included in the study were not randomized.

^d Received only by patients in the intervention group.

^e The study is an interventional trial.

Table 3. Results of meta-analyses of studies with death as the outcome.

Authors, year of publication [reference]	Patients in rooms with HEPA/LAF ventilation, no.		Patients in rooms with no ventilation system, no.		Total patients, no.	RR (95% CI)	Mortality rate, %		
	Who died	Who survived	Who died	Who survived			With HEPA/LAF ventilation	Without ventilation	Overall
RCTs with death as the outcome									
Yates et al., 1973 [26]	11	24	17	35	87	0.96 (0.51–1.78)	31	33	32
Levine et al., 1973 [27]	1	21	9	29	60	0.19 (0.03–1.42)	5	24	17
Buckner et al., 1978 [24]	23	6	25	2	56	0.86 (0.69–1.06)	79	93	86
Storb et al., 1983 [25]	5	34	28	63	130	0.42 (0.17–1.00)	13	31	25
Petersen et al., 1987 [29]	13	36	12	38	99	1.11 (0.56–2.18)	27	24	25
Petersen et al., 1988 [28]	13	128	15	186	342	1.24 (0.61–2.51)	9	7	8
All	66	249	106	353	774	0.86 ^a (0.65–1.14)	21	23	22
Non-RCTs with death as the outcome									
Rodriguez et al., 1978 [24]	39	24	69	13	145	0.74 (0.59–0.91)	62	84	74
Schmeiser et al., 1988 [30]	1	25	0	15	41	1.78 (0.08–41.1)	4	0	2
Gamillscheg et al., 1991 [31]	16	9	11	9	45	1.16 (0.71–1.91)	64	55	60
All	56	58	80	37	231	0.87 ^a (0.60–1.25)	49	68	59

NOTE. CI, confidence interval; HEPA, high-efficiency particulate air; LAF, laminar airflow; non-RCT, nonrandomized controlled trial; RCT, randomized controlled trial; RR, relative risk.

^a Pooled RR determined by the DerSimonian and Laird method.

The results for fungal infection as the outcome are shown in table 4. The rate of fungal infection was 2%–18%. Three of the RCTs reported no fungal infection among patients in the intervention group. Most (9 of 10) studies pointed to a decrease in the rate of fungal infection in association with the use of HEPA filtration or LAF. In 1 of the 4 RCTs with fungal infection as the outcome, an increased risk was noted (pooled RR, 0.57 [95% CI, 0.13–2.53]).

Forrest plots of the 6 RCTs that had death as an outcome and the 4 RCTs that had fungal infection as an outcome are shown in figure 2; the corresponding funnel plots are shown in figure 3. The funnel plots show no publication bias for death as an outcome, but they show a huge bias for fungal infection as an outcome.

All meta-analyses were calculated using the random-effects method, because the clinical heterogeneity of the studies suggests that the effect differs with each study. However, the test for statistical heterogeneity was not significant for any of the 4 meta-analyses ($P > .05$).

DISCUSSION

Of the 923 articles identified by a systematic search of the literature, only 16 were useful for analysis.

Rates of fungal infection and death. All the meta-analyses indicated a decrease in the rates of death or fungal infection in protected areas, but the result was significant only for non-RCTs for which fungal infection was an outcome. The statistical homogeneity was considerable (the results of tests of hetero-

geneity of the meta-analyses were all not significant). Even if all studies—RCTs and non-RCTs—with death as an outcome are included in one analysis, the result of the test of heterogeneity is not statistically significant ($P = .27$).

The huge differences in rates of infection and death between the studies are, in part, a consequence of study design, but there is, in fact, no satisfactory explanation. Only 3 of 10 studies with fungal infection as an outcome already had fungal infection noted in the intervention group. That would mean that all fungal infections that occurred during hospitalization were acquired in the hospital. This is unlikely, because the sinuses of the patients could have been colonized before admission to the hospital.

The funnel plot of the 4 RCTs with fungal infection as an outcome revealed publication bias. Studies that showed a small effect and no influence of ventilation on fungal infection are missing.

Heterogeneity of the studies. Although there is only little overall statistical heterogeneity in the results, the clinical heterogeneity is huge. We considered different kinds of studies. The patients in the trials had different underlying diseases, and their treatment programs were variable. Fungal infection as an outcome is the least common denominator for a range of outcome definitions. During the 28-year period during which the publications appeared (from 1973 to 2001), much with regard to study design, treatment, and technical equipment had, of course, changed. It is difficult to combine data from studies conducted during such a long period. Because only the 2 newest

Table 4. Results of meta-analyses of studies with fungal infection as the outcome.

Authors, year of publication [reference]	Patients in rooms with HEPA/LAF ventilation, no.		Patients in rooms with no ventilation system, no.		Total patients, no.	RR (95% CI)	Fungal infection rate, %		
	With fungal infection	Without fungal infection	With fungal infection	Without fungal infection			With HEPA/LAF ventilation	Without ventilation	Overall
	RCTs with fungal infection as the outcome								
Levine et al., 1973 [27]	0	22	3	35	60	0.24 (0.013–4.48)	0	8	5
Schimff et al., 1975 [21]	0	24	1	18	43	0.27 (0.011–6.20)	0	5	2
Buckner et al., 1978 [24]	0	46	3	41	90	0.14 (0.0073–2.57)	0	7	3
Lohner et al., 1979 [32]	5	19	2	19	45	2.19 (0.47–10.1)	21	10	16
All	5	111	9	113	238	0.57 ^a (0.13–2.53)	4	7	6
Non-RCTs with fungal infection as the outcome									
Rodriguez et al., 1978 [23]	3	60	9	73	145	0.43 (0.12–1.54)	5	11	8
Navari et al., 1984 [33]	0	36	1	30	67	0.29 (0.012–6.83)	0	3	1
Rhame et al., 1984 [34]	9	158	12	55	234	0.30 (0.13–0.68)	5	18	9
Sherertz et al., 1987 [35]	0	39	14	74	127	0.077 (0.0047–1.25)	0	16	11
Withington et al., 1998 [36]	0	51	1	63	115	0.41 (0.017–10.0)	0	2	1
Oren et al., 2001 [37]	0	26	13	32	71	0.063 (0.0039–1.02)	0	29	18
All	12	370	50	327	759	0.29 ^a (0.15–0.54)	3	13	8

NOTE. CI, confidence interval; HEPA, high-efficiency particulate air; LAF, laminar airflow; non-RCT, nonrandomized controlled trial; RCT, randomized controlled trial; RR, relative risk.

^a Pooled RR, determined by the DerSimonian and Laird method.

studies [36, 37] provide definitions of nosocomial aspergillosis, it now becomes clear why we cannot provide information regarding its definition.

In 4 studies [23–25, 31], the duration of follow-up for the different patients was between months and years, with the authors having set specific dates for follow-up analyses. The long follow-up times explain why, for 3 of these studies [23, 24, 31], mortality rates were 60%–86%. Because 2 of the 3 studies in the analysis were non-RCTs with death as an outcome, the mean mortality rate in non-RCTs was high (59%).

In the cohort study of Gamillscheg et al. [31], which had a historical control group, it was not considered appropriate to set a fixed date for follow-up analysis for all patients. It is more surprising that the control group with a much longer follow-up (2–12 years, compared with 10 months to 2 years of follow-up in the intervention group) had a lower mortality rate (55% vs. 64%).

Two important explanations for this heterogeneity in the mortality rate are probably the duration and severity of neutropenia. Only a small number of the studies mentioned the severity and duration of neutropenia, although immunosuppression was the constant underlying theme in all the studies.

In 3 studies, decontamination (with oral nonabsorbable antibiotics) was part of the intervention. A meta-analysis conducted by Cruciani et al. [38] indicated that routine gut de-

contamination was not effective in preventing infection-related death; we may, therefore, assume that the reduction in mortality and/or fungal infection was the result of isolation and not decontamination.

In 2 of the 16 studies, only HEPA filtration, without LAF, was used [34, 37]. Environmental studies [4, 39] showed differences between LAF and HEPA filtration. The reduction in the number of fungal infections in these 2 studies did not differ from that noted in other non-RCTs with fungal infection as an outcome.

Limitations of all the studies. Another important point is that none of the studies was blinded. In each study, the medical team, as well as the patients, were aware of whether or not the patients were situated in a protected area. No studies involved the appropriate control subjects, who should have been situated in rooms with air conditioning but without HEPA filters. Of course, in these trials, the benefit of freedom of movement for the patients, which supports well-being, would be lost.

The only existing information about ventilation concerns HEPA filtration with or without LAF. However, of course, problems like pressure, location of filters (terminal HEPA), and protection of individual rooms only or protection of the whole unit are of concern.

Other studies. Two multicenter studies supported the benefit of a protected environment [40, 41]. Fischer et al. [40] an-

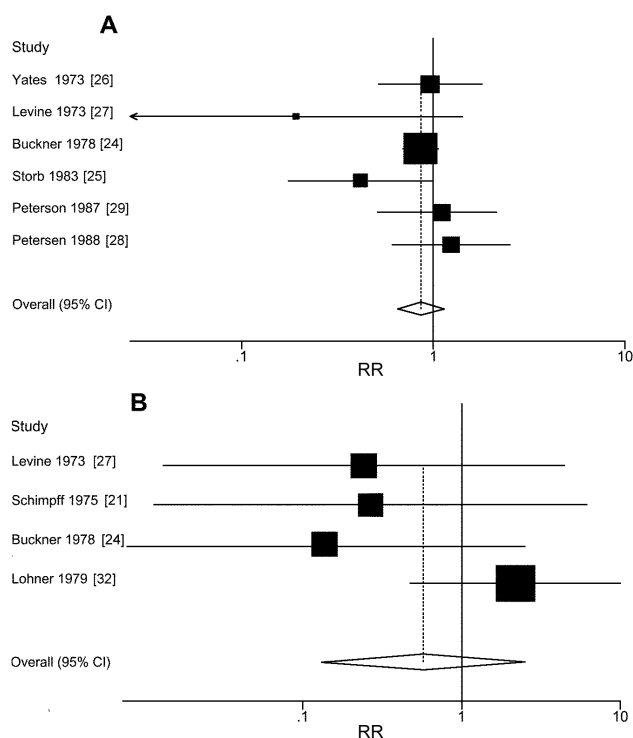


Figure 2. Forrest plot of relative risks (RRs) and 95% confidence intervals (CIs) for mortality (A) in 6 randomized controlled trials (RCTs) of air filtration and for fungal infection (B) in 4 RCTs of air filtration.

alyzed 183 patients from 15 European health care centers who had severe combined immunodeficiency and who had received BMTs. The RR for cumulative 2-year survival in a protected environment was 0.51 (95% CI, 0.37–0.69). This was a very specific group of patients who were not comparable to other patients who had also received BMT. Passweg et al. [41] analyzed 5065 patients (from 222 research teams) with leukemia who received BMT. The RR of survival after 1 year was 0.85 (95% CI, 0.78–0.92). This RR is similar to our results. Because of the large number of patients included in the study, the result is significant. It is not, however, possible to reproduce the allocation of the patients in the different centers, although this is an important factor for the outcome.

The epidemiological profile of *Aspergillus* infection in patients undergoing BMT at the Fred Hutchinson Cancer Research Center (Seattle, WA) between 1980 and 1987 and between 1987 and 1993 was analyzed in 2 retrospective cohort studies [42, 43]. During the first study period, the risk of *Aspergillus* infection was not significantly altered by methods of infection prevention, including the provision of a protective environment [42]. During the second study period, Wald et al. [43] analyzed the RR of infection for patients within 40 days after transplantation was performed. Transplantations performed outside protected environments were associated with a significantly increased risk of aspergillosis.

Existing guidelines. In 4 CDC guidelines, the installation of HEPA filters according to categories BIII or IB is recommended for immunosuppressed patients. These 4 guidelines present different categories for the use of HEPA filtration, although most of the references provided in the guidelines do not allow these conclusions. The recommendation in guidelines from 2000 for the prevention of opportunistic infections among hematopoietic stem cell transplant recipients [10] refers to 3 references [9, 34, 44] (table 5), with only one reference presenting data that provide evidence of a reduction in risk occurring in association with the use of special ventilation.

In the Healthcare Infection Control Practices Advisory Committee's 1997 guidelines for preventing nosocomial pneumonia, only staff education is included in category IA to prevent nosocomial aspergillosis [9]. This shows that definitive scientific studies are not available for any other measures. The guideline

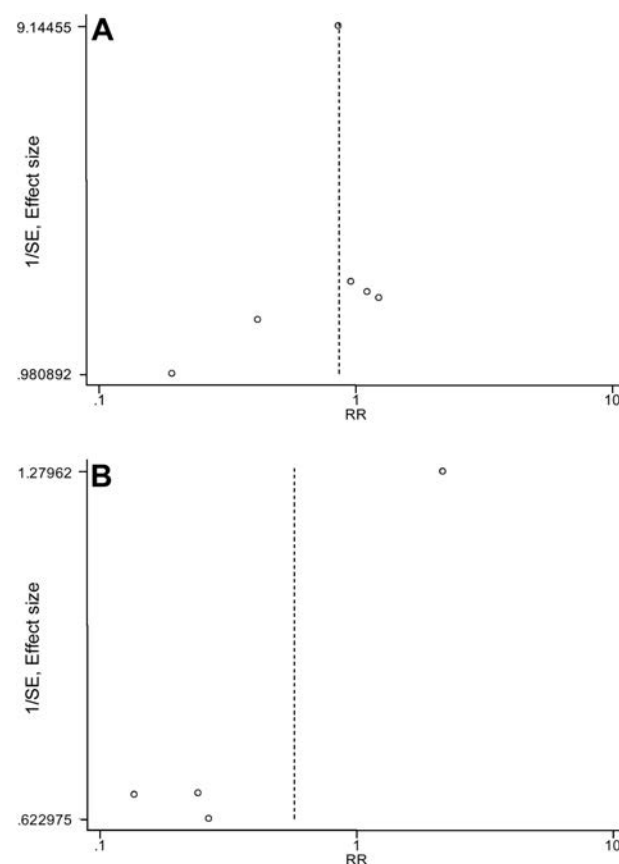


Figure 3. Funnel plot of precision (1/SE) against relative risk (RR) for mortality (A) in 6 randomized controlled trials (RCTs) of air filtration and for invasive fungal infection (B) in 4 RCTs of air filtration [17, 18]. Note: Panel A shows no publication bias, because the study with the biggest effect is shown exactly on the line of the overall RR, and because the smaller studies are symmetrical around the overall RR (symmetrical plot). Panel B shows an asymmetrical plot (publication bias); small studies have an RR of <1, and the study with the biggest effect has an RR of >1 (overall RR, slightly <1).

Table 5. Different guidelines of the Centers for Disease Control and Prevention (CDC) that recommend the installation of high-efficiency particulate air (HEPA) filters, categories of use, and the content of references included in the guidelines.

CDC guidelines	Category of HEPA filter use	References in guidelines and their content
Guidelines for the prevention of opportunistic infections in recipients of hematopoietic stem cell transplants [10]	BIII ^a	Guidelines for prevention of nosocomial pneumonia [9] Rhame et al. [34] were considered in the present review Opal et al. [44] conducted a study during hospital renovation
Guidelines for preventing nosocomial pneumonia [9]	IB ^b	Studies by Buckner et al. [24] and Sherertz et al. [35] were considered in the present review Murray et al. [45] and Streifel et al. [46] focused on technical data regarding the use of ventilation for controlling microbes Opal et al. [44] and Barnes et al. [47] conducted studies during hospital renovation Neither McWhinney et al. [48] nor Rogers [49] showed a reduction in mortality or fungal infection as a result of use of HEPA filtration
Guidelines for preventing health care–associated pneumonia [11]	IB ^b	Guidelines for environmental infection control in health care facilities [12] Studies by Sherertz et al. [35] and Oren et al. [37] were considered in the present review Thio et al. [50] conducted an investigation of an outbreak of invasive aspergillosis Rice et al. [51] focused on technical data regarding the use of ventilation for controlling microbes
Guidelines for environmental infection control in health care facilities [12]	IB ^b and IC ^c	2001 guidelines for the prevention of nosocomial pneumonia [9] 2001 guidelines for the design and construction of hospital and health care facilities [52] Siegler et al. [53] contributed a book section Studies by Buckner et al. [24] and Sherertz et al. [35] were considered in the present review Arnow et al. [54], Breton et al. [55], Guarro et al. [56], Burton et al. [57], Kyriakides et al. [58], McWhinney et al. [48], and Rhame [59] did not show a reduction in mortality or fungal infection resulting from the use of HEPA filtration Weems et al. [60], Barnes et al. [47], and Overberger et al. [61] conducted studies during hospital renovation Murray et al. [45] and Streifel et al. [46] focused on technical data regarding the use of ventilation for controlling microbes

NOTE. HEPA, high-efficiency particulate air.
^a B: Strong or moderate evidence for efficacy, but only limited clinical benefit; generally recommended. III: Evidence from opinions of respected authorities based on clinical experience, descriptive studies, or reports of expert committees.
^b IB: Strongly recommended for implementation and supported by certain experimental, clinical, or epidemiological studies and a strong theoretical rationale.
^c IC: Required by state or federal regulation, or representing an established association standard.

refers to 8 references [24, 35, 44–49], with only 2 providing evidence that there is a reduction.

The 2004 guidelines for preventing health care–associated pneumonia [11] refer to 5 references, with 2 providing evidence that there is a reduction. The 2003 guidelines for environmental infection control in health care facilities refer to 17 references [9, 24, 35, 45–48, 52–61], including 2 studies that provide evidence in favor of the installation of HEPA filters.

Conclusion. Many experts recommend the general housing of patients in hospital rooms with HEPA filtration, although this approach is expensive. Even if it is feasible for the highest-risk patient groups for a limited period, it cannot be applied for all patients who are at risk for longer periods.

Therefore, the objective of this study was to deliver and present a systematic overview of data on the prevention of fungal infection and death by use of appropriate ventilation systems. In 1984, Armstrong stated, “The only place for protected environments today appears to be in a limited number of centers where carefully studies should be conducted” [62, p. 689]. Research scientists have rather missed the chance for conducting such studies. Only 2 additional RCTs have been performed since this statement appeared; both RCTs revealed no benefit of installing a protected environment. Because most centers now have special rooms for patients with neutropenia, a multicenter double-blinded RCT is not practicable, from the ethical viewpoint.

The results of these meta-analyses suggest that patients with hematological malignancies with severe neutropenia or patients with bone marrow transplants receive some benefit if they are placed in a protected environment. Nevertheless, the evidence is still somewhat ambiguous. Even if it does seem to be beneficial to place in protected areas patients with hematological malignancies and severe neutropenia or patients with bone marrow transplants, at present, no final conclusion can be drawn from the data available.

References

- Pannuti CS, Gingrich RD, Pfaller MA, Wenzel RP. Nosocomial pneumonia in adult patients undergoing bone marrow transplantation: a 9-year study. *J Clin Oncol* **1991**; 9:77–84.
- Morrison VA, Haake RJ, Weisdorf DJ. Non-*Candida* fungal infections after bone marrow transplantation: risk factors and outcome. *Am J Med* **1994**; 96:497–503.
- Denning DW. Therapeutic outcome in invasive aspergillosis. *Clin Infect Dis* **1996**; 23:608–15.
- Alberti C, Bouakline A, Ribaud P, et al. Relationship between environmental fungal contamination and the incidence of invasive aspergillosis in haematology patients. *J Hosp Infect* **2001**; 48:198–206.
- Rhame FS. Prevention of nosocomial aspergillosis. *J Hosp Infect* **1991**; 18(Suppl A):466–72.
- Krüger WH, Hornung RJ, Hertenstein B, et al. Practices of infectious disease prevention and management during hematopoietic stem cell transplantation: a survey from the European group for blood and marrow transplantation. *J Hematother Stem Cell Res* **2001**; 10:895–903.
- Schweigkofler H, Sperner-Unterwieser B, Kopp M, Trojer-Zeidler M, Holzner B. Psychiatric problems in bone marrow transplantation patients during isolation [in German]. *Nervenarzt* **1996**; 67:799–804.
- Sasaki T, Akaho R, Sakamaki H, et al. Mental disturbances during isolation in bone marrow transplant patients with leukemia. *Bone Marrow Transplant* **2000**; 25:315–8.
- Centers for Disease Control and Prevention. Guidelines for prevention of nosocomial pneumonia. *MMWR Recomm Rep* **1997**; 46(RR-1):1–79.
- Centers for Disease Control and Prevention. Guidelines for preventing opportunistic infections among hematopoietic stem cell transplant recipients. *MMWR Recomm Rep* **2000**; 49(RR-10):1–125, CE1–7.
- Tablan OC, Anderson LJ, Besser R, et al. Guidelines for preventing health-care-associated pneumonia, 2003: recommendations of CDC and the Healthcare Infection Control Practices Advisory Committee. *MMWR Recomm Rep* **2004**; 53(RR-3):1–36.
- Sehulster L, Chinn RY, Centers for Disease Control and Prevention, Healthcare Infection Control Practices Advisory Committee. Guideline for environmental infection control in health-care facilities: recommendations of CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC). *MMWR Recomm Rep* **2003**; 52(RR-10):1–42.
- Hayes-Lattin B, Leis JE, Maziarz RT. Isolation in the allogeneic transplant environment: how protective is it? *Bone Marrow Transplant* **2005**; 36:373–81.
- Rhame FS. The inanimate environment. In: Bennett JV, Brachman PS, eds. *Hospital infections*. 3rd ed. Boston: Little, Brown, **1992**:299–331.
- Pannuti S. Hospital environment for high risk patients. In: Wenzel RP, ed. *Prevention and control of nosocomial infections*. 3rd ed. Baltimore: Williams & Wilkins, **1997**:463–89.
- Perl TM, Chotani R, Agawala R. Infection control and prevention in bone marrow transplant patients. In: Mayhall CG, ed. *Hospital epidemiology and infection control*. 2nd ed. Philadelphia: Williams & Wilkins, **1999**:803–44.
- Lau J, Ioannidis PA, Schmid CH. Quantitative synthesis in systematic reviews. In: Mulrow C, Cook D, eds. *Systematic reviews: synthesis of best evidence for health care decisions*. Philadelphia: American College of Physicians, **1998**:91–101.
- Egger M, Davey Smith G, O'Rourke K. Rationale, potentials, and promise of systematic reviews. In: Egger M, Davey Smith G, Altman DG, eds. *Systematic reviews in healthcare: meta-analysis in context*. London: BMJ Books, **2001**:3–19.
- Stata: statistics/data analysis. 7.0 ed. College Station, TX: StataCorp, **2001**.
- Bodey GP, Gehan EA, Freireich EJ, Frei E III. Protected environment—prophylactic antibiotic program in the chemotherapy of acute leukemia. *Am J Med Sci* **1971**; 262:138–51.
- Schimpff SC, Greene WH, Young VM, et al. Infection prevention in acute nonlymphocytic leukemia: laminar air flow room reverse isolation with oral, nonabsorbable antibiotic prophylaxis. *Ann Intern Med* **1975**; 82:351–8.
- Freireich EJ, Bodey GP, Rodriguez V, et al. A controlled clinical trial to evaluate a protected environment and prophylactic antibiotic program in the treatment of adult acute leukemia. *Trans Assoc Am Physicians* **1975**; 88:109–19.
- Rodriguez V, Bodey GP, Freireich EJ, et al. Randomized trial of protected environment—prophylactic antibiotics in 145 adults with acute leukemia. *Medicine (Baltimore)* **1978**; 57:253–66.
- Buckner CD, Clift RA, Sanders JE, et al. Protective environment for marrow transplant recipients: a prospective study. *Ann Intern Med* **1978**; 89:893–901.
- Storb R, Prentice RL, Buckner CD, et al. Graft-versus-host disease and survival in patients with aplastic anemia treated by marrow grafts from HLA-identical siblings: beneficial effect of a protective environment. *N Engl J Med* **1983**; 308:302–7.
- Yates JW, Holland JF. A controlled study of isolation and endogenous microbial suppression in acute myelocytic leukemia patients. *Cancer* **1973**; 32:1490–8.

27. Levine AS, Siegel SE, Schreiber AD, et al. Protected environments and prophylactic antibiotics: a prospective controlled study of their utility in the therapy of acute leukemia. *N Engl J Med* **1973**;288:477–83.
28. Petersen F, Thornquist M, Buckner C, et al. The effects of infection prevention regimens on early infectious complications in marrow transplant patients: a four arm randomized study. *Infection* **1988**;16:199–208.
29. Petersen FB, Buckner CD, Clift RA, et al. Infectious complications in patients undergoing marrow transplantation: a prospective randomized study of the additional effect of decontamination and laminar air flow isolation among patients receiving prophylactic systemic antibiotics. *Scand J Infect Dis* **1987**;19:559–67.
30. Schmeiser T, Kurrle E, Arnold R, Krieger D, Heit W, Heimpel H. Antimicrobial prophylaxis in neutropenic patients after bone marrow transplantation. *Infection* **1988**;16:19–24.
31. Gamillscheg A, Urban C, Slavic I, Lackner H, Hauer C. Infections in the neutropenic phase following bone marrow transplantation: comparison of laminar airflow isolation with conventional isolation [in German]. *Wien Klin Wochenschr* **1991**;103:82–7.
32. Lohner D, Debusscher L, Prevost JM, Klastersky J. Comparative randomized study of protected environment plus oral antibiotics versus oral antibiotics alone in neutropenic patients. *Cancer Treat Rep* **1979**;63:363–8.
33. Navari RM, Buckner CD, Clift RA, et al. Prophylaxis of infection in patients with aplastic anemia receiving allogeneic marrow transplants. *Am J Med* **1984**;76:564–72.
34. Rhame FS, Streifel AJ, Kersey JH Jr, McGlave PB. Extrinsic risk factors for pneumonia in the patient at high risk of infection. *Am J Med* **1984**;76:42–52.
35. Sherertz RJ, Belani A, Kramer BS, et al. Impact of air filtration on nosocomial *Aspergillus* infections: unique risk of bone marrow transplant recipients. *Am J Med* **1987**;83:709–18.
36. Withington S, Chambers ST, Beard ME, et al. Invasive aspergillosis in severely neutropenic patients over 18 years: impact of intranasal amphotericin B and HEPA filtration. *J Hosp Infect* **1998**;38:11–8.
37. Oren I, Haddad N, Finkelstein R, Rowe JM. Invasive pulmonary aspergillosis in neutropenic patients during hospital construction: before and after chemoprophylaxis and institution of HEPA filters. *Am J Hematol* **2001**;66:257–62.
38. Cruciani M, Rampazzo R, Malena M, et al. Prophylaxis with fluoroquinolones for bacterial infections in neutropenic patients: a meta-analysis. *Clin Infect Dis* **1996**;23:795–805.
39. Cornet M, Levy V, Fleury L, et al. Efficacy of prevention by high-efficiency particulate air filtration or laminar airflow against *Aspergillus* airborne contamination during hospital renovation. *Infect Control Hosp Epidemiol* **1999**;20:508–13.
40. Fischer A, Landais P, Friedrich W, et al. European experience of bone-marrow transplantation for severe combined immunodeficiency. *Lancet* **1990**;336:850–4.
41. Passweg JR, Rowlings PA, Atkinson KA, et al. Influence of protective isolation on outcome of allogeneic bone marrow transplantation for leukemia. *Bone Marrow Transplant* **1998**;21:1231–8.
42. Meyers JD. Fungal infections in bone marrow transplant patients. *Semin Oncol* **1990**;17:10–3.
43. Wald A, Leisenring W, van Burik JA, Bowden RA. Epidemiology of *Aspergillus* infections in a large cohort of patients undergoing bone marrow transplantation. *J Infect Dis* **1997**;175:1459–66.
44. Opal SM, Asp AA, Cannady PB Jr, Morse PL, Burton LJ, Hammer PG II. Efficacy of infection control measures during a nosocomial outbreak of disseminated aspergillosis associated with hospital construction. *J Infect Dis* **1986**;153:634–7.
45. Murray B, Streifel AJ, O'Dea TJ, Rhame FS. Ventilation for protection of immune compromised patients. ASHARE (American Society of Heating, Refrigerating, and Air Conditioning Engineers) Transactions **1988**;94:1185–91.
46. Streifel AJ, Vesley D, Rhame FS, Murray B. Control of airborne fungal spores in a university hospital. *Environment International* **1989**;12:441–4.
47. Barnes RA, Rogers TR. Control of an outbreak of nosocomial aspergillosis by laminar air-flow isolation. *J Hosp Infect* **1989**;14:89–94.
48. McWhinney PH, Kibbler CC, Hamon MD, et al. Progress in the diagnosis and management of aspergillosis in bone marrow transplantation: 13 years' experience. *Clin Infect Dis* **1993**;17:397–404.
49. Rogers TR. Infections in hematologic malignancy. *Infect Control* **1986**;7:140–3.
50. Thio CL, Smith D, Merz WG, et al. Refinements of environmental assessment during an outbreak investigation of invasive aspergillosis in a leukemia and bone marrow transplant unit. *Infect Control Hosp Epidemiol* **2000**;21:18–23.
51. Rice N, Streifel A, Vesley D. An evaluation of hospital special-ventilation-room pressures. *Infect Control Hosp Epidemiol* **2001**;22:19–23.
52. American Institute of Architects. Guidelines for design and construction of hospital and health care facilities, 2001. Washington, DC: American Institute of Architects Press, **2001**.
53. Siegler L, Kennedy MJ. *Aspergillus*, *Fusarium*, and other opportunistic monilaceous fungi. In: Murray PR, Baron EJ, Pfaller MA, Tenover FC, Tenover RH, eds. Manual of clinical microbiology. 7th ed. Washington, DC: American Society for Microbiology Press, **1999**:1212–41.
54. Arnow PM, Sadigh M, Costas C, Weil D, Chudy R. Endemic and epidemic aspergillosis associated with in-hospital replication of *Aspergillus* organisms. *J Infect Dis* **1991**;164:998–1002.
55. Breton P, Germaud P, Leroy C, Madelaine J, Bland J, Clavier J. Unusual pulmonary mycoses in patients with hematologic disease. *Rev Pneumol Clin* **1998**;54:253–7.
56. Guarro J, Nucci M, Akiti T, Gene J, Barreiro MD, Goncalves RT. Fungemia due to *Fusarium sacchari* in an immunosuppressed patient. *J Clin Microbiol* **2000**;38:419–21.
57. Burton JR, Zachery JB, Bessin R. Aspergillosis in four renal transplant patients: diagnosis and effective treatment with amphotericin B. *Ann Intern Med* **1972**;77:383–8.
58. Kyriakides GK, Zinnemann HH, Hall WH. Immunologic monitoring and aspergillosis in renal transplant patients. *Am J Surg* **1972**;131:246–52.
59. Rhame FS. Endemic nosocomial filamentous fungal disease: a proposed structure for conceptualizing and studying the environmental hazard. *Infect Control* **1986**;7:124–5.
60. Weems JJ Jr, Davis BJ, Tablan OC, Kaufman L, Martone WJ. Construction activity: an independent risk factor for invasive aspergillosis and zygomycosis in patients with hematologic malignancy. *Infect Control* **1987**;8:71–5.
61. Overberger PA, Wadowsky RM, Schaper MM. Evaluation of airborne particulates and fungi during hospital renovation. *Am Ind Hyg Assoc J* **1995**;56:706–12.
62. Armstrong D. Symposium on infectious complications of neoplastic disease (part II): protected environments are discomfiting and expensive and do not offer meaningful protection. *Am J Med* **1984**;76:685–9.



EVIDENCE SUPPORTS THE HIGH BARRIER TO RESISTANCE OF DOVATO UP TO 5 YEARS¹⁻³

CONFIDENCE IN DOVATO ACROSS TREATMENT SETTINGS⁴⁻⁹

Treatment-naïve resistance rates, with up to **3 years** of evidence⁵⁻⁷

0%

(n=0/1,885)⁴
REAL-WORLD EVIDENCE

0.1%

(n=1/953)⁸ *^{1,3,5-7}
RANDOMISED CONTROLLED TRIALS

Treatment-experienced resistance rates, with up to **5 years** of evidence¹⁻³

0.03%

(n=10/35,888)^{7,4}
REAL-WORLD EVIDENCE

0%

(n=0/615)^{11,12,13}
RANDOMISED CONTROLLED TRIALS

>300,000 PEOPLE LIVING WITH HIV HAVE BEEN TREATED WITH DOVATO GLOBALLY¹⁰

DOVATO is supported by a wealth of evidence, with the outcomes of **>40,000** people living with HIV captured within clinical trials and real-world evidence, including those with:^{4-9,11,12}



NO PRIOR TREATMENT EXPERIENCE¹³



NO BASELINE RESISTANCE TESTING¹³

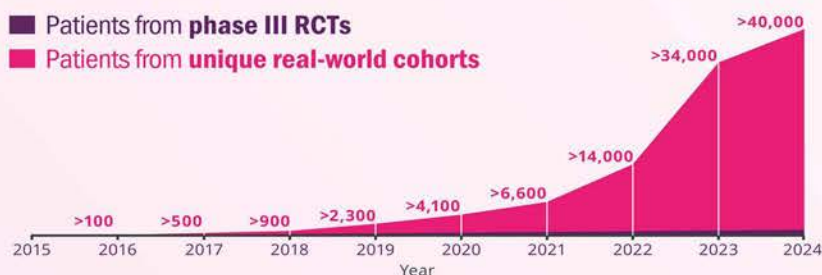


HIGH BASELINE VIRAL LOAD
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■ Patients from phase III RCTs
■ Patients from unique real-world cohorts



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REFERENCES

- Maggiolo F et al. BMC Infect Dis 2022; 22(1): 782.
- Taramasso L et al. AIDS Patient Care STDS 2021; 35(9): 342–353.
- Ciccullo A et al. JAIDS 2021; 88(3): 234–237.
- ViiV Healthcare. Data on File. REF-223795. 2024.
- Cahn P et al. AIDS 2022; 36(1): 39–48.
- Rolle C et al. Open Forum Infect Dis 2023; 10(3): ofad101.
- Cordova E et al. Poster presented at 12th IAS Conference on HIV Science. 23–26 July 2023. Brisbane, Australia. TUPEB02.
- De Wit S et al. Slides presented at HIV Glasgow. 23–26 October 2022. Virtual and Glasgow, UK. M041.
- Llibre J et al. Clin Infect Dis 2023; 76(4): 720–729.
- ViiV Healthcare. Data on File. REF-220949. 2024.
- Rolle C et al. Poster presented IDWeek. 11–15 October 2023. Virtual and Boston, USA. 1603.
- Slim J et al. Abstract presented IDWeek. 11–15 October 2023. Virtual and Boston, USA. 1593.
- DOVATO. Summary of Product Characteristics. June 2023.

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ABBREVIATIONS

3TC, lamivudine; **CD4**, cluster of differentiation 4; **DTG**, dolutegravir; **FDA**, United States Food and Drug Administration; **FTC**, emtricitabine; **HIV**, human immunodeficiency virus; **ITT-E**, intention-to-treat exposed; **NRTI**, nucleoside/nucleotide reverse transcriptase inhibitor; **RCT**, randomised controlled trial; **RNA**, ribonucleic acid; **TAF**, tenofovir alafenamide fumarate; **TDF**, tenofovir disoproxil fumarate; **XTC**, emtricitabine.

FOOTNOTES

*Data extracted from a systematic literature review of DTG+3TC real-world evidence. Overlap between cohorts cannot be fully excluded.

**The reported rate reflects the sum-total of resistance cases calculated from GEMINI I and II (n=1/716, through 144 weeks), STAT (n=0/131, through 52 weeks), and D2ARLING (n=0/106, through 24 weeks).⁵⁻⁷

†GEMINI I and II are two identical 148-week, phase III, randomised, double-blind, multicentre, parallel-group, non-inferiority, controlled clinical trials testing the efficacy of DTG/3TC in treatment-naïve patients. Participants with screening HIV-1 RNA ≤500,000 copies/mL were randomised 1:1 to once-daily DTG/3TC (n=716, pooled) or DTG + TDF/FTC (n=717, pooled). The primary endpoint of each GEMINI study was the proportion of participants with plasma HIV-1 RNA <50 copies/mL at Week 48 (ITT-E population, snapshot algorithm).¹³

‡STAT is a phase IIIb, open-label, 48-week, single-arm pilot study evaluating the feasibility, efficacy, and safety of DTG/3TC in 131 newly diagnosed HIV-1 infected adults as a first line regimen. The primary endpoint was the proportion of participants with plasma HIV-1 RNA <50 copies/mL at Week 24.⁶

§D2ARLING is a randomised, open-label, phase IV study designed to assess the efficacy and safety of DTG/3TC in treatment-naïve people with HIV with no available baseline HIV-1 resistance testing. Participants were randomised in a 1:1 ratio to receive DTG/3TC (n=106) or DTG + TDF/XTC (n=108). The primary endpoint was the proportion of participants with plasma HIV-1 RNA <50 copies/mL at Week 48.⁷ Results at week 24 of the study.

||The reported rate reflects the sum-total of resistance cases calculated from TANGO (n=0/369, through 196 weeks) and SALSA (n=0/246, through 48 weeks).^{8,9}

¶TANGO is a randomised, open-label, trial testing the efficacy of DOVATO in virologically suppressed patients. Participants were randomised in a 1:1 ratio to receive DOVATO (n=369) or continue with TAF-containing regimens (n=372) for up to 200 weeks. At Week 148, 298 of those on TAF-based regimens switched to DOVATO. The primary efficacy endpoint was the proportion of subjects with plasma HIV-1 RNA ≥50 copies/mL (virologic non-response) as per the FDA Snapshot category at Week 48 (adjusted for randomisation stratification factor).^{8,13}

#SALSA is a phase III, randomised, open-label, non-inferiority clinical trial evaluating the efficacy and safety of switching to DTG/3TC compared with continuing current antiretroviral regimens in virologically suppressed adults with HIV. Eligible participants were randomised 1:1 to switch to once-daily DTG/3TC (n=246) or continue current antiretroviral regimens (n=247). The primary endpoint was the proportion of subjects with plasma HIV-1 RNA ≥50 copies/mL at Week 48 (ITT-E population, snapshot algorithm).⁹



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Brief Report

Exploring the role of infection preventionists in antimicrobial stewardship programs through several lenses: A brief report

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Key Words:

Antibiotic stewardship
Antimicrobial stewardship
Multidisciplinary collaboration
Barriers
Survey

This study explored perceptions of the role of infection preventionists (IPs) in antimicrobial stewardship programs (ASPs) among IPs, pharmacists, infectious diseases physicians, and hospital executives. Expert telephone interviews, using a validated survey tool, were conducted from November 1, 2016 to December 12, 2016 (n = 28). Participants with clinical responsibilities reported modest expectations of the IP in ASPs. Competing IP job responsibilities and limited ASP role clarity were cited as common barriers to IP engagement.

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Antimicrobial resistance is one of the greatest public health challenges of our time. In 2013, the Centers for Disease Control and Prevention published a comprehensive analysis outlining the top 18 threats of antimicrobial resistance in the United States.¹ It is estimated that 20%–50% of all antimicrobials prescribed in acute care facilities throughout the United States are inappropriate or unnecessary.^{2,3} Antimicrobial stewardship programs (ASPs) have demonstrated a decrease in the development of antimicrobial resistance and are critical components of ensuring patient safety.⁴ Previous research has shown that infection preventionists (IPs) are important contributors to hospital ASPs.^{5,6} Although ASPs warrant a multidisciplinary team model, the role of the IP is not well defined.⁷ The objectives of this study were (1) to assess multidisciplinary perspectives of IPs' contributions to ASPs; and (2) identify perceived barriers to optimal participation of IPs in ASPs.

METHODS

Expert telephone interviews, using a validated survey tool, were conducted from November 1, 2016 to December 12, 2016. Two IP leaders and 2 (non-IP) ASP leaders were recruited to assist with validation of the survey instruments prior to use and establish content validity. The interview was conducted with each leader as if they were actual participants. Subsequently, a copy of the interview

questions was provided to these individuals for review and feedback. Survey materials were assessed by this group for content appropriateness, item formatting, usability, and clarity. Expert feedback from the survey instrument validation efforts was incorporated prior to use in participant interviews. Reliability was assessed through calculation of Cronbach's alpha using analysis of variance 2-factor without replication within Microsoft Excel (Microsoft, Redmond, WA), resulting in a value of 0.468. This mixed-methods study used participant interviews and a survey framework to collect data on (1) facility demographics and ASP characteristics; (2) IP role characterization in ASP; (3) barriers to optimal IP engagement in ASPs; (4) metrics for measuring ASP success; and (5) participant demographics from a convenience sample of health care personnel within the professional networks of the research team to include IPs, infectious diseases (ID) physicians, pharmacists, and hospital executives. A truncated, 1-section survey was developed for use with participating hospital executives to assess perspectives on the state of their own ASP, perceived ownership of ASP among clinical roles, and antimicrobial stewardship as an organizational priority. The study was approved by the University of South Florida institutional review board. To facilitate validation of the surveys, 2 infection prevention and control (IPC) leaders and 2 (non-IP) ASP leaders assessed content appropriateness, item formatting, and clarity. Characteristics of each ASP, IPC involvement, and barriers were analyzed using descriptive statistics including frequencies and rates. Qualitative feedback from participants underwent content analysis for themes highlighting ASP characteristics and IPC engagement. Interview notes and audio recordings were reviewed, and codes were assigned to classify observations and aid in data summation and analysis.

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Conflicts of interest: None to report.

Thematic summaries for IPC involvement and experienced barriers were defined to categorize perceptions on IPC engagement.

RESULTS

The study sample was comprised of 28 individuals across 10 states including 8 IPs, 6 ID physicians, 10 pharmacists, and 4 hospital executives. The vast majority (86%) of participants held a master's or doctoral degree.

Sixty-three percent of participants indicated representation from IPs on the antimicrobial stewardship committee. The majority of the IP participants spent either no time (12%) or up to 5 hours per week (63%) on ASP activities, whereas 25% reported ≥ 5 hours per week.

Table 1 summarizes barriers to IP involvement in ASP activities. Forty-two percent of participants indicated that IPs have deficiencies in antimicrobial stewardship knowledge. When asked whether political/social tensions hindered IP involvement, 38% indicated yes and were mostly physicians (21%). The most common barriers cited were antimicrobial stewardship as a lower priority (58%), time constraints (54%), IP staffing levels (46%), and communication difficulties (46%). Interestingly, several participants cited that antimicrobial stewardship is not part of the IP role (33%) and some (21%) suggested no barriers exist.

The qualitative content analysis revealed 3 major themes. First, most non-IP clinician peer groups expect IP involvement in ASP to focus mostly on contributing data on rates of *Clostridium difficile* infection and multidrug-resistant pathogens. Second, there was little expectation that the IP contributes to the ASP through patient-level review, consultation, or intervention. Finally, hospital executives viewed IP involvement as “necessary” and “supportive” to the mission of their ASP, but not as critical as the ID physician or pharmacist.

Table 1
Barriers to IP involvement in ASPs by participant role (n = 24)

Barriers	n (%)
Deficiencies in antimicrobial stewardship knowledge	10 (42)
IP	4 (16)
Pharmacist	3 (13)
Physician	3 (13)
Political/social tensions in the hospital	9 (38)
IP	3 (13)
Pharmacist	1 (4)
Physician	5 (21)
Time constraints	13 (54)
IP	5 (21)
Pharmacist	5 (21)
Physician	3 (13)
AMS is a lower priority relative to competing activities or demands	14 (58)
IP	4 (17)
Pharmacist	4 (17)
Physician	6 (25)
IP staffing levels	11 (46)
IP	4 (17)
Pharmacist	4 (17)
Physician	3 (13)
Communication difficulties between concerned groups	11 (46)
IP	3 (13)
Pharmacist	3 (13)
Physician	5 (21)
Outside of IP role definition “It's not my job”	8 (33)
IP	2 (8)
Pharmacist	2 (8)
Physician	4 (17)
No barriers exist	5 (21)
IP	2 (8)
Pharmacist	2 (8)
Physician	1 (4)

For n = 24, items were multiselectable, resulting in some participants selecting no barriers and some more than 1 barrier.

AMS, antimicrobial stewardship; ASPs, antimicrobial stewardship programs; IP, infection preventionist.

DISCUSSION

The optimal engagement of IPs in ASPs is being challenged by varying expectations among ASP clinician peer groups. Additionally, the absence of a role definition for IPs in ASPs is likely hindering IPs from contributing in consistent, meaningful ways. The revised 2017 Competency Self-Assessment and Professional Development Plan as part of the IP Competency Model from the Association for Professionals in Infection Control and Epidemiology outlines a future-oriented IPC domain that encourages participation of IPs in ASPs.⁸ The Certification Board of Infection Control and Epidemiology also indicates antimicrobial stewardship as an IPC strategy within its examination content outline.⁹ In concordance with Manning and Pogorzelska-Maziarz,⁷ summary analysis of our qualitative feedback revealed that current IP engagement in ASPs is predominately focused on provision of data tied to health care–associated infections and multidrug-resistant organisms. However, our study results also suggest that IPs are currently contributing to ASPs in some undefined ways. Clarifying the role and responsibilities of IPs in ASPs would help to define and recognize specific contributions.

This study was limited by the small sample size and may not be representative of all US acute care hospital stakeholders eligible for participation in this study. Adding more items to the survey instrument in future studies may raise the value of Cronbach's alpha, and thus increase instrument reliability. All participant data were self-reported, and it is possible that not all participants were fully aware of the spectrum of ASP activity occurring within their institution. Despite these limitations, this study provides valuable insights on the current state of IPC engagement in ASPs from the perspective of several hospital stakeholders who share common interests and responsibilities in antimicrobial stewardship.

CONCLUSIONS

To our knowledge, this is the first evaluation of perceptions among multidisciplinary hospital-based peer groups of the IP role in ASP. Additional studies should further explore the barriers identified by IPs and other ASP clinicians. Removing these barriers and establishing more definitive roles may better facilitate IPs to become integral contributors to ASPs.

References

- Centers for Disease Control and Prevention. Antibiotic resistance threats in the United States, 2013. 2013. Available from: <http://www.cdc.gov/drugresistance/threat-report-2013/pdf/ar-threats-2013-508.pdf>. Accessed November 15, 2018.
- Centers for Disease Control and Prevention. Core elements of hospital antibiotic stewardship programs. 2014. Available from: <https://www.cdc.gov/antibiotic-use/healthcare/pdfs/core-elements.pdf>. Accessed January 11, 2018.
- Dellit TH, Owens RC, McGowan JE Jr, Gerding DN, Weinstein RA, Burke JP, et al. Infectious Diseases Society of America and the Society for Healthcare Epidemiology of America guidelines for developing an institutional program to enhance antimicrobial stewardship. *Clin Infect Dis* 2007;44:159–77.
- Fishman N. Antimicrobial stewardship. *Am J Infect Control* 2006;34(5 Suppl 1):55–63.
- Moody J, Cosgrove SE, Olmsted R, Septimus E, Aureden K, Oriola S, et al. Antimicrobial stewardship: a collaborative partnership between infection preventionists and health care epidemiologists. *Am J Infect Control* 2012;40:94–5.
- Manning ML, Septimus EJ, Ashley ESD, Cosgrove SE, Fakih MG, Schweon SJ, et al. Antimicrobial stewardship and infection prevention—leveraging the synergy: a position paper update. *Infect Control Hosp Epidemiol* 2018;39:467–72.
- Manning ML, Pogorzelska-Maziarz M. Health care system leaders' perspectives on infection preventionist and registered nurse engagement in antibiotic stewardship. *Am J Infect Control* 2018;46:498–502.
- Association for Professionals in Infection Control and Epidemiology. Competency self-assessment and professional development plan. 2017. Available from: http://www.apic.org/Resource_/TinyMceFileManager/Practice_Guidance/IP_Comp_Self_Assessment.docx. Accessed February 15, 2019.
- Certification Board of Infection Control and Epidemiology. CBIC exam content outline. 2019. Available from: <https://www.cbic.org/OffNav/Content-Outline1.htm>. Accessed February 11, 2019.



Recommendations and Reports

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Guidelines for Environmental Infection Control in Health-Care Facilities

Recommendations of CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC)

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The material in this report originated in the National Center for Infectious Diseases, James M. Hughes, M.D., Director; and the Division of Healthcare Quality Promotion, Steven L. Solomon, M.D., Acting Director.

Summary

*The health-care facility environment is rarely implicated in disease transmission, except among patients who are immunocompromised. Nonetheless, inadvertent exposures to environmental pathogens (e.g., *Aspergillus* spp. and *Legionella* spp.) or airborne pathogens (e.g., *Mycobacterium tuberculosis* and varicella-zoster virus) can result in adverse patient outcomes and cause illness among health-care workers. Environmental infection-control strategies and engineering controls can effectively prevent these infections. The incidence of health-care--associated infections and pseudo-outbreaks can be minimized by 1) appropriate use of cleaners and disinfectants; 2) appropriate maintenance of medical equipment (e.g., automated endoscope reprocessors or hydrotherapy equipment); 3) adherence to water-quality standards for hemodialysis, and to ventilation standards for specialized care environments (e.g., airborne infection isolation rooms, protective environments, or operating rooms); and 4) prompt management of water intrusion into the facility. Routine environmental sampling is not usually advised, except for water quality determinations in hemodialysis settings and other situations where sampling is directed by epidemiologic principles, and results can be applied directly to infection-control decisions.*

This report reviews previous guidelines and strategies for preventing environment-associated infections in health-care facilities and offers recommendations. These include 1) evidence-based recommendations supported by studies; 2) requirements of federal agencies (e.g., Food and Drug Administration, U.S. Environmental Protection Agency, U.S. Department of Labor, Occupational Safety and Health

Administration, and U.S. Department of Justice); 3) guidelines and standards from building and equipment professional organizations (e.g., American Institute of Architects, Association for the Advancement of Medical Instrumentation, and American Society of Heating, Refrigeration, and Air-Conditioning Engineers); 4) recommendations derived from scientific theory or rationale; and 5) experienced opinions based upon infection-control and engineering practices. The report also suggests a series of performance measurements as a means to evaluate infection-control efforts.

Introduction

Parameters of the Report

This report, which contains the complete list of recommendations with pertinent references, is Part II of *Guidelines for Environmental Infection Control in Health-Care Facilities*. The full four-part guidelines will be available on CDC's Division of Healthcare Quality Promotion (DHQP) website. Relative to previous CDC guidelines, this report

- revises multiple sections (e.g., cleaning and disinfection of environmental surfaces, environmental sampling, laundry and bedding, and regulated medical waste) from previous editions of CDC's *Guideline for Handwashing and Hospital Environmental Control*;
- incorporates discussions of air and water environmental concerns from CDC's *Guideline for Prevention of Nosocomial Pneumonia*;
- consolidates relevant environmental infection-control measures from other CDC guidelines; and
- includes two topics not addressed in previous CDC guidelines --- infection-control concerns related to animals in health-care facilities and water quality in hemodialysis settings.

In the full guidelines, Part I, Background Information: Environmental Infection Control in Health-Care Facilities, provides a comprehensive review of the relevant scientific literature. Attention is given to engineering and infection-control concerns during construction, demolition, renovation, and repair of health-care facilities. Use of an infection-control risk assessment is strongly supported before the start of these or any other activities expected to generate dust or water aerosols. Also reviewed in Part I are infection-control measures used to recover from catastrophic events (e.g., flooding, sewage spills, loss of electricity and ventilation, or disruption of water supply) and the limited effects of environmental surfaces, laundry, plants, animals, medical wastes, cloth furnishings, and carpeting on disease transmission in health-care facilities. Part III and Part IV of the full guidelines provide references (for the complete guideline) and appendices, respectively.

Part II (this report) contains recommendations for environmental infection control in health-care facilities, describing control measures for preventing infections associated with air, water, or other elements of the environment. These recommendations represent the views of different divisions within CDC's National Center for Infectious Diseases and the Healthcare Infection Control Practices Advisory Committee (HICPAC), a 12-member group that advises CDC on concerns related to the surveillance, prevention, and control of health-care-associated infections, primarily in U.S. health-care facilities. In 1999, HICPAC's infection-control focus was expanded from acute-care hospitals to all venues where health care is provided (e.g., outpatient surgical centers, urgent care centers, clinics, outpatient dialysis centers, physicians' offices, and skilled nursing facilities). The topics addressed in this report are applicable to the majority of health-care facilities in the United States. This report is intended for use primarily by infection-control practitioners, epidemiologists, employee health and safety personnel, engineers, facility managers, information systems professionals, administrators, environmental service professionals, and architects. Key recommendations include

- infection-control impact of ventilation system and water system performance;
- establishment of a multidisciplinary team to conduct infection-control risk assessment;
- use of dust-control procedures and barriers during construction, repair, renovation, or demolition;
- environmental infection-control measures for special areas with patients at high risk;
- use of airborne-particle sampling to monitor the effectiveness of air filtration and dust-control measures;

- procedures to prevent airborne contamination in operating rooms when infectious tuberculosis (TB) patients require surgery;
- guidance regarding appropriate indications for routine culturing of water as part of a comprehensive control program for legionellae;
- guidance for recovering from water-system disruptions, water leaks, and natural disasters (e.g., flooding);
- infection-control concepts for equipment using water from main lines (e.g., water systems for hemodialysis, ice machines, hydrotherapy equipment, dental unit water lines, and automated endoscope reprocessors);
- environmental surface cleaning and disinfection strategies with respect to antibiotic-resistant microorganisms;
- infection-control procedures for health-care laundry;
- use of animals in health care for activities and therapy;
- managing the presence of service animals in health-care facilities;
- infection-control strategies for when animals receive treatment in human health-care facilities; and
- a call to reinstate the practice of inactivating amplified cultures and stocks of microorganisms onsite during medical waste treatment.

Topics outside the scope of this report include 1) noninfectious adverse events (e.g., sick building syndrome), 2) environmental concerns in the home, 3) home health care, 4) terrorism, and 5) health-care--associated foodborne illness.

Wherever possible, the recommendations in this report are based on data from well-designed scientific studies. However, certain of these studies were conducted by using narrowly defined patient populations or specific health-care settings (e.g., hospitals versus long-term care facilities), making generalization of findings potentially problematic. Construction standards for hospitals or other health-care facilities may not apply to residential home-care units. Similarly, infection-control measures indicated for immunosuppressed patient care are usually not necessary in those facilities where such patients are not present.

Other recommendations were derived from knowledge gained during infectious disease investigations in health-care facilities, where successful termination of the outbreak was often the result of multiple interventions, the majority of which cannot be independently and rigorously evaluated. This is especially true for construction situations involving air or water.

Other recommendations were derived from empiric engineering concepts and may reflect industry standards rather than evidence-based conclusions. Where recommendations refer to guidance from the American Institute of Architects (AIA), the statements reflect standards intended for new construction or renovation. Existing structures and engineered systems are expected to be in continued compliance with those standards in effect at the time of construction or renovation.

Also, in the absence of scientific confirmation, certain infection-control recommendations that cannot be rigorously evaluated are based on strong theoretic rationale and suggestive evidence. Finally, certain recommendations are derived from existing federal regulations.

Performance Measurements

Infections caused by the microorganisms described in this guideline are rare events, and the effect of these recommendations on infection rates in a facility may not be readily measurable. Therefore, the following steps to measure performance are suggested to evaluate these recommendations:

1. Document whether infection-control personnel are actively involved in all phases of a health-care facility's demolition, construction, and renovation. Activities should include performing a risk assessment of the necessary types of construction barriers, and daily monitoring and documenting of the presence of negative airflow within the construction zone or renovation area.
2. Monitor and document daily the negative airflow in AII rooms and positive airflow in PE rooms, especially when patients are in these rooms.
3. Perform assays at least once a month by using standard quantitative methods for endotoxin in water used to reprocess hemodialyzers, and for heterotrophic and mesophilic bacteria in water used to

prepare dialysate and for hemodialyzer reprocessing.

4. Evaluate possible environmental sources (e.g., water, laboratory solutions, or reagents) of specimen contamination when nontuberculous mycobacteria (NTM) of unlikely clinical importance are isolated from clinical cultures. If environmental contamination is found, eliminate the probable mechanisms.
5. Document policies to identify and respond to water damage. Such policies should result in either repair and drying of wet structural or porous materials within 72 hours, or removal of the wet material if drying is unlikely within 72 hours.

Updates to Previous Recommendations

Contributors to this report reviewed primarily English-language manuscripts identified from reference searches using the National Library of Medicine's MEDLINE, bibliographies of published articles, and infection-control textbooks. All the recommendations may not reflect the opinions of all reviewers. This report updates the following published guidelines and recommendations:

CDC. Guideline for handwashing and hospital environmental control. MMWR 1998;37(No. 24). Replaces sections on microbiologic sampling, laundry, infective waste, and housekeeping.

Tablan OC, Anderson LJ, Arden NH, et al., Hospital Infection Control Practices Advisory Committee. Guideline for prevention of nosocomial pneumonia. Infect Control Hosp Epidemiol 1994;15:587--627. Updates and expands environmental infection-control information for aspergillosis and Legionnaires disease; online version incorporates Appendices B, C, and D addressing environmental control and detection of *Legionella* spp.

CDC. Guidelines for preventing the transmission of *Mycobacterium tuberculosis* in health-care facilities. MMWR 1994;43(No. RR13). Provides supplemental information on engineering controls.

CDC. Recommendations for preventing the spread of vancomycin resistance: recommendations of the Hospital Infection Control Practices Advisory Committee (HICPAC). MMWR 1995;44(No. RR12). Supplements environmental infection-control information from the section, Hospitals with Endemic VRE or Continued VRE Transmission.

Garner JS, Hospital Infection Control Practices Advisory Committee. Guideline for isolation precautions in hospitals. Infect Control Hosp Epidemiol 1996;17:53--80. Supplements and updates topics in Part II --- Recommendations for Isolation Precautions in Hospitals (linen and laundry, routine and terminal cleaning, airborne precautions).

Mangram AJ, Horan TC, Pearson ML, Silver LC, Jarvis WR, Hospital Infection Control Practices Advisory Committee. Guideline for prevention of surgical site infection. Infect Control Hosp Epidemiol 1999;4:250--78. Updates operating room ventilation and surface cleaning/disinfection recommendations from the section, Intraoperative Issues: Operating Room Environment.

U.S. Public Health Service, Infectious Diseases Society of America, Prevention of Opportunistic Infections Working Group. USPHS/IDSA guidelines for the prevention of opportunistic infections in persons infected with human immunodeficiency virus. Infect Dis Obstet Gynecol 2002; 10:3--64. Supplements information regarding patient interaction with pets and animals in the home.

CDC, Infectious Diseases Society of America, American Society of Blood and Marrow Transplantation. Guidelines for preventing opportunistic infections among hematopoietic stem cell transplant recipients. Cytotherapy 2001;3:41--54. Supplements and updates the section, Hospital Infection Control.

Key Terms

Airborne infection isolation (AII) refers to the isolation of patients infected with organisms spread via airborne droplet nuclei $<5\ \mu\text{m}$ in diameter. This isolation area receives numerous air changes per hour (ACH) (≥ 12 ACH for new construction as of 2001; ≥ 6 ACH for construction before 2001), and is under negative pressure, such that the direction of the air flow is from the outside adjacent space (e.g., the corridor) into the room. The air in an AII room is preferably exhausted to the outside, but may be

recirculated provided that the return air is filtered through a high-efficiency particulate air (HEPA) filter. The use of personal respiratory protection is also indicated for persons entering these rooms when caring for TB or smallpox patients and for staff who lack immunity to airborne viral diseases (e.g., measles or varicella zoster virus [VZV] infection).

Protective environment (PE) is a specialized patient-care area, usually in a hospital, with a positive air flow relative to the corridor (i.e., air flows from the room to the outside adjacent space). The combination of HEPA filtration, high numbers of air changes per hour (≥ 12 ACH), and minimal leakage of air into the room creates an environment that can safely accommodate patients who have undergone allogeneic hematopoietic stem cell transplant (HSCT).

Immunocompromised patients are those patients whose immune mechanisms are deficient because of immunologic disorders (e.g., human immunodeficiency virus [HIV] infection or congenital immune deficiency syndrome), chronic diseases (e.g., diabetes, cancer, emphysema, or cardiac failure), or immunosuppressive therapy (e.g., radiation, cytotoxic chemotherapy, anti-rejection medication, or steroids). Immunocompromised patients who are identified as high-risk patients have the greatest risk of infection caused by airborne or waterborne microorganisms. Patients in this subset include persons who are severely neutropenic for prolonged periods of time (i.e., an absolute neutrophil count [ANC] of ≤ 500 cells/mL), allogeneic HSCT patients, and those who have received the most intensive chemotherapy (e.g., childhood acute myelogenous leukemia patients).

Abbreviations

AAMI Association for the Advancement of Medical Instrumentation

ACH air changes per hour

AER automated endoscope reprocessor

AHJ authority having jurisdiction

AIA American Institute of Architects

AIH airborne infection isolation

ANSI American National Standards Institute

ASHRAE American Society of Heating, Refrigeration, and Air-Conditioning Engineers

BMBL Biosafety in Microbiological and Biomedical Laboratories (CDC/National Institutes of Health)

CFR Code of Federal Regulations

CJD Creutzfeldt-Jakob disease

CPL compliance document (OSHA)

DFA direct fluorescence assay

DHHS U.S. Department of Health and Human Services

DOT U.S. Department of Transportation

EC environment of care

EPA U. S. Environmental Protection Agency

FDA U.S. Food and Drug Administration

HBV hepatitis B virus

HEPA high efficiency particulate air

HIV human immunodeficiency virus

HSCT hematopoietic stem cell transplant

HVAC heating, ventilation, air conditioning

ICRA infection-control risk assessment

JCAHO Joint Commission on Accreditation of Healthcare Organizations

NaOH sodium hydroxide

NTM nontuberculous mycobacteria

OSHA Occupational Safety and Health Administration

PE protective environment

PPE personal protective equipment

TB tuberculosis

USC United States Code

USDA U.S. Department of Agriculture

UV ultraviolet

UVGI ultraviolet germicidal irradiation

VHF viral hemorrhagic fever

VRE vancomycin-resistant *Enterococcus*

VRSA vancomycin-resistant *Staphylococcus aureus*

VZV varicella zoster virus

Recommendations for Environmental Infection Control in Health-Care Facilities

Rationale for Recommendations

As in previous CDC guidelines, each recommendation is categorized on the basis of existing scientific data, theoretic rationale, applicability, and possible economic effect. The recommendations are evidence-based wherever possible. However, certain recommendations are derived from empiric infection-control or engineering principles, theoretic rationale, or from experience gained from events that cannot be readily studied (e.g., floods).

The HICPAC system for categorizing recommendations has been modified to include a category for engineering standards and actions required by state or federal regulations. Guidelines and standards published by the AIA, American Society of Heating, Refrigeration, and Air-Conditioning Engineers (ASHRAE), and the Association for the Advancement of Medical Instrumentation (AAMI) form the basis of certain recommendations. These standards reflect a consensus of expert opinions and extensive consultation with agencies of the U.S. Department of Health and Human Services. Compliance with these standards is usually voluntary. However, state and federal governments often adopt these standards as regulations. For example, the standards from AIA regarding construction and design of new or renovated health-care facilities, have been adopted by reference by >40 states. Certain recommendations have two

category ratings (e.g., Categories IA and IC or Categories IB and IC), indicating the recommendation is evidence-based as well as a standard or regulation.

Rating Categories

Recommendations are rated according to the following categories:

Category IA. Strongly recommended for implementation and strongly supported by well-designed experimental, clinical, or epidemiologic studies.

Category IB. Strongly recommended for implementation and supported by certain experimental, clinical, or epidemiologic studies and a strong theoretic rationale.

Category IC. Required by state or federal regulation, or representing an established association standard. (Note: Abbreviations for governing agencies and regulatory citations are listed where appropriate. Recommendations from regulations adopted at state levels are also noted. Recommendations from AIA guidelines cite the appropriate sections of the standards.)

Category II. Suggested for implementation and supported by suggestive clinical or epidemiologic studies, or a theoretic rationale.

Unresolved issue. No recommendation is offered. No consensus or insufficient evidence exists regarding efficacy.

Recommendations --- Air

I. Air-Handling Systems in Health-Care Facilities

- A. Use AIA guidelines as minimum standards where state or local regulations are not in place for design and construction of ventilation systems in new or renovated health-care facilities. Ensure that existing structures continue to meet the specifications in effect at the time of construction (*I*). Category IC (AIA: 1.1.A, 5.4)
- B. Monitor ventilation systems in accordance with engineers' and manufacturers' recommendations to ensure preventive engineering, optimal performance for removal of particulates, and elimination of excess moisture (*I--8*). Category IB, IC (AIA: 7.2, 7.31.D, 8.31.D, 9.31.D, 10.31.D, 11.31.D, Environmental Protection Agency [EPA] guidance)
 1. Ensure that heating, ventilation, air conditioning (HVAC) filters are properly installed and maintained to prevent air leakages and dust overloads (*2,4,6,9*). Category IB
 2. Monitor areas with special ventilation requirements (e.g., AII or PE) for ACH, filtration, and pressure differentials (*1,7,8,10--26*). Category IB, IC (AIA: 7.2.C7, 7.2.D6)
 - a. Develop and implement a maintenance schedule for ACH, pressure differentials, and filtration efficiencies by using facility-specific data as part of the multidisciplinary risk assessment. Take into account the age and reliability of the system.
 - b. Document these parameters, especially the pressure differentials.
 3. Engineer humidity controls into the HVAC system and monitor the controls to ensure adequate moisture removal (*I*). Category IC (AIA: 7.31.D9)
 - a. Locate duct humidifiers upstream from the final filters.
 - b. Incorporate a water-removal mechanism into the system.
 - c. Locate all duct takeoffs sufficiently downstream from the humidifier so that moisture is completely absorbed.
 4. Incorporate steam humidifiers, if possible, to reduce potential for microbial proliferation within the system, and avoid use of cool-mist humidifiers. Category II
 5. Ensure that air intakes and exhaust outlets are located properly in construction of new facilities and

renovation of existing facilities (1,27). Category IC (AIA: 7.31.D3, 8.31.D3, 9.31.D3, 10.31.D3, 11.31.D3)

- a. Locate exhaust outlets >25 ft from air-intake systems.
- b. Locate outdoor air intakes ≥ 6 ft above ground or ≥ 3 ft above roof level.
- c. Locate exhaust outlets from contaminated areas above roof level to minimize recirculation of exhausted air.

6. Maintain air intakes and inspect filters periodically to ensure proper operation (1,11--16,27). Category IC (AIA: 7.31.D8)

7. Bag dust-filled filters immediately upon removal to prevent dispersion of dust and fungal spores during transport within the facility (4,28). Category IB

- a. Seal or close the bag containing the discarded filter.
- b. Discard spent filters as regular solid waste, regardless of the area from which they were removed (28).

8. Remove bird roosts and nests near air intakes to prevent mites and fungal spores from entering the ventilation system (27,29,30). Category IB

9. Prevent dust accumulation by cleaning air-duct grilles in accordance with facility-specific procedures and schedules and when rooms are not occupied by patients (1,10--16).

Category IC, II (AIA: 7.31.D10)

10. Periodically measure output to monitor system function; clean ventilation ducts as part of routine HVAC maintenance to ensure optimum performance (1,31,32). Category IC, II (AIA: 7.31.D10)

C. Use portable, industrial-grade HEPA filter units capable of filtration rates in the range of 300--800 ft³/min to augment removal of respirable particles as needed (33). Category II

1. Select portable HEPA filters that can recirculate all or nearly all of the room air and provide the equivalent of ≥ 12 ACH (34). Category II

2. Portable HEPA filter units placed in construction zones can be used later in patient-care areas, provided all internal and external surfaces are cleaned, and the filter replaced or its performance verified by appropriate particle testing. Category II

3. Situate portable HEPA units with the advice of facility engineers to ensure that all room air is filtered (34). Category II

4. Ensure that fresh-air requirements for the area are met (33,35). Category II

D. Follow appropriate procedures for use of areas with through-the-wall ventilation units (1). Category IC (AIA: 8.31.D1, 8.31.D8, 9.31.D23, 10.31.D18, 11.31.D15)

1. Do not use such areas as PE rooms (1). Category IC (AIA: 7.2.D3)

2. Do not use a room with a through-the-wall ventilation unit as an AII room unless it can be demonstrated that all required AII engineering controls are met (1,34). Category IC (AIA: 7.2.C3)

E. Conduct an infection-control risk assessment (ICRA) and provide an adequate number of AII and PE rooms (if required) or other areas to meet the needs of the patient population (1,2,7,8,17,19, 20,34,36--43). Category IA, IC (AIA: 7.2.C, 7.2.D)

F. When ultraviolet germicidal irradiation (UVGI) is used as a supplemental engineering control, install fixtures 1) on the wall near the ceiling or suspended from the ceiling as an upper air unit; 2) in the air-return duct of an AII area; or 3) in designated enclosed areas or booths for sputum induction (34). Category II

G. Seal windows in buildings with centralized HVAC systems, including PE areas (1,3,44). Category IB, IC (AIA: 7.2.D3)

H. Keep emergency doors and exits from PE rooms closed except during an emergency; equip emergency doors and exits with alarms. Category II

- I. Develop a contingency plan for backup capacity in the event of a general power failure (45). Category IC (Joint Commission on Accreditation of Healthcare Organizations [JCAHO]: Environment of Care [EC] 1.4)

1. Emphasize restoration of appropriate air quality and ventilation conditions in All rooms, PE rooms, operating rooms, emergency departments, and intensive care units (1,45).

Category IC (AIA: 1.5.A1; JCAHO: EC 1.4)

2. Deploy infection-control procedures to protect occupants until power and systems functions are restored (1,36,45). Category IC (AIA: 5.1, 5.2; JCAHO: EC 1.4)

- J. Do not shut down HVAC systems in patient-care areas except for maintenance, repair, testing of emergency backup capacity, or new construction (1,46). Category IB, IC (AIA: 5.1, 5.2.B, C)

1. Coordinate HVAC system maintenance with infection-control staff and relocate immunocompromised patients if necessary (1). Category IC (AIA: 5.1, 5.2)

2. Provide backup emergency power and air-handling and pressurization systems to maintain filtration, constant ACH, and pressure differentials in PE rooms, All rooms, operating rooms, and other critical-care areas (1,37,47). Category IC (AIA: 5.1, 5.2)

3. For areas not served by installed emergency ventilation and backup systems, use portable units and monitor ventilation parameters and patients in those areas (33). Category II

4. Coordinate system startups with infection-control staff to protect patients in PE rooms from bursts of fungal spores (1,3,37,47). Category IC (AIA: 5.1, 5.2)

5. Allow sufficient time for ACH to clean the air once the system is operational (Table 1) (1,33). Category IC (AIA: 5.1, 5.2)

- K. HVAC systems serving offices and administrative areas may be shut down for energy conservation purposes, but the shutdown must not alter or adversely affect pressure differentials maintained in laboratories or critical-care areas with specific ventilation requirements (i.e., PE rooms, All rooms, operating rooms). Category II

- L. Whenever possible, avoid inactivating or shutting down the entire HVAC system, especially in acute-care facilities. Category II

- M. Whenever feasible, design and install fixed backup ventilation systems for new or renovated construction of PE rooms, All rooms, operating rooms, and other critical-care areas identified by ICRA (1). Category IC (AIA: 1.5.A1)

II. Construction, Renovation, Remediation, Repair, and Demolition

- A. Establish a multidisciplinary team that includes infection-control staff to coordinate demolition, construction, and renovation projects and consider proactive preventive measures at the inception; produce and maintain summary statements of the team's activities (1,9,11--16,38,48--51). Category IB, IC (AIA: 5.1)

- B. Educate both the construction team and health-care staff in immunocompromised patient-care areas regarding the airborne infection risks associated with construction projects, dispersal of fungal spores during such activities, and methods to control the dissemination of fungal spores (11--16,27,50,52--56). Category IB

- C. Incorporate mandatory adherence agreements for infection control into construction contracts, with penalties for noncompliance and mechanisms to ensure timely correction of problems (1,11,13--16,27,50). Category IC (AIA: 5.1)

- D. Establish and maintain surveillance for airborne environmental disease (e.g., aspergillosis) as appropriate during construction, renovation, repair, and demolition activities to ensure the health and safety of immunocompromised patients (27,57--59). Category IB

1. Using active surveillance, monitor for airborne infections in immunocompromised patients (27,37,57,58). Category IB

2. Periodically review the facility's microbiologic, histopathologic, and postmortem data to identify additional cases (27,37,57,58). Category IB

3. If cases of aspergillosis or other health-care--associated airborne fungal infections occur, aggressively pursue the diagnosis with tissue biopsies and cultures as feasible (11,13--

E. Implement infection-control measures relevant to construction, renovation, maintenance, demolition, and repair (1,16,49,50,60). Category IB, IC (AIA: 5.1, 5.2)

1. Before the project gets under way, perform an ICRA to define the scope of the activity and the need for barrier measures (1,11,13--16,48--51,60). Category IB, IC (AIA: 5.1)

a. Determine if immunocompromised patients may be at risk for exposure to fungal spores from dust generated during the project (13--16,48,51).

b. Develop a contingency plan to prevent such exposures (13--16,48,51).

2. Implement infection-control measures for external demolition and construction activities (11,13--16,50,61,62). Category IB

a. Determine if the facility can operate temporarily on recirculated air; if feasible, seal off adjacent air intakes.

b. If this is not possible or practical, check the low-efficiency (roughing) filter banks frequently and replace as needed to avoid buildup of particulates.

c. Seal windows and reduce wherever possible other sources of outside air intrusion (e.g., open doors in stairwells and corridors), especially in PE areas.

3. Avoid damaging the underground water system (i.e., buried pipes) to prevent soil and dust contamination of the water (1,63). Category IB, IC (AIA: 5.1)

4. Implement infection-control measures for internal construction activities (1,11,13--16,48--50,64). Category IB, IC (AIA: 5.1, 5.2)

a. Construct barriers to prevent dust from construction areas from entering patient-care areas; ensure that barriers are impermeable to fungal spores and in compliance with local fire codes (1,45,48,49,55,64--66).

b. Seal off and block return air vents if rigid barriers are used for containment (1,16,50).

c. Implement dust-control measures on surfaces and divert pedestrian traffic away from work zones (1,48,49,64).

d. Relocate patients whose rooms are adjacent to work zones, depending on their immune status, the scope of the project, the potential for generation of dust or water aerosols, and the methods used to control these aerosols (1,64,65).

5. Perform those engineering and work-site related infection-control measures as needed for internal construction, repairs, and renovations (1,48,49,51,64,66). Category IB, IC (AIA: 5.1, 5.2)

a. Ensure proper operation of the air-handling system in the affected area after erection of barriers and before the room or area is set to negative pressure (39,47,50,64). Category IB

b. Create and maintain negative air pressure in work zones adjacent to patient-care areas and ensure that required engineering controls are maintained (1,48,49,51,64,66).

c. Monitor negative airflow inside rigid barriers (1,67).

d. Monitor barriers and ensure integrity of the construction barriers; repair gaps or breaks in barrier joints (1,65,66,68).

e. Seal windows in work zones if practical; use window chutes for disposal of large pieces of debris as needed, but ensure that the negative pressure differential for the area is maintained (1,13,48).

f. Direct pedestrian traffic from construction zones away from patient-care areas to minimize dispersion of dust (1,13--16,44,48--51,64).

g. Provide construction crews with 1) designated entrances, corridors, and elevators wherever practical; 2) essential services (e.g., toilet facilities) and convenience services (e.g., vending machines); 3) protective clothing (e.g., coveralls, footgear, and headgear) for travel to patient-care areas; and 4) a space or anteroom for changing clothing and storing

equipment (1,11,13--16,50).

h. Clean work zones and their entrances daily by 1) wet-wiping tools and tool carts before their removal from the work zone; 2) placing mats with tacky surfaces inside the entrance; and 3) covering debris and securing this covering before removing debris from the work zone (1,11,13--16,50).

i. In patient-care areas, for major repairs that include removal of ceiling tiles and disruption of the space above the false ceiling, use plastic sheets or prefabricated plastic units to contain dust; use a negative pressure system within this enclosure to remove dust; and either pass air through an industrial-grade, portable HEPA filter capable of filtration rates of 300--800 ft³/min., or exhaust air directly to the outside (16,50,64,67,69).

j. Upon completion of the project, clean the work zone according to facility procedures, and install barrier curtains to contain dust and debris before removing rigid barriers (1,11,13--16,48--50).

k. Flush the water system to clear sediment from pipes to minimize waterborne microorganism proliferation (1,63).

l. Restore appropriate ACH, humidity, and pressure differential; clean or replace air filters; dispose of spent filters (3,4,28,47).

F. Use airborne-particle sampling as a tool to evaluate barrier integrity (3,70). Category II

G. Commission the HVAC system for newly constructed health-care facilities and renovated spaces before occupancy and use, with emphasis on ensuring proper ventilation for operating rooms, AII rooms, and PE areas (1,70--72). Category IC (AIA: 5.1; ASHRAE: 1-1996)

H. No recommendation is offered regarding routine microbiologic air sampling before, during, or after construction, or before or during occupancy of areas housing immunocompromised patients (9,48,49,51,64,73,74). Unresolved issue

I. If a case of health-care--acquired aspergillosis or other opportunistic environmental airborne fungal disease occurs during or immediately after construction, implement appropriate follow-up measures (40,48,75--78). Category IB

1. Review pressure-differential monitoring documentation to verify that pressure differentials in the construction zone and in PE rooms are appropriate for their settings (1,40,78).

Category IB, IC (AIA: 5.1)

2. Implement corrective engineering measures to restore proper pressure differentials as needed (1,40,78). Category IB, IC (AIA: 5.1)

3. Conduct a prospective search for additional cases and intensify retrospective epidemiologic review of the hospital's medical and laboratory records (27,48,76,79,80). Category IB

4. If no epidemiologic evidence of ongoing transmission exists, continue routine maintenance in the area to prevent health-care--acquired fungal disease (27,75). Category IB

J. If no epidemiologic evidence exists of ongoing transmission of fungal disease, conduct an environmental assessment to find and eliminate the source (11,13--16,27,44,49--51,60,81). Category IB

1. Collect environmental samples from potential sources of airborne fungal spores, preferably by using a high-volume air sampler rather than settle plates (2,4,11,13--16,27,44,49,50,64,65,81--86). Category IB

2. If either an environmental source of airborne fungi or an engineering problem with filtration or pressure differentials is identified, promptly perform corrective measures to eliminate the source and route of entry (49,60). Category IB

3. Use an EPA-registered antifungal biocide (e.g., copper-8-quinolinolate) for decontaminating structural materials (16,61,66,87). Category IB

4. If an environmental source of airborne fungi is not identified, review infection-control measures, including engineering controls, to identify potential areas for correction or improvement (88,89). Category IB

5. If possible, perform molecular subtyping of *Aspergillus* spp. isolated from patients and the environment to compare their strain identities (90--94). Category II

- K. If air-supply systems to high-risk areas (e.g., PE rooms) are not optimal, use portable, industrial-grade HEPA filters on a temporary basis until rooms with optimal air-handling systems become available (1,13--16,27,50). Category II

III. Infection Control and Ventilation Requirements for PE rooms

- A. Minimize exposures of severely immunocompromised patients (e.g., solid-organ transplant patients or allogeneic neutropenic patients) to activities that might cause aerosolization of fungal spores (e.g., vacuuming or disruption of ceiling tiles) (37,48,51,73). Category IB
- B. Minimize the length of time that immunocompromised patients in PE are outside their rooms for diagnostic procedures and other activities (37,62). Category IB
- C. Provide respiratory protection for severely immunocompromised patients when they must leave PE for diagnostic procedures and other activities; consult the most recent revision of CDC's *Guideline for Prevention of Health-Care--Associated Pneumonia* for information regarding the appropriate type of respiratory protection. (27,37). Category II
- D. Incorporate ventilation engineering specifications and dust-controlling processes into the planning and construction of new PE units (Figure 1). Category IB, IC
 - 1. Install central or point-of-use HEPA filters for supply (incoming) air (1,2,27,48,56,70, 80,82,85,95--102). Category IB, IC (AIA: 5.1, 5.2, 7.2.D)
 - 2. Ensure that rooms are well-sealed by 1) properly constructing windows, doors, and intake and exhaust ports; 2) maintaining ceilings that are smooth and free of fissures, open joints, and crevices; 3) sealing walls above and below the ceiling; and 4) monitoring for leakage and making any necessary repairs (1,27,44,100,101). Category IB, IC (AIA: 7.2.D3)
 - 3. Ventilate the room to maintain ≥ 12 ACH (1,27,37,100,101,103). Category IC (AIA: 7.2.D)
 - 4. Locate air supply and exhaust grilles so that clean, filtered air enters from one side of the room, flows across the patient's bed, and exits from the opposite side of the room (1,27,100,101). Category IC (AIA: 7.31.D1)
 - 5. Maintain positive room air pressure (≥ 2.5 Pa [0.01-inch water gauge]) in relation to the corridor (1,3,27,100,101). Category IB, IC (AIA: Table 7.2)
 - 6. Maintain airflow patterns and monitor these on a daily basis by using permanently installed visual means of detecting airflow in new or renovated construction, or by using other visual methods (e.g., flutter strips or smoke tubes) in existing PE units. Document the monitoring results (1,13). Category IC (AIA: 7.2.D6)
 - 7. Install self-closing devices on all room exit doors in PE rooms (1). Category IC (AIA: 7.2.D4)
- E. Do not use laminar air flow systems in newly constructed PE rooms (99,101). Category II
- F. Take measures to protect immunocompromised patients who would benefit from a PE room and who also have an airborne infectious disease (e.g., acute VZV infection or tuberculosis).
 - 1. Ensure that the patient's room is designed to maintain positive pressure.
 - 2. Use an anteroom to ensure appropriate air-balance relationships and provide independent exhaust of contaminated air to the outside, or place a HEPA filter in the exhaust duct if the return air must be recirculated (1,100) (Figure 2). Category IC (AIA: 7.2.D1, A7.2.D)
 - 3. If an anteroom is not available, place the patient in AII and use portable, industrial-grade HEPA filters to enhance filtration of spores in the room (33). Category II
- G. Maintain backup ventilation equipment (e.g., portable units for fans or filters) for emergency provision of required ventilation for PE areas and take immediate steps to restore the fixed ventilation system (1,37,47). Category IC (AIA: 5.1)

IV. Infection-Control and Ventilation Requirements for AII Rooms

- A. Incorporate certain specifications into the planning and construction or renovation of AII units (1,34,100,101,104) (Figure 3). Category IB, IC
 - 1. Maintain continuous negative air pressure (2.5 Pa [0.01 inch water gauge]) in relation to the air pressure in the corridor; monitor air pressure periodically, preferably daily, with

audible manometers or smoke tubes at the door (for existing AII rooms), or with a permanently installed visual monitoring mechanism. Document the results of monitoring

(1,100,101). Category IC (AIA: 7.2.C7, Table 7.2)

2. Ensure that rooms are well-sealed by properly constructing windows, doors, and air-intake and exhaust ports; when monitoring indicates air leakage, locate the leak and make necessary repairs (1,99,100). Category IB, IC (AIA: 7.2.C3)

3. Install self-closing devices on all AII room exit doors (1). Category IC (AIA: 7.2.C4)

4. Provide ventilation to ensure ≥ 12 ACH for renovated rooms and new rooms, and ≥ 6 ACH for existing AII rooms (1,34,104). Category IB, IC (AIA: Table 7.2)

5. Direct exhaust air to the outside, away from air-intake and populated areas. If this is not practical, air from the room can be recirculated after passing through a HEPA filter (1,34).

Category IC (AIA: Table 7.2)

B. Where supplemental engineering controls for air cleaning are indicated from a risk assessment of the AII area, install UVGI units in the exhaust air ducts of the HVAC system to supplement HEPA filtration or install UVGI fixtures on or near the ceiling to irradiate upper room air (34). Category II

C. Implement environmental infection-control measures for persons with diagnosed or suspected airborne infectious diseases.

1. Use AII rooms for patients with or suspected of having an airborne infection who also require cough-inducing procedures, or use an enclosed booth that is engineered to provide 1)

≥ 12 ACH; 2) air supply and exhaust rate sufficient to maintain a 2.5 Pa (0.01-inch water gauge) negative pressure difference with respect to all surrounding spaces with an exhaust

rate of ≥ 50 ft³/min; and 3) air exhausted directly outside away from air intakes and traffic or exhausted after HEPA filtration before recirculation (1,34,105--107). Category IB, IC

(AIA: 7.15.E, 7.31.D23, 9.10, Table 7.2)

2. Although airborne spread of viral hemorrhagic fever (VHF) has not been documented in a health-care setting, prudence dictates placing a VHF patient in an AII room, preferably with an anteroom, to reduce the risk of occupational exposure to aerosolized infectious material in blood, vomitus, liquid stool, and respiratory secretions present in large amounts during the end stage of a patient's illness (108--110). Category II

a. If an anteroom is not available, use portable, industrial-grade HEPA filters in the patient's room to provide additional ACH equivalents for removing airborne particulates.

b. Ensure that health-care workers wear face shields or goggles with appropriate respirators when entering the rooms of VHF patients with prominent cough, vomiting, diarrhea, or hemorrhage (109).

3. Place smallpox patients in negative pressure rooms at the onset of their illness, preferably using a room with an anteroom, if available (36). Category II

D. No recommendation is offered regarding negative pressure or isolation for patients with *Pneumocystis carinii* pneumonia (111--113). Unresolved issue.

E. Maintain backup ventilation equipment (e.g., portable units for fans or filters) for emergency provision of ventilation requirements for AII rooms, and take immediate steps to restore the fixed ventilation system (1,34,47). Category IC (AIA: 5.1)

V. Infection-Control and Ventilation Requirements for Operating Rooms

A. Implement environmental infection-control and ventilation measures for operating rooms.

1. Maintain positive-pressure ventilation with respect to corridors and adjacent areas (1,114,115). Category IB, IC (AIA: Table 7.2)

2. Maintain ≥ 15 ACH, of which ≥ 3 ACH should be fresh air (1,116,117). Category IC (AIA: Table 7.2)

3. Filter all recirculated and fresh air through the appropriate filters, providing 90% efficiency (dust-spot testing) at a minimum (1,118). Category IC (AIA: Table 7.3)

4. In rooms not engineered for horizontal laminar airflow, introduce air at the ceiling and exhaust air

near the floor (1,115,119). Category IC (AIA: 7.31.D4)

5. Do not use ultraviolet (UV) lights to prevent surgical-site infections (115,120--126). Category IB

6. Keep operating room doors closed except for the passage of equipment, personnel, and patients, and limit entry to essential personnel (127,128). Category IB

B. Follow precautionary procedures for infectious TB patients who also require emergency surgery (34,129,130). Category IB, IC

1. Use an N95 respirator approved by the National Institute for Occupational Safety and Health without exhalation valves in the operating room (129,131). Category IC (Occupational

Safety and Health Administration [OSHA]; 29 Code of Federal Regulations [CFR] 1910.134,139)

2. Intubate the patient in either the AII room or the operating room; if intubating the patient in the operating room, do not allow the doors to open until 99% of the airborne contaminants are removed (Table 1) (34,117). Category IB

3. When anesthetizing a patient with confirmed or suspected TB, place a bacterial filter between the anesthesia circuit and patient's airway to prevent contamination of anesthesia equipment or discharge of tubercle bacilli into the ambient air (130,132). Category IB

4. Extubate and allow the patient to recover in an AII room (34,117). Category IB

5. If the patient has to be extubated in the operating room, allow adequate time for ACH to clean 99% of airborne particles from the air (Table 1), because extubation is a cough-producing procedure (34,117). Category IB

C. Use portable, industrial-grade HEPA filters temporarily for supplemental air cleaning during intubation and extubation for TB patients who require surgery (33,34,117). Category II

1. Position the units appropriately so that all room air passes through the filter; obtain engineering consultation to determine the appropriate placements (34). Category II

2. Switch the portable unit off during the surgical procedure. Category II

3. Provide fresh air as per ventilation standards for operating rooms; portable units do not meet the requirements for the number of fresh ACH (1,33,133). Category II

D. If possible, schedule TB patients as the last surgical cases of the day to maximize the time available for removal of airborne contamination. Category II

E. No recommendation is offered for performing orthopedic implant operations in rooms supplied with laminar airflow (118,120). Unresolved issue

F. Maintain backup ventilation equipment (e.g., portable units for fans or filters) for emergency ventilation of operating rooms, and take immediate steps to restore the fixed ventilation system (1,47,131,134). Category IB, IC (AIA: 5.1)

VI. Other Potential Infectious Aerosol Hazards in Health-Care Facilities

A. In settings where surgical lasers are used, wear appropriate personal protective equipment (PPE), including N95 or N100 respirators, to minimize exposure to laser plumes (129,135,136). Category IC (OSHA; 29 CFR 1910.134,139)

B. Use central wall suction units with in-line filters to evacuate minimal laser plumes (135--138). Category II

C. Use a mechanical smoke evacuation system with a high-efficiency filter to manage the generation of large amounts of laser plume, when ablating tissue infected with human papilloma virus (HPV) or performing procedures on a patient with extrapulmonary TB (34,136,137,139--141). Category II

Recommendations --- Water

I. Controlling the Spread of Waterborne Microorganisms

A. Practice hand hygiene to prevent the hand transfer of waterborne pathogens, and use barrier precautions (e.g., gloves) as defined by other guidelines (36,142--146). Category IA

B. Eliminate contaminated water or fluid environmental reservoirs (e.g., in equipment or solutions) wherever possible (142,147). Category IB

- C. Clean and disinfect sinks and wash basins on a regular basis by using an EPA-registered product as set by facility policies. Category II
- D. Evaluate for possible environmental sources (e.g., potable water) of specimen contamination when waterborne microorganisms (e.g., NTM) of unlikely clinical importance are isolated from clinical cultures (e.g., specimens collected aseptically from sterile sites or, if postprocedural, colonization after use of tap water in patient care) (148--151). Category IB
- E. Avoid placing decorative fountains and fish tanks in patient-care areas; ensure disinfection and fountain maintenance if decorative fountains are used in public areas of the health-care facility (152). Category IB

II. Routine Prevention of Waterborne Microbial Contamination Within the Distribution System

- A. Maintain hot water temperature at the return at the highest temperature allowable by state regulations or codes, preferably $\geq 124^{\circ}\text{F}$ ($\geq 51^{\circ}\text{C}$), and maintain cold water temperature at $< 68^{\circ}\text{F}$ ($< 20^{\circ}\text{C}$) (27, 153). Category IC (States; ASHRAE: 12:2000)
- B. If the hot water temperature can be maintained at $\geq 124^{\circ}\text{F}$ ($\geq 51^{\circ}\text{C}$), explore engineering options (e.g., installing preset thermostatic valves in point-of-use fixtures) to help minimize the risk of scalding (153). Category II
- C. When state regulations or codes do not allow hot water temperatures above the range of 105°F -- 120°F (40.6°C -- 49°C) for hospitals or 95°F -- 110°F (35°C -- 43.3°C) for nursing care facilities or when buildings cannot be retrofitted for thermostatic mixing valves, follow either of these alternative preventive measures to minimize the growth of *Legionella* spp. in water systems. Category II
 - 1. Periodically increase the hot water temperature to $\geq 150^{\circ}\text{F}$ ($\geq 66^{\circ}\text{C}$) at the point of use (153). Category II
 - 2. Alternatively, chlorinate the water and then flush it through the system (153--155). Category II
- D. Maintain constant recirculation in hot-water distribution systems serving patient-care areas (1). Category IC (AIA: 7.31.E.3)

III. Remediation Strategies for Distribution System Repair or Emergencies

- A. Whenever possible, disconnect the ice machine before planned water disruptions. Category II
- B. Prepare a contingency plan to estimate water demands for the entire facility in advance of significant water disruptions (i.e., those expected to result in extensive and heavy microbial or chemical contamination of the potable water), sewage intrusion, or flooding (45, 156). Category IC (JCAHO: EC 1.4)
- C. When a significant water disruption or an emergency occurs, adhere to any advisory to boil water issued by the municipal water utility (157). Category IB, IC (Municipal order)
 - 1. Alert patients, families, staff, and visitors not to consume water from drinking fountains, ice, or drinks made from municipal tap water, while the advisory is in effect, unless the water has been disinfected (e.g., by bringing to a rolling boil for ≥ 1 minute) (157). Category IB, IC (Municipal order)
 - 2. After the advisory is lifted, run faucets and drinking fountains at full flow for ≥ 5 minutes, or use high-temperature water flushing or chlorination (153, 157). Category IC, II (Municipal order; ASHRAE: 12:2000)
- D. Maintain a high level of surveillance for waterborne disease among patients after a boil water advisory is lifted. Category II
- E. Corrective decontamination of the hot water system might be necessary after a disruption in service or a cross-connection with sewer lines has occurred.
 - 1. Decontaminate the system when the fewest occupants are present in the building (e.g., nights or weekends) (27, 153). Category IC (ASHRAE: 12:2000)
 - 2. If using high-temperature decontamination, raise the hot-water temperature to 160°F -- 170°F (71°C --

-77°C) and maintain that level while progressively flushing each outlet around the system for ≥ 5 minutes (27,153). Category IC (ASHRAE: 12:2000)

3. If using chlorination, add enough chlorine, preferably overnight, to achieve a free chlorine residual of ≥ 2 mg/L (≥ 2 ppm) throughout the system (153). Category IC (ASHRAE: 12:2000)

a. Flush each outlet until chlorine odor is detected.

b. Maintain the elevated chlorine concentration in the system for ≥ 2 (but ≤ 24 hrs).

4. Use a thorough flushing of the water system instead of chlorination if a highly chlorine-resistant microorganism (e.g., *Cryptosporidium* spp.) is suspected as the water contaminant.

Category II

F. Flush and restart equipment and fixtures according to manufacturer's instructions. Category II

G. Change the pretreatment filter and disinfect the dialysis water system with an EPA-registered product to prevent colonization of the reverse osmosis membrane and downstream microbial contamination (158). Category II

H. Run water softeners through a regeneration cycle to restore their capacity and function. Category II

I. If the facility has a water-holding reservoir or water-storage tank, consult the facility engineer or local health department to determine whether this equipment needs to be drained, disinfected with an EPA-registered product, and refilled. Category II

J. Implement facility procedures to manage a sewage system failure or flooding (e.g., arranging with other health-care facilities for temporary transfer of patients or provision of services), and establish communications with the local municipal water utility and the local health department to ensure that advisories are received in a timely manner after release (45,156). Category IC (JCAHO: EC 1.4; Municipal order)

K. Implement infection-control measures during sewage intrusion, flooding, or other water-related emergencies.

1. Relocate patients and clean or sterilize supplies from affected areas. Category II

2. If hands are not visibly soiled or contaminated with proteinaceous material, include an alcohol-based hand rub in the hand hygiene process 1) before performing invasive procedures;

2) before and after each patient contact; and 3) whenever hand hygiene is indicated (146).

Category II

3. If hands are visibly soiled or contaminated with proteinaceous material, use soap and bottled water for handwashing (146). Category II

4. If the potable water system is not affected by flooding or sewage contamination, process surgical instruments for sterilization according to standard procedures. Category II

5. Contact the manufacturer of the automated endoscope reprocessor (AER) for specific instructions on the use of this equipment during a water advisory. Category II

L. Remediate the facility after sewage intrusion, flooding, or other water-related emergencies.

1. Close off affected areas during cleanup procedures. Category II

2. Ensure that the sewage system is fully functional before beginning remediation so contaminated solids and standing water can be removed. Category II

3. If hard-surfaced equipment, floors, and walls remain in good repair, ensure that these are dry within 72 hours; clean with detergent according to standard cleaning procedures.

Category II

4. Clean wood furniture and materials (if still in good repair); allow them to dry thoroughly before restoring varnish or other surface coatings. Category II

5. Contain dust and debris during remediation and repair as outlined in air recommendations (Air: IIG 4, 5). Category II

M. Regardless of the original source of water damage (e.g., flooding versus water leaks from point-of-use fixtures or roofs), remove wet, absorbent structural items (e.g., carpeting, wallboard, and wallpaper) and cloth furnishings if they cannot be easily and thoroughly cleaned and dried within 72

hours (e.g., moisture content $\leq 20\%$ as determined by moisture meter readings); replace with new materials as soon as the underlying structure is declared by the facility engineer to be thoroughly dry (2,47,159,160). Category IB

IV. Additional Engineering Measures as Indicated by Epidemiologic Investigation for Controlling Waterborne, Health-Care--Associated Legionnaires Disease

- A. When using a pulse or one-time decontamination method, superheat the water by flushing each outlet for ≥ 5 minutes with water at 160°F -- 170°F (71°C -- 77°C) or hyperchlorinate the system by flushing all outlets for ≥ 5 minutes with water containing ≥ 2 mg/L (≥ 2 ppm) free residual chlorine using a chlorine-based product registered by the EPA for water treatment (e.g., sodium hypochlorite [chlorine bleach]) (153,155,161--164). Category IB
- B. After a pulse treatment, maintain both the heated water temperature at the return and the cold water temperature per the recommendation (Water: II A) wherever practical and permitted by state codes, or chlorinate heated water to achieve 1--2 mg/L (1--2 ppm) free residual chlorine at the tap by using a chlorine-based product registered by the EPA for water treatment (e.g., sodium hypochlorite [bleach]) (153,165--169). Category IC (States; ASHRAE: 12:2000)
- C. Explore engineering or educational options (e.g., install preset thermostatic mixing valves in point-of-use fixtures or post warning signs at each outlet) to minimize the risk of scalding for patients, visitors, and staff. Category II
- D. No recommendation is offered for treating water in the facility's distribution system with chlorine dioxide, heavy-metal ions (e.g., copper or silver), monochloramines, ozone, or UV light (170--188). Unresolved issue

V. General Infection-Control Strategies for Preventing Legionnaires Disease

- A. Conduct an infection-control risk assessment of the facility to determine if patients at risk or severely immunocompromised patients are present (27,189,190). Category IB
- B. Implement general strategies for detecting and preventing Legionnaires disease in facilities that do not provide care for severely immunocompromised patients (i.e., facilities that do not have HSCT or solid-organ transplant programs) (see Appendix) (27,189,190). Category IB
 1. Establish a surveillance process to detect health-care--associated Legionnaires disease (27,189,190). Category IB
 2. Inform health-care personnel (e.g., infection control, physicians, patient-care staff, engineering) regarding the potential for Legionnaires disease to occur and measures to prevent and control health-care--associated legionellosis (166,191). Category IB
 3. Establish mechanisms to provide clinicians with laboratory tests (e.g., culture, urine antigen, direct fluorescence assay [DFA], and serology) for the diagnosis of Legionnaires disease (27,189). Category IB
- C. Maintain a high index of suspicion for health-care--associated Legionnaires disease, and perform laboratory diagnostic tests for legionellosis on suspected cases, especially in patients at risk who do not require a PE for care (e.g., patients receiving systemic steroids; patients aged ≥ 65 years; or patients with chronic underlying disease (e.g., diabetes mellitus, congestive heart failure, or chronic obstructive lung disease) (27,166,190,192--198). Category IA
- D. Periodically review the availability and clinicians' use of laboratory diagnostic tests for Legionnaires disease in the facility; if clinicians' use of the tests on patients with diagnosed or suspected pneumonia is limited, implement measures (e.g., an educational campaign) to enhance clinicians' use of the test(s) (193). Category IB
- E. If one case of laboratory-confirmed, health-care--associated Legionnaires disease is identified, or if two or more cases of laboratory-suspected, health-care-associated Legionnaires disease occur during a 6-month period, certain activities should be initiated (181,189,191,193,199,200). Category IB
 1. Report the cases to state and local health departments where required. Category IC (States)
 2. If the facility does not treat severely immunocompromised patients, conduct an epidemiologic investigation, including retrospective review of microbiologic, serologic, and postmortem data to look for previously unidentified cases of health-care--associated Legionnaires disease, and

begin intensive prospective surveillance for additional cases

([27,181,189,191,193,199,200](#)). Category IB

3. If no evidence of continued health-care--associated transmission exists, continue intensive prospective surveillance for ≥ 2 months after the initiation of surveillance ([27,181,189,191,193,199,200](#)). Category IB

F. If there is evidence of continued health-care--associated transmission (i.e., an outbreak), conduct an environmental assessment to determine the source of *Legionella* spp. (199--207). Category IB

1. Collect water samples from potential aerosolized water sources ([Box 1](#) and [Box 2](#)) (208). Category IB

2. Save and subtype isolates of *Legionella* spp. obtained from patients and the environment (163,199--207,209). Category IB

3. If a source is identified, promptly institute water system decontamination measures per recommendations (see Water IV) (164,210). Category IB

4. If *Legionella* spp. are detected in ≥ 1 culture (e.g., conducted at 2-week intervals during 3 months), reassess the control measures, modify them accordingly, and repeat the decontamination procedures; consider intensive use of techniques used in the initial decontamination, or a combination of superheating and hyperchlorination ([27,210,211](#)). Category IB

G. If an environmental source is not identified during a Legionnaires disease outbreak, continue surveillance for new cases for ≥ 2 months. Either defer decontamination pending identification of the source of *Legionella* spp. or proceed with decontamination of the hospital's water distribution system, with special attention to areas involved in the outbreak. Category II

H. No recommendation is offered regarding routine culturing of water systems in health-care facilities that do not have patient-care areas (i.e., PE or transplant units) for persons at high risk for *Legionella* spp. infection (see Appendix) (161,165,167, 198,212--214). Unresolved issue

I. No recommendation is offered regarding the removal of faucet aerators in areas for immunocompetent patients. Unresolved issue

J. Keep adequate records of all infection-control measures and environmental test results for potable water systems. Category II

VI. Preventing Legionnaires Disease in Protective Environments and Transplant Units

A. When implementing strategies for preventing Legionnaires disease among severely immunocompromised patients housed in facilities with HSCT or solid-organ transplant programs, incorporate these specific surveillance and epidemiologic measures in addition to the steps outlined previously (see Appendix).

1. Maintain a high index of suspicion for legionellosis in transplant patients even when environmental surveillance cultures do not yield legionellae (189,215). Category IB

2. If a case occurs in a severely immunocompromised patient, or if severely immunocompromised patients are present in high-risk areas of the hospital (e.g., PE or transplant units) and cases are identified elsewhere in the facility, conduct a combined epidemiologic and environmental investigation to determine the source of *Legionella* spp. (189,210). Category IB

B. Implement culture strategies and potable water and fixture treatment measures in addition to those previous outlined (Water: V). Category II

1. Depending on state regulations on potable water temperature in public buildings (216), hospitals housing patients at high risk for health-care--associated legionellosis should either

maintain heated water with a minimum return temperature of $\geq 124^{\circ}\text{F}$ ($\geq 51^{\circ}\text{C}$) and cold water at $< 68^{\circ}\text{F}$ ($< 20^{\circ}\text{C}$), or chlorinate heated water to achieve 1--2 mg/L (1--2 ppm) of free residual chlorine at the tap (153--155,165,167--169,217). Category II

2. Periodic culturing for legionellae in potable water samples from HSCT or solid-organ transplant units can be performed as part of a comprehensive strategy to prevent Legionnaires

disease in these units ([37,154,189,218](#)). Category II

3. No recommendation is offered regarding the optimal methodology (i.e., frequency or number of sites) for environmental surveillance cultures in HSCT or solid-organ transplant units.

Unresolved issue

4. In areas with patients at risk, when *Legionella* spp. are not detectable in unit water, remove, clean, and disinfect shower heads and tap aerators monthly by using a chlorine-based,

EPA-registered product. If an EPA-registered chlorine disinfectant is not available, use a chlorine bleach solution (500--615 ppm [1:100 v/v dilution]) ([153,187](#)). Category II

C. If *Legionella* spp. are determined to be present in the water of a transplant unit, implement certain measures until *Legionella* spp. are no longer detected by culture.

1. Decontaminate the water supply as outlined previously (Water: IV) ([27,37,153,164,210](#)). Category IB

2. Do not use water from the faucets in patient-care rooms to avoid creating infectious aerosols ([37,219](#)). Category IB

3. Restrict severely immunocompromised patients from taking showers ([37,219](#)). Category IB

4. Use water that is not contaminated with *Legionella* spp. for HSCT patients' sponge baths ([37,219](#)). Category IB

5. Provide patients with sterile water for tooth brushing, drinking, and for flushing nasogastric tubing during legionellosis outbreaks ([37,219](#)). Category IB

D. Do not use large-volume room air humidifiers that create aerosols (e.g., by Venturi principle, ultrasound, or spinning disk) unless they are subjected to high-level disinfection and filled only with sterile water ([27,37,201,220](#)). Category IB

VII. Cooling Towers and Evaporative Condensers

A. When planning construction of new health-care facilities, locate cooling towers so that the drift is directed away from the air-intake system, and design the towers to minimize the volume of aerosol drift ([153,203,221](#)). Category IC (ASHRAE 12-2000)

B. Implement infection-control procedures for operational cooling towers ([153,203,222](#)). Category IC (ASHRAE 12-2000)

1. Install drift eliminators ([153,203,222](#)). Category IC (ASHRAE 12-2000)

2. Use an effective EPA-registered biocide on a regular basis ([153](#)). Category IC (ASHRAE 12-2000)

3. Maintain towers according to manufacturers' recommendations, and keep detailed maintenance and infection-control records, including environmental test results from legionellosis outbreak investigations ([153](#)). Category IC (ASHRAE 12-2000)

C. If cooling towers or evaporative condensers are implicated in health-care--associated legionellosis, decontaminate the cooling-tower system ([199,203,221,223](#)). Category IB

VIII. Dialysis Water Quality and Dialysate

A. Adhere to current AAMI standards for quality-assurance performance of devices and equipment used to treat, store, and distribute water in hemodialysis centers (both acute and maintenance [chronic] settings) and for the preparation of concentrates and dialysate ([224--235](#)). Category IA, IC (AAMI: American National Standards Institute [ANSI]/AAMI RD5:1992, ANSI/AAMI RD47:1993)

B. No recommendation is offered regarding whether more stringent requirements for water quality should be imposed in hemofiltration and hemodiafiltration. Unresolved issue

C. Conduct microbiologic testing specific to water in dialysis settings ([229,230,236--238](#)). Category IA, IC (AAMI: ANSI/AAMI RD5:1992, ANSI/AAMI RD47:1993, RD62:2001)

1. Perform bacteriologic assays of water and dialysis fluids at least once a month and during outbreaks by using standard quantitative methods ([236--238](#)). Category IA, IC (AAMI: ANSI/AAMI RD62:2001)

- a. Assay for heterotrophic, mesophilic bacteria (e.g., *Pseudomonas* spp).
- b. Do not use nutrient-rich media (e.g., blood agar or chocolate agar).

2. In conjunction with microbiologic testing, perform endotoxin testing on product water used to reprocess dialyzers for multiple use (229,230,239--242). Category IA, IC (AAMI: ANSI/AAMI RD5:1992, ANSI/AAMI RD47:1993)

3. Ensure that water does not exceed the limits for microbial counts and endotoxin concentrations ([Table 2](#)) (229--231). Category IA, IC (AAMI: ANSI/AAMI RD5:1992, ANSI/AAMI RD47:1993)

D. Disinfect water distribution systems in dialysis settings at least weekly (226--228,231,236). Category IA, IC (AAMI: ANSI/AAMI RD62:2001)

E. Wherever practical, design and engineer water systems in dialysis settings to avoid incorporating joints, dead-end pipes, and unused branches and taps that can harbor bacteria (226-- 228,231,236). Category IA, IC (AAMI: ANSI/AAMI RD62:2001)

F. When storage tanks are used in dialysis systems, they should be routinely drained, disinfected with an EPA-registered product, and fitted with an ultrafilter or pyrogenic filter (membrane filter with a pore size sufficient to remove particles and molecules ≥ 1 kilodalton) installed in the water line distal to the storage tank (236). Category IC (AAMI: ANSI/AAMI RD62:2001)

IX. Ice Machines and Ice

A. Do not handle ice directly by hand, and wash hands before obtaining ice. Category II

B. Use a smooth-surface ice scoop to dispense ice (243,244). Category II

1. Keep the ice scoop on a chain short enough that the scoop cannot touch the floor or keep the scoop on a clean, hard surface when not in use (243,244). Category II

2. Do not store the ice scoop in the ice bin. Category II

C. Do not store pharmaceuticals or medical solutions on ice intended for consumption; use sterile ice to keep medical solutions cold, or use equipment specifically manufactured for this purpose (244,245). Category IB

D. Machines that dispense ice are preferred to those that require ice to be removed from bins or chests with a scoop (246,247). Category II

E. Limit access to ice-storage chests, and keep container doors closed except when removing ice (244). Category II

F. Clean, disinfect, and maintain ice-storage chests on a regular basis. Category II

1. Follow the manufacturer's instructions for cleaning. Category II

2. Use an EPA-registered disinfectant suitable for use on ice machines, dispensers, or storage chests in accordance with label instructions. Category II

3. If instructions and EPA-registered disinfectants suitable for use on ice machines are not available, use a general cleaning/disinfecting regimen ([Box 3](#)) (244). Category II

4. Flush and clean ice machines and dispensers if they have not been disconnected before anticipated lengthy water disruptions. Category II

G. Install proper air gaps where the condensate lines meet the waste lines. Category II.

H. Conduct microbiologic sampling of ice, ice chests, and ice-making machines and dispensers where indicated during an epidemiologic investigation (244,248,249). Category IB

X. Hydrotherapy Tanks and Pools

A. Drain and clean hydrotherapy equipment (e.g., Hubbard tanks, tubs, whirlpools, whirlpool spas, or birthing tanks) after each patient's use, and disinfect equipment surfaces and components by using an EPA-registered product in accordance with the manufacturer's instructions. Category II

B. In the absence of an EPA-registered product for water treatment, add sodium hypochlorite to the water:

1. Maintain a 15-ppm chlorine residual in the water of small hydrotherapy tanks, Hubbard tanks, and tubs (250). Category II
2. Maintain a 2--5-ppm chlorine residual in the water of whirlpools and whirlpool spas (251). Category II
3. If the pH of the municipal water is in the basic range (e.g., when chloramine is used as the primary drinking water disinfectant in the community), consult the facility engineer regarding the possible need to adjust the pH of the water to a more acidic level before disinfection, to enhance the biocidal activity of the chlorine (252). Category II

- C. Clean and disinfect hydrotherapy equipment after using tub liners. Category II
- D. Clean and disinfect inflatable tubs unless they are single-use equipment. Category II
- E. No recommendation is offered regarding the use of antiseptic chemicals (e.g., chloramine-T) in the water during hydrotherapy sessions. Unresolved issue
- F. Conduct a risk assessment of patients before their use of large hydrotherapy pools, deferring patients with draining wounds or fecal incontinence from pool use until their condition resolves. Category II
- G. For large hydrotherapy pools, use pH and chlorine residual levels appropriate for an indoor pool as provided by local and state health agencies. Category IC (States)
- H. No recommendation is offered regarding the use in health-care settings of whirlpool or spa equipment manufactured for home or recreational use. Unresolved issue

XI. Miscellaneous Medical Equipment Connected to Water Systems

- A. Clean, disinfect, and maintain AER equipment according to the manufacturer's instructions and relevant scientific literature to prevent inadvertent contamination of endoscopes and bronchoscopes with waterborne microorganisms (253--257). Category IB
 1. To rinse disinfected endoscopes and bronchoscopes, use water of the highest quality practical for the system's engineering and design (e.g., sterile water or bacteriologically filtered water [water filtered through 0.1--0.2- μ m filters]) (254,256--258). Category IB
 2. Dry the internal channels of the reprocessed endoscope or bronchoscope by using a proven method (e.g., 70% alcohol followed by forced-air treatment) to lessen the potential for proliferation of waterborne microorganisms and to help prevent biofilm formation (259--263). Category IB
- B. Use water that meets nationally recognized standards set by the EPA for drinking water (<500 CFU/mL for heterotrophic plate count) for routine dental treatment output water (264--267). Category IC (EPA: 40 CFR 1 Part 141, Subpart G)
- C. Take precautions to prevent waterborne contamination of dental unit water lines and instruments.
 1. After each patient, discharge water and air for a minimum of 20--30 seconds from any dental device connected to the dental water system that enters a patient's mouth (e.g., handpieces, ultrasonic scalers, or air/water syringes) (265,268). Category II
 2. Consult with dental water-line manufacturers to 1) determine suitable methods and equipment to obtain the recommended water quality; and 2) determine appropriate methods for monitoring the water to ensure quality is maintained (265,269). Category II
 3. Consult with the dental unit manufacturer regarding the need for periodic maintenance of antiretraction mechanisms (268,269). Category IB

Recommendations ---Environmental Services

I. Cleaning and Disinfecting Strategies for Environmental Surfaces in Patient-Care Areas

- A. Select EPA-registered disinfectants, if available, and use them in accordance with the manufacturer's instructions (270--272). Category IC (EPA: 7 United States Code [USC] § 136 et seq.)
- B. Do not use high-level disinfectants/liquid chemical sterilants for disinfection of either noncritical instruments and devices or any environmental surfaces; such use is counter to label instructions for these toxic chemicals (273--278). Category IC (Food and Drug Administration [FDA]: 21 CFR 801.5, 807.87.e)

C. Follow manufacturers' instructions for cleaning and maintaining noncritical medical equipment. Category II

D. In the absence of a manufacturer's cleaning instructions, follow certain procedures.

1. Clean noncritical medical equipment surfaces with a detergent/disinfectant. This may be followed by an application of an EPA-registered hospital disinfectant with or without a tuberculocidal claim (depending on the nature of the surface and the degree of contamination), in accordance with germicide label instructions (274). Category II
2. Do not use alcohol to disinfect large environmental surfaces (273). Category II
3. Use barrier protective coverings as appropriate for noncritical surfaces that are 1) touched frequently with gloved hands during the delivery of patient care; 2) likely to become contaminated with blood or body substances; or 3) difficult to clean (e.g., computer keyboards) (265). Category II

E. Keep housekeeping surfaces (e.g., floors, walls, tabletops) visibly clean on a regular basis and clean up spills promptly (279). Category II

1. Use a one-step process and an EPA-registered hospital detergent/disinfectant designed for general housekeeping purposes in patient-care areas where 1) uncertainty exists as to the nature of the soil on the surfaces (e.g., blood or body fluid contamination versus routine dust or dirt); or 2) uncertainty exists regarding the presence of multidrug resistant organisms on such surfaces (272,274,280,281). Category II
2. Detergent and water are adequate for cleaning surfaces in nonpatient-care areas (e.g., administrative offices). Category II
3. Clean and disinfect high-touch surfaces (e.g., doorknobs, bed rails, light switches, and surfaces in and around toilets in patients' rooms) on a more frequent schedule than minimal-touch housekeeping surfaces. Category II
4. Clean walls, blinds, and window curtains in patient-care areas when they are visibly dusty or soiled (270,282--284). Category II

F. Do not perform disinfectant fogging in patient-care areas (270,285). Category IB

G. Avoid large-surface cleaning methods that produce mists or aerosols, or disperse dust in patient-care areas (37,48,51,73). Category IB

H. Follow proper procedures for effective uses of mops, cloths, and solutions. Category II

1. Prepare cleaning solutions daily or as needed, and replace with fresh solution frequently according to facility policies and procedures (280,281). Category II
2. Change the mop head at the beginning of each day and also as required by facility policy, or after cleaning up large spills of blood or other body substances. Category II
3. Clean mops and cloths after use and allow to dry before reuse; or use single-use, disposable mop heads and cloths (282,286--288). Category II

I. After the last surgical procedure of the day or night, wet vacuum or mop operating room floors with a single-use mop and an EPA-registered hospital disinfectant (114). Category IB

J. Do not use mats with tacky surfaces at the entrances to operating rooms or infection-control suites (114). Category IB

K. Use appropriate dusting methods for patient-care areas designated for immunocompromised patients (e.g., HSCT patients) (37,40,280). Category IB

1. Wet-dust horizontal surfaces daily by moistening a cloth with a small amount of an EPA-registered hospital detergent/disinfectant (37,40,280). Category IB
2. Avoid dusting methods that disperse dust (e.g., feather-dusting) (40). Category IB

L. Keep vacuums in good repair and equip vacuums with HEPA filters for use areas with patients at risk (37,40,280,289). Category IB

M. Close the doors of immunocompromised patients' rooms when vacuuming, waxing, or buffing corridor floors to minimize exposure to airborne dust (37,40,289). Category IB

- N. When performing low- or intermediate-level disinfection of environmental surfaces in nurseries and neonatal units, avoid unnecessary exposure of neonates to disinfectant residues on these surfaces by using EPA-registered germicides in accordance with manufacturers' instructions and safety advisories (271,290--292). Category IB, IC (EPA: 7 USC § 136 et seq.)
1. Do not use phenolics or any other chemical germicide to disinfect bassinets or incubators during an infant's stay (271,290--292). Category IB
 2. Rinse disinfectant-treated surfaces, especially those treated with phenolics, with water (290--292). Category IB
- O. When using phenolic disinfectants in neonatal units, prepare solutions to correct concentrations in accordance with manufacturers' instructions, or use premixed formulations (271,290--292). Category IB, IC (EPA: 7 USC § 136 et seq.)

II. Cleaning Spills of Blood and Body Substances

- A. Promptly clean and decontaminate spills of blood or other potentially infectious materials (293--300). Category IB, IC (OSHA: 29 CFR 1910.1030 § d.4.ii.A)
- B. Follow proper procedures for site decontamination of spills of blood or blood-containing body fluids (293--300). Category IC (OSHA: 29 CFR 1910.1030 § d.4.ii.A)
1. Use protective gloves and other PPE appropriate for this task (293). Category IC (OSHA: 29 CFR 1910.1030 § d.3.i, ii)
 2. If the spill contains large amounts of blood or body fluids, clean the visible matter with disposable absorbent material, and discard the used cleaning materials in appropriate, labeled containers (293,298,299,301,302). Category IC (OSHA: 29 CFR 1910.1030 § d.4.iii.B)
 3. Swab the area with a cloth or paper towels moderately wetted with disinfectant, and allow the surface to dry (293,301). Category IC (OSHA: 29 CFR 1910.1030 § d.4.ii.A)
- C. Use germicides registered by the EPA for use as hospital disinfectants and labeled tuberculocidal or registered germicides on the EPA Lists D and E (i.e., products with specific label claims for HIV or hepatitis B virus [HBV]) in accordance with label instructions to decontaminate spills of blood and other body fluids (293,301,303). Category IC (OSHA 29 CFR 1910.1030 § d.4.ii. A memorandum 2/28/97; compliance document [CPL] 2-2.44D [11/99])
- D. An EPA-registered sodium hypochlorite product is preferred, but if such products are not available, generic sodium hypochlorite solutions (e.g., household chlorine bleach) may be used.
1. Use a 1:100 dilution (500--615 ppm available chlorine) to decontaminate nonporous surfaces after cleaning a spill of either blood or body fluids in patient-care settings (301,304). Category IB
 2. If a spill involves large amounts of blood or body fluids, or if a blood or culture spill occurs in the laboratory, use a 1:10 dilution (5,000--6,150 ppm available chlorine) for the first application of germicide before cleaning (279,301). Category IB

III. Carpeting and Cloth Furnishings

- A. Vacuum carpeting in public areas of health-care facilities and in general patient-care areas regularly with well-maintained equipment designed to minimize dust dispersion (280). Category II
- B. Periodically perform a thorough, deep cleaning of carpeting as determined by facility policy by using a method that minimizes the production of aerosols and leaves little or no residue (44). Category II
- C. Avoid use of carpeting in high-traffic zones in patient-care areas or where spills are likely (e.g., burn therapy units, operating rooms, laboratories, or intensive care units) (44,305,306). Category IB
- D. Follow appropriate procedures for managing spills on carpeting.
1. Spot-clean blood or body substance spills promptly (293,301,304,307). Category IC (OSHA: 29 CFR 1910.1030 § d.4.ii.A, interpretation)
 2. If a spill occurs on carpet tiles, replace any tiles contaminated by blood and body fluids or body

- E. Thoroughly dry wet carpeting to prevent the growth of fungi; replace carpeting that remains wet after 72 hours ([37,160](#)). Category IB
 - F. No recommendation is offered regarding the routine use of fungicidal or bactericidal treatments for carpeting in public areas of a health-care facility or in general patient-care areas. Unresolved issue
 - G. Do not use carpeting in hallways and patient rooms in areas housing immunosuppressed patients (e.g., PE areas) ([37,44](#)). Category IB
 - H. Avoid using upholstered furniture and furnishings in high-risk patient-care areas and in areas with increased potential for body substance contamination (e.g., pediatrics units) ([37](#)). Category II
 - I. No recommendation is offered regarding whether upholstered furniture and furnishings should be avoided in general patient-care areas. Unresolved issue
1. Maintain upholstered furniture in good repair. Category II
 2. Maintain the surface integrity of the upholstery by repairing tears and holes. Category II
 3. If upholstered furniture in a patient's room requires cleaning to remove visible soil or body substance contamination, move that item to a maintenance area where it can be adequately cleaned with a process appropriate for the type of upholstery and nature of the soil. Category II

IV. Flowers and Plants in Patient-Care Areas

- A. Flowers and potted plants need not be restricted from areas for immunocompetent patients (308-311). Category II
- B. Designate care and maintenance of flowers and potted plants to staff not directly involved with patient care (309). Category II
- C. If plant or flower care by patient-care staff is unavoidable, instruct the staff to wear gloves when handling plants and flowers and perform hand hygiene after glove removal (309). Category II
- D. Do not allow fresh or dried flowers, or potted plants, in patient-care areas for immunosuppressed patients ([37,51,308,312](#)). Category II

V. Pest Control

- A. Develop pest-control strategies, with emphasis on kitchens, cafeterias, laundries, central sterile supply areas, operating rooms, loading docks, construction activities, and other areas prone to infestations (313--315). Category II
- B. Install screens on all windows that open to the outside; keep screens in good repair (314). Category IB
- C. Contract for routine pest control service by a credentialed pest-control specialist who will tailor the application to the needs of a health-care facility (315). Category II
- D. Place laboratory specimens (e.g., fixed sputum smears) in covered containers for overnight storage (316,317). Category II

VI. Special Pathogens

- A. Use appropriate hand hygiene, PPE (e.g., gloves), and isolation precautions during cleaning and disinfecting procedures (146,274,[318,319](#)). Category IB
 - B. Use standard cleaning and disinfection protocols to control environmental contamination with antibiotic-resistant, gram-positive cocci (e.g., methicillin-resistant *Staphylococcus aureus*, vancomycin intermediate sensitive *Staphylococcus aureus*, or vancomycin-resistant *Enterococcus* [VRE]) ([318,320--322](#)). Category IB
1. Pay close attention to cleaning and disinfection of high-touch surfaces in patient-care areas (e.g., bed rails, carts, charts, bedside commodes, bed rails, doorknobs, or faucet handles) ([318,320--322](#)). Category IB
 2. Ensure compliance by housekeeping staff with cleaning and disinfection procedures ([318,320--322](#)). Category IB
 3. Use EPA-registered chemical germicides appropriate for the surface to be disinfected (e.g., either low- or intermediate-level disinfection) as specified by the manufacturer's

instructions (271,322--327). Category IB, IC (EPA: 7 USC § 136 et seq.)

4. When contact precautions are indicated for patient care, use disposable patient-care items (e.g., blood pressure cuffs) wherever possible to minimize cross-contamination with multiple-resistant microorganisms (328). Category IB

5. Follow these same surface-cleaning and disinfecting measures for managing the environment of VRSA patients (320--322,327). Category II

C. Environmental-surface culturing can be used to verify the efficacy of hospital policies and procedures before and after cleaning and disinfecting rooms that house patients with VRE (318,329--333). Category II

1. Obtain prior approval from infection-control staff and the clinical laboratory before performing environmental-surface culturing. Category II

2. Infection-control staff, with clinical laboratory staff consultation, must supervise all environmental culturing. Category II

D. Thoroughly clean and disinfect environmental and medical equipment surfaces on a regular basis by using EPA-registered disinfectants in accordance with manufacturers' instructions (271,274,319,334). Category IB, IC (EPA: 7 USC § 136 et seq.)

E. Advise families, visitors, and patients regarding the importance of hand hygiene to minimize the spread of body substance contamination (e.g., respiratory secretions or fecal matter) to surfaces (274). Category II

F. Do not use high-level disinfectants (i.e., liquid chemical sterilants) on environmental surfaces; such use is inconsistent with label instructions because of the toxicity of the chemicals (270,273,274,278). Category IC (FDA: 21 CFR 801.5, 807.87.e)

G. Because no EPA-registered products are specific for inactivating *Clostridium difficile* spores, use hypochlorite-based products for disinfection of environmental surfaces in accordance with guidance from the scientific literature in those patient-care areas where surveillance and epidemiology indicate ongoing transmission of *C. difficile* (274,319,334). Category II

H. No recommendation is offered regarding the use of specific EPA-registered hospital disinfectants with respect to environmental control of *C. difficile*. Unresolved issue

I. Apply standard cleaning and disinfection procedures to control environmental contamination with respiratory and enteric viruses in pediatric-care units and care areas for immunocompromised patients (280,335). Category IC (EPA: 7 USC § 136 et seq.)

J. Clean surfaces that have been contaminated with body substances; perform low- to intermediate-level disinfection on cleaned surfaces with an EPA-registered disinfectant in accordance with the manufacturer's instructions (271,293,335). Category IC (OSHA: 29 CFR 1910.1030 § d.4.ii.A; EPA: 7 USC § 136 et seq.)

K. Use disposable barrier coverings as appropriate to minimize surface contamination. Category II

L. Develop and maintain cleaning and disinfection procedures in patient-care areas to control environmental contamination with agents of Creutzfeldt-Jakob disease (CJD), for which no EPA-registered product exists. Category II

1. In the absence of contamination with central nervous system tissue, extraordinary measures (e.g., use of 2N sodium hydroxide [NaOH] or applying full-strength sodium hypochlorite) are not needed for routine cleaning or terminal disinfection of a room housing a confirmed or suspected CJD patient (273,336). Category II

2. After removing gross tissue from the surface, use either 1N NaOH or a sodium hypochlorite solution containing approximately 10,000--20,000 ppm available chlorine (dilutions of 1:5 to 1:3 v/v, respectively, of U.S. household chlorine bleach; contact the manufacturers of commercially available sodium hypochlorite products for advice) to decontaminate operating room or autopsy surfaces with central nervous system or cerebral spinal fluid contamination from a diagnosed or suspected CJD patient (273,337--342). Category II

a. The contact time for the chemical used during this process should be 30 min--1 hour (339,340,342).

b. Blot up the chemical with absorbent material and rinse the treated surface thoroughly with water.

c. Discard the used, absorbent material into appropriate waste containers.

3. Use disposable, impervious covers to minimize body substance contamination to autopsy tables and surfaces (340,342). Category II

M. Use standard procedures for containment, cleaning, and decontamination of blood spills on surfaces as previously described (Environmental Services: II) (293). Category IC (OSHA: 29 CFR 1910.1030 § d.4.ii.A)

1. Wear PPE appropriate for a surface decontamination and cleaning task (293,336). Category IC (OSHA 29 CFR 1910.1030 § d.3.i, ii)

2. Discard used PPE by using routine disposal procedures or decontaminate reusable PPE as appropriate (293,336). Category IC (OSHA 29 CFR 1910.1030 § d.3.viii)

Recommendations ---Environmental Sampling

I. General Information

- A. Do not conduct random, undirected, microbiologic sampling of air, water, and environmental surfaces in health-care facilities (270,343). Category IB
- B. When indicated, conduct microbiologic sampling as part of an epidemiologic investigation or during assessment of hazardous environmental conditions to detect contamination or verify abatement of a hazard (270,343). Category IB
- C. Limit microbiologic sampling for quality assurance purposes to 1) biologic monitoring of sterilization processes; 2) monthly cultures of water and dialysate in hemodialysis units; and 3) short-term evaluation of the impact of infection-control measures or changes in infection-control protocols (270,343). Category IB

II. Air, Water, and Environmental Surface Sampling

- A. When conducting any form of environmental sampling, identify existing comparative standards and fully document departures from standard methods (343--347). Category II
- B. Select a high-volume air sampling device if anticipated levels of microbial airborne contamination are expected to be low (345,346,348,349). Category II
- C. Do not use settle plates to quantify the concentration of airborne fungal spores (348). Category II
- D. When sampling water, choose growth media and incubation conditions that will facilitate recovery of waterborne organisms (344). Category II
- E. When using a sample/rinse method for sampling an environmental surface, develop and document a procedure for manipulating the swab, gauze, or sponge in a reproducible manner so that results are comparable (347). Category II
- F. When environmental samples and patient specimens are available for comparison, perform the laboratory analysis on the recovered microorganisms down to the species level at a minimum, and beyond the species level if possible (343). Category II

Recommendations ---Laundry and Bedding

I. Employer Responsibilities

- A. Employers must launder workers' personal protective garments or uniforms that are contaminated with blood or other potentially infectious materials (293). Category IC (OSHA: 29 CFR 1910.1030 § d.3.iv)

II. Laundry Facilities and Equipment

- A. Maintain the receiving area for contaminated textiles at negative pressure compared with the clean areas of the laundry in accordance with AIA construction standards in effect during the time of facility construction (1,350--352). Category IC (AIA: 7.23.B1, B2)

- B. Ensure that laundry areas have handwashing facilities and products and appropriate PPE available for workers (1,293). Category IC (AIA: 7.23.D4; OSHA: 29 CFR 1910.1030 § d.2.iii)
- C. Use and maintain laundry equipment according to manufacturers' instructions (353,354). Category II
- D. Do not leave damp textiles or fabrics in machines overnight (353). Category II
- E. Disinfection of washing and drying machines in residential care is not needed as long as gross soil is removed from items before washing and proper washing and drying procedures are used. Category II

III. Routine Handling of Contaminated Laundry

- A. Handle contaminated textiles and fabrics with minimum agitation to avoid contamination of air, surfaces, and persons (36,293,355,356). Category IC (OSHA: 29 CFR 1910.1030 § d.4.iv)
- B. Bag or otherwise contain contaminated textiles and fabrics at the point of use (293). Category IC (OSHA: 29 CFR 1910.1030 § d.4.iv)
 - 1. Do not sort or prerinse contaminated textiles or fabrics in patient-care areas (293). Category IC (OSHA: 29 CFR 1910.1030 § d.4.iv)
 - 2. Use leak-resistant containment for textiles and fabrics contaminated with blood or body substances (293,355). Category IC (OSHA: 29 CFR 1910.1030 § d.4.iv)
 - 3. Identify bags or containers for contaminated textiles with labels, color coding, or other alternative means of communication as appropriate (293). Category IC (OSHA: 29 CFR 1910.1030 § d.4.iv)
- C. Covers are not needed on contaminated textile hampers in patient-care areas. Category II
- D. If laundry chutes are used, ensure that they are properly designed, maintained, and used in a manner to minimize dispersion of aerosols from contaminated laundry (357--361). Category IC (AAMI: ANSI/AAMI ST65:2000)
 - 1. Ensure that laundry bags are closed before tossing the filled bag into the chute. Category II
 - 2. Do not place loose items in the laundry chute. Category II
- E. Establish a facility policy to determine when textiles or fabrics should be sorted in the laundry facility (i.e., before or after washing) (362,363). Category II

IV. Laundry Process

- A. If hot-water laundry cycles are used, wash with detergent in water $\geq 160^{\circ}\text{F}$ ($\geq 71^{\circ}\text{C}$) for ≥ 25 minutes (1,270). Category IC (AIA: 7.31.E3)
- B. No recommendation is offered regarding a hot-water temperature setting and cycle duration for items laundered in residence-style health-care facilities. Unresolved issue
- C. Follow fabric-care instructions and special laundering requirements for items used in the facility (364). Category II
- D. Choose chemicals suitable for low-temperature washing at proper use concentration if low-temperature ($< 160^{\circ}\text{F}$ [$< 70^{\circ}\text{C}$]) laundry cycles are used (365--370). Category II
- E. Package, transport, and store clean textiles and fabrics by methods that will ensure their cleanliness and protect them from dust and soil during interfacility loading, transport, and unloading (270). Category II

V. Microbiologic Sampling of Textiles

- A. Do not conduct routine microbiologic sampling of clean textiles (270,371). Category IB
- B. Use microbiologic sampling during outbreak investigations if epidemiologic evidence indicates a role for health-care textiles and clothing in disease transmission (371). Category IB

VI. Special Laundry Situations

- A. Use sterilized textiles, surgical drapes, and gowns for situations requiring sterility in patient care (114). Category IB

- B. Use hygienically clean textiles (i.e., laundered, but not sterilized) in neonatal intensive care units (292,372). Category IB
- C. Follow manufacturers' recommendations for cleaning fabric products, including those with coated or laminated surfaces. Category II
- D. Do not use dry cleaning for routine laundering in health-care facilities (373--375). Category II
- E. Use caution when considering use of antimicrobial mattresses, textiles, and clothing as replacements for standard bedding and other fabric items; EPA has not approved public health claims asserting protection against human pathogens for such treated items (376). Category II
- F. No recommendation is offered regarding using disposable fabrics and textiles versus durable goods. Unresolved issue

VII. Mattresses and Pillows

- A. Keep mattresses dry; discard them if they remain wet or stained, particularly in burn units (377--382). Category IB
- B. Clean and disinfect mattress covers by using EPA-registered disinfectants that are compatible with the materials to prevent the development of tears, cracks, or holes in the covers (377--382). Category IB
- C. Maintain the integrity of mattress and pillow covers. Category II
 - 1. Replace mattress and pillow covers if they become torn or otherwise in need of repair. Category II
 - 2. Do not stick needles into a mattress through the cover. Category II
- D. Clean and disinfect moisture-resistant mattress covers between patient use by using an EPA-registered product (377--382). Category IB
- E. If using a mattress cover completely made of fabric, change these covers and launder between patient use (377--382). Category IB
- F. Launder pillow covers and washable pillows in the hot-water cycle between patients or when they become contaminated with body substances (382). Category IB

VIII. Air-Fluidized Beds

- A. Follow manufacturers' instructions for air-fluidized bed maintenance and decontamination. Category II
- B. Change the polyester filter sheet at least weekly or as indicated by the manufacturer (383--386). Category II
- C. Clean and disinfect the polyester filter sheet thoroughly, especially between patients, using an EPA-registered product (383--386). Category IB
- D. Consult the facility engineer to determine the proper placement of air-fluidized beds in negative-pressure rooms (387). Category II

Recommendations --- Animals in Health-Care Facilities

I. General Infection-Control Measures for Animal Encounters

- A. Minimize contact with animal saliva, dander, urine, and feces (388--390). Category II
- B. Practice hand hygiene after any animal contact (146,270). Category II
 - 1. Wash hands with soap and water, especially if hands are visibly soiled or contaminated with proteinaceous material (146). Category II
 - 2. Use either soap and water or alcohol-based hand rubs when hands are not visibly soiled or contaminated (146). Category II

II. Animal-Assisted Activities and Resident Animal Programs

- A. Avoid selection of nonhuman primates and reptiles in animal-assisted activities, animal-assisted therapy, or resident animal programs (391--393). Category IB

- B. Enroll animals that are fully vaccinated for zoonotic diseases and that are healthy, clean, well-groomed, and negative for enteric parasites or otherwise have completed recent anthelmintic treatment under the regular care of a veterinarian (391,394). Category II
- C. Enroll animals that are trained with the assistance or under the direction of persons who are experienced in this field (391). Category II
- D. Ensure that animals are controlled by persons trained in providing activities or therapies safely, and who know the animal's health status and behavior traits (391,394). Category II
- E. Take prompt action when an incident of biting or scratching by an animal occurs during an animal-assisted activity or therapy.
 - 1. Remove the animal permanently from these programs (391). Category II
 - 2. Report the incident promptly to appropriate authorities (e.g., infection-control staff, animal program coordinator, or local animal control personnel) (391). Category II
 - 3. Promptly clean and treat scratches, bites, or other breaks in the skin. Category II
- F. Perform an ICRA and work actively with the animal handler before conducting an animal-assisted activity or therapy to determine whether the session should be held in a public area of the facility or in individual patient rooms (391,394). Category II
- G. Take precautions to mitigate allergic responses to animals. Category II
 - 1. Minimize shedding of animal dander by bathing animals <24 hours before a visit (391). Category II
 - 2. Groom animals to remove loose hair before a visit, or use a therapy animal cape (395). Category II
- H. Use routine cleaning protocols for housekeeping surfaces after therapy sessions. Category II
- I. Restrict resident animals, including fish in tanks, from access to patient-care areas, food-preparation areas, dining areas, laundry, central sterile supply areas, sterile and clean supply storage areas, medication preparation areas, operating rooms, isolation areas, and PE areas. Category II
- J. Establish a facility policy for regular cleaning of fish tanks, rodent cages, and bird cages, and any other animal dwellings and assign this cleaning task to a nonpatient-care staff member; avoid splashing tank water or contaminating environmental surfaces with animal bedding. Category II

III. Protective Measures for Immunocompromised Patients

- A. Advise patients to avoid contact with animal feces, saliva, urine, or solid litter box material (396). Category II
- B. Promptly clean and treat scratches, bites, or other wounds that break the skin (396). Category II
- C. Advise patients to avoid direct or indirect contact with reptiles (397). Category IB
- D. Conduct a case-by-case assessment to determine if animal-assisted activities or animal-assisted therapy programs are appropriate for immunocompromised patients (394). Category II
- E. No recommendation is offered regarding permitting pet visits to terminally ill immunocompromised patients outside their PE units. Unresolved issue.

IV. Service Animals

- A. Avoid providing facility access to nonhuman primates and reptiles as service animals (393,397). Category IB
- B. Allow service animals access to the facility in accordance with the Americans with Disabilities Act of 1990, unless the presence of the animal creates a direct threat to other persons or a fundamental alteration in the nature of services (389,398). Category IC (U.S. Department of Justice: 28 CFR § 36.302)
- C. When a decision must be made regarding a service animal's access to any particular area of the health-care facility, evaluate the service animal, patient, and health-care situation on a case-by-case basis to determine whether significant risk of harm exists and whether reasonable modifications in policies and procedures will mitigate this risk (398). Category IC (U.S. Department of Justice: 28 CFR § 36.208)
- D. If a patient must be separated from his or her service animal while in the health-care facility 1) ascertain from the person what arrangements have been made for supervision or care of the animal

during this period of separation; and 2) make appropriate arrangements to address the patient's needs in the absence of the service animal. Category II

V. Animals as Patients in Human Health-Care Facilities

- A. Develop health-care facility policies to address the treatment of animals in human health-care facilities.
 - 1. Use the multidisciplinary team approach to policy development, including public media relations efforts to disclose and discuss these activities. Category II
 - 2. Exhaust all veterinary facility, equipment, and instrument options before undertaking the procedure. Category II
 - 3. Ensure that the care of the animal is supervised by a licensed veterinarian. Category II
- B. When animals are treated in human health-care facilities, avoid treating animals in operating rooms or other patient-care areas where invasive procedures are performed (e.g., cardiac catheterization laboratories or invasive nuclear medicine areas). Category II
- C. Schedule the animal procedure for the last procedure of the day in the area, at a time when human patients are not scheduled to be in the vicinity. Category II
- D. Adhere strictly to standard precautions. Category II
- E. Clean and disinfect environmental surfaces thoroughly by using an EPA-registered product in the room after the animal has been removed. Category II
- F. Allow sufficient ACH to clean the air and help remove airborne dander, microorganisms, and allergens ([Table 1](#)). Category II
- G. Clean and disinfect using EPA-registered products or sterilize equipment that has been in contact with the animal; or use disposable equipment. Category II
- H. If reusable medical or surgical instruments are used in an animal procedure, restrict future use of these instruments to animals only. Category II

VI. Research Animals in Health-Care Facilities

- A. Use animals obtained from quality stock, or quarantine incoming animals to detect zoonotic diseases. Category II
- B. Treat sick animals or remove them from the facility. Category II
- C. Provide prophylactic vaccinations, as available, to animal handlers and contacts at high risk. Category II
- D. Ensure proper ventilation through appropriate facility design and location (399). Category IC (U.S. Department of Agriculture [USDA]: 7 USC 2131)
 - 1. Keep animal rooms at negative pressure relative to corridors (399). Category IC (USDA: 7 USC 2131)
 - 2. Prevent air in animal rooms from recirculating elsewhere in the health-care facility (399). Category IC (USDA: 7 USC 2131)
- E. Keep doors to animal research rooms closed. Category II
- F. Restrict access to animal facilities to essential personnel. Category II
- G. Establish employee occupational health programs specific to the animal research facility, and coordinate management of postexposure procedures specific to zoonoses with occupational health clinics in the health-care facility (400,401). Category IC (U.S. Department of Health and Human Services [DHHS]: Biosafety in Microbiological and Biomedical Laboratories [BMBL]; OSHA: 29 CFR 1910.1030.132-139)
- H. Document standard operating procedures for the unit (400). Category IC (DHHS: BMBL)
- I. Conduct routine employee training on worker safety concerns relevant to the animal research facility (e.g., working safely with animals, animal handling) (400,401). Category IC (DHHS: BMBL; OSHA: 29 CFR 1910.1030.132--139)
- J. Use precautions to prevent development of animal-induced asthma in animal workers (400). Category IC (DHHS: BMBL)

I. Categories of Regulated Medical Waste

- A. Designate the following as major categories of medical waste that require special handling and disposal precautions: 1) microbiology laboratory wastes [e.g., cultures and stocks of microorganisms]; 2) bulk blood, blood products, blood, and bloody body fluid specimens; 3) pathology and anatomy waste; and 4) sharps [e.g., needles and scalpels] (270). Category II
- B. Consult federal, state, and local regulations to determine if other waste items are considered regulated medical wastes (293,402,403). Category IC (States; OSHA: 29 CFR 1910.1030 § g.2.1; Department of Transportation [DOT]: 49 CFR 171-180; U.S. Postal Service: CO23.8)

II. Disposal Plan for Regulated Medical Wastes

- A. Develop a plan for the collection, handling, predisposal treatment, and terminal disposal of regulated medical wastes (293,404). Category IC (States; OSHA: 29 CFR 1910.1030 § g.2.i)
- B. Designate a person or persons as responsible for establishing, monitoring, reviewing, and administering the plan. Category II

III. Handling, Transporting, and Storing Regulated Medical Wastes

- A. Inform personnel involved in handling and disposal of potentially infective waste of possible health and safety hazards; ensure that they are trained in appropriate handling and disposal methods (293). Category IC (OSHA: 29 CFR 1910.1030 § g.2.i)
- B. Manage the handling and disposal of regulated medical wastes generated in isolation areas by using the same methods used for regulated medical wastes from other patient-care areas (270). Category II
- C. Use proper sharps disposal strategies (293). Category IC (OSHA: 29 CFR 1910.1030 § d.4.iii.A)
 - 1. Use a sharps container capable of maintaining its impermeability after waste treatment to avoid subsequent physical injuries during final disposal (293). Category IC (OSHA: 29 CFR 1910.1030 § d.4.iii.A)
 - 2. Place disposable syringes with needles, including sterile sharps that are being discarded, scalpel blades, and other sharp items into puncture-resistant containers located as close as practical to the point of use (293). Category IC (OSHA: 29 CFR 1910.1030 § d.4.iii.A)
 - 3. Do not bend, recap, or break used syringe needles before discarding them into a container (36,293,405). Category IC (OSHA: 29 CFR 1910.1030 § d.2.vii and § d.2.vii.A)
- D. Store regulated medical wastes awaiting treatment in a properly ventilated area inaccessible to vertebrate pests; use waste containers that prevent development of noxious odors. Category IC (States)
- E. If treatment options are not available at the site where the medical waste is generated, transport regulated medical wastes in closed, impervious containers to the on-site treatment location or to another facility for treatment as appropriate. Category IC (States)

IV. Treatment and Disposal of Regulated Medical Wastes

- A. Treat regulated medical wastes by using a method (e.g., steam sterilization, incineration, interment, or an alternative treatment technology) approved by the appropriate authority having jurisdiction (AHJ) (e.g., state, Indian Health Service, or Veterans Administration) before disposal in a sanitary landfill. Category IC (States, AHJ)
- B. Follow precautions for treating microbiologic wastes (e.g., amplified cultures and stocks of microorganisms) (400). Category IC (DHHS: BMBL)
 - 1. Biosafety level 4 laboratories must inactivate microbiologic wastes in the laboratory by using an approved inactivation method (e.g., autoclaving) before transport to and disposal in a sanitary landfill (400). Category IC (DHHS: BMBL)
 - 2. Biosafety level 3 laboratories must inactivate microbiologic wastes in the laboratory by using an approved inactivation method (e.g., autoclaving) or incinerate them at the facility

before transport to and disposal in a sanitary landfill (400). Category IC (DHHS: BMBL)

- C. Biosafety levels 1 and 2 laboratories should develop strategies to inactivate amplified microbial cultures and stocks onsite by using an approved inactivation method (e.g., autoclaving) instead of packaging and shipping untreated wastes to an offsite facility for treatment and disposal (400,406-408). Category II
- D. Laboratories that isolate select agents from clinical specimens must comply with federal regulations for receipt, transfer, management, and appropriate disposal of these agents (409). Category IC (DHHS: 42 CFR 72 § 72.6.i.1.iii)
- E. Sanitary sewers may be used for safe disposal of blood, suctioned fluids, ground tissues, excretions, and secretions, provided that local sewage discharge requirements are met and that the state has declared this to be an acceptable method of disposal (410). Category II

V. Special Precautions for Wastes Generated During Care of Patients with Rare Diseases

- A. When discarding items contaminated with blood and body fluids from VHF patients, contain these regulated medical wastes with minimal agitation during handling (36,109). Category II
- B. Manage properly contained wastes from areas providing care to VHF patients in accordance with recommendations for other isolation areas (Regulated Medical Waste: III B) (36,109,270). Category II
- C. Decontaminate bulk blood and body fluids from VHF patients by using approved inactivation methods (e.g., autoclaving or chemical treatment) before disposal (36,109). Category IC, II (States)
- D. When discarding regulated medical waste generated during the routine (i.e., nonsurgical) care of CJD patients, contain these wastes and decontaminate them by using approved inactivation methods (e.g., autoclaving or incineration) appropriate for the medical waste category (e.g., blood, sharps, or pathological waste) (36,270,273,336). Category IC, II (States)
- E. Incinerate medical wastes (e.g., central nervous system tissues or contaminated disposable materials) from brain autopsy or biopsy procedures of diagnosed or suspected CJD patients (340,342). Category IB

References

1. The American Institute of Architects and The Facilities Guidelines Institute. Guidelines for design and construction of hospital and health care facilities, 2001. Washington, DC: American Institute of Architects Press, 2001.
2. Arnow PM, Sadigh M, Costas C, Weil D, Chudy R. Endemic and epidemic aspergillosis associated with in-hospital replication of *Aspergillus* organisms. J Infect Dis 1991;164:998--1002.
3. Streifel AJ. Design and maintenance of hospital ventilation systems and the prevention of airborne nosocomial infections [Chapter 80]. In: Mayhall, CG, ed. Hospital epidemiology and infection control. 2nd ed. Philadelphia, PA: Lippincott Williams and Wilkins, 1999.
4. Pittet D, Huguenin T, Dharan S, et al. Unusual cause of lethal pulmonary aspergillosis in patients with chronic obstructive pulmonary disease. Am J Respir Crit Care Med 1996;154(2 Pt 1):541--4.
5. US Environmental Protection Agency, Office of Air and Radiation, and US Department of Health and Human Services, National Institute of Occupational Safety and Health. Building air quality: a guide for building owners and facility managers. Washington, DC: 1991; DHHS publication (NIOSH)91-114 and EPA/400/1--91/033. Available at <http://www.cdc.gov/niosh/baqtoc.html>.
6. Rao CY, Burge HA, Chang JC. Review of quantitative standards and guidelines for fungi in indoor air. J Air & Waste Manage Assoc 1996;46:899--908.
7. Beck-Sagué CM, Dooley SW, Hutton MD, et al. Hospital outbreak of multidrug-resistant *Mycobacterium tuberculosis* infections: factors in transmission to staff and HIV-infected patients. JAMA 1992;268:1280--6.
8. Dooley SW, Villarino ME, Lawrence M, et al. Nosocomial transmission of tuberculosis in a hospital unit for HIV-infected patients. JAMA 1992;267:2632--4.
9. Sarubbi FA Jr, Kopf HB, Wilson MB, McGinnis MR, Rutala WA. Increased recovery of *Aspergillus flavus* from respiratory specimens during hospital construction. Am Rev Respir Dis 1982;125:33--8.
10. Streifel AJ, Stevens PP, Rhame FS. In-hospital source of airborne *Penicillium* species spores. J Clin Microbiol 1987;25:1--4.

11. Hansen W. The need for an integrated indoor air quality program. In: Hansen W, ed. A guide to managing indoor air quality in health care organizations. Oakbrook Terrace, IL: Joint Commission on Accreditation of Healthcare Organizations, 1997:xiii-- xviii.
12. Bartley J. Ventilation. In: Pfeiffer J, ed. APIC text of infection control and epidemiology. Washington, DC: Association for Professionals in Infection Control and Epidemiology, Inc (APIC), 2000:77.1--77.11.
13. Bartley J. Construction and renovation. In: Pfeiffer J, ed. APIC text of infection control and epidemiology. Washington DC: Association for Professionals in Infection Control and Epidemiology, Inc (APIC), 2000:72.1--77.11.
14. Harvey MA. Critical-care--unit bedside design and furnishing: impact on nosocomial infections. *Infect Control Hosp Epidemiol* 1998;19:597--601.
15. Infection Control Focus Group. Patient care focus groups 1998: assessing organizational readiness for infection control issues related to construction, renovation, and physical plant projects. National Association of Children's Hospitals and Related Institutions.
16. Carter CD, Barr BA. Infection control issues in construction and renovation. *Infect Control Hosp Epidemiol* 1997;18:587--96.
17. Coronado VG, Beck-Sagué CM, Hutton MD, et al. Transmission of multidrug-resistant *Mycobacterium tuberculosis* among persons with human immunodeficiency virus infection in an urban hospital: epidemiologic and restriction fragment length polymorphism analysis. *J Infect Dis* 1993;168:1052--5.
18. Coronado VG, Valway S, Finelli L, et al. Nosocomial transmission of multidrug-resistant *Mycobacterium tuberculosis* among intravenous drug users with human immunodeficiency virus infection [Abstract S50]. In: Abstracts of the Third Annual Meeting of the Society for Hospital Epidemiology of America. Chicago, IL. *Infect Control Hosp Epidemiol* 1993;14:428.
19. Edlin BR, Tokars JI, Grieco MH, et al. An outbreak of multidrug-resistant tuberculosis among hospitalized patients with the acquired immunodeficiency syndrome. *N Engl J Med* 1992;326:1514--21.
20. Fischl MA, Uttamchandani RB, Daikos GL, et al. An outbreak of tuberculosis caused by multiple-drug--resistant tubercle bacilli among patients with HIV infection. *Ann Intern Med* 1992;117:177--83.
21. Ikeda RM, Birkhead GS, DeFerdinando Jr GT, et al. Nosocomial tuberculosis: an outbreak of a strain resistant to seven drugs. *Infect Control Hosp Epidemiol* 1995;16:152--9.
22. Jarvis WR. Nosocomial transmission of multidrug-resistant *Mycobacterium tuberculosis*. *Res Microbiol* 1992;144:117--22.
23. Jarvis WR. Nosocomial transmission of multidrug-resistant *Mycobacterium tuberculosis*. *Am J Infect Control* 1995;23:146--51.
24. Jereb JA, Klevens RM, Privett TD, et al. Tuberculosis in health care workers at a hospital with an outbreak of multidrug-resistant *Mycobacterium tuberculosis*. *Arch Intern Med* 1995;155:854--9.
25. Moran GJ, McCabe F, Morgan MT, Talan DA. Delayed recognition and infection control for tuberculosis patients in the emergency department. *Ann Emerg Med* 1995;26:283--9.
26. Pearson ML, Jereb JA, Frieden TR, et al. Nosocomial transmission of multidrug-resistant *Mycobacterium tuberculosis*: a risk to patients and health care workers. *Ann Intern Med* 1992;117:191--6.
27. [CDC. Guidelines for prevention of nosocomial pneumonia. MMWR 1997;46\(No. RR-1\):1--79.](#)
28. Ko G, Burge HA, Muilenberg M, Rudnick S, First M. Survival of mycobacteria on HEPA filter material. *J Am Biol Safety Assoc* 1998;3:65--78.
29. Gage AA, Dean DC, Schimert G, Minsley N. *Aspergillus* infection after cardiac surgery. *Arch Surg* 1970;101:384--7.
30. Vargo JA, Ginsberg MM, Mizrahi M. Human infestation by the pigeon mite: a case report. *Am J Infect Control* 1983;11:24--5.
31. National Air Duct Cleaners Association. NADCA general specifications for the cleaning of commercial HVAC systems. Publication #NAD--06. Washington, DC: National Air Duct Cleaners Association, 2002. Available at <http://www.nadca.com/standards/standards.asp>.
32. US Environmental Protection Agency, Office of Pesticide Programs. Use of disinfectants and sanitizers in heating, ventilation, air conditioning, and refrigeration systems [Letter]. March 14, 2002. Available at <http://www.epa.gov/oppad001/hvac.htm>.
33. Rutala WA, Jones SM, Worthington JM, Reist PC, Weber DJ. Efficacy of portable filtration units in reducing aerosolized particles in the size range of *Mycobacterium tuberculosis*. *Infect Control Hosp*

Epidemiol 1995;16:391--8.

34. [CDC. Guidelines for preventing the transmission of *Mycobacterium tuberculosis* in health-care facilities. MMWR 1994;43\(No. RR-13\).](#)
35. American Society of Heating, Refrigerating and Air-Conditioning Engineers, Inc. Ventilation for acceptable indoor air quality. Atlanta, GA, 1999; ASHRAE Standard 62-1999.
36. Garner JS, Hospital Infection Control Practices Advisory Committee. Guideline for isolation precautions in hospitals. Infect Control Hosp Epidemiol 1996;17:53--80.
37. [CDC. Guidelines for preventing opportunistic infections among hematopoietic stem cell transplant recipients. MMWR 2000;49\(No. RR-10\).](#)
38. Flynn PM, Williams BG, Hethrington SV, Williams BF, Giannini MA, Pearson TA. *Aspergillus terreus* during hospital renovation [Letter]. Infect Control Hosp Epidemiol 1993;14:363--5.
39. Tabbara KF, Al Jabarti A. Hospital construction-associated outbreak of ocular aspergillosis after cataract surgery. Ophthalmology 1998;105:522--6.
40. Rhame FS, Streifel AJ, Kersey JH Jr, McGlave PB. Extrinsic risk factors for pneumonia in the patient at high risk of infection. Am J Med 1984;76:42--52.
41. Wells WF. Aerodynamics of droplet nuclei [Chapter 3]. In: Wells WF. Airborne contagion and air hygiene. Cambridge, MA: Harvard University Press, 1955:13--9.
42. [CDC. Epidemiologic notes and reports: nosocomial transmission of multidrug-resistant tuberculosis among HIV-infected persons --- Florida and New York, 1988--1991. MMWR 1991;40:585--91.](#)
43. [CDC. Outbreak of multidrug-resistant tuberculosis at a hospital --- New York City, 1991. MMWR 1993;42:427--34.](#)
44. Gerson SL, Parker P, Jacobs MR, Creger R, Lazarus HM. Aspergillosis due to carpet contamination [Letter]. Infect Control Hosp Epidemiol 1994;15:221--3.
45. Joint Commission on Accreditation of Healthcare Organizations. 2001 hospital accreditation standards. Oakbrook Terrace, IL: JCAHO Press, 2001:193--220.
46. Fridkin SK, Kremer FB, Bland LA, Padhye A, McNeil MM, Jarvis WR. *Acremonium kiliense* endophthalmitis that occurred after cataract extraction in an ambulatory surgical center and was traced to an environmental reservoir. Clin Infect Dis 1996;22:222--7.
47. Streifel AJ. Maintenance and engineering. In: Pfeiffer J, ed. APIC text of infection control and epidemiology. Washington, DC: Association for Professionals in Infection Control and Epidemiology, Inc., 2000:76.1--76.8.
48. Weems JJ Jr, Davis BJ, Tablan OC, Kaufman L, Martone WJ. Construction activity: an independent risk factor for invasive aspergillosis and zygomycosis in patients with hematologic malignancy. Infect Control 1987;8:71--5.
49. Krasinski K, Holzman RS, Hanna B, Greco MA, Graff M, Bhogal M. Nosocomial fungal infection during hospital renovation. Infect Control 1985;6:278--82.
50. Bartley JM. APIC state-of-the-art report: the role of infection control during construction in health care facilities. Am J Infect Control 2000;28:156--69.
51. Walsh TJ, Dixon DM. Nosocomial aspergillosis: environmental microbiology, hospital epidemiology, diagnosis and treatment. Eur J Epidemiol 1989;5:131--42.
52. Johnson MW, Mitch WE, Heller AH, Spector R. The impact of an educational program on gentamicin use in a teaching hospital. Am J Med 1982;73:9--14.
53. Soumerai SB, Salem-Schatz S, Avorn J, Casteris CS, Ross-Degnan D, Popovsky MA. A controlled trial of educational outreach to improve blood transfusion practice. JAMA 1993;270:961--6.
54. Eisenberg JM. An educational program to modify laboratory use by house staff. J Med Educ 1977;52:578--81.
55. Rello J, Quintana E, Ausina V, Puzo V, Puzo C, Net A, Prats G. Risk factors for *Staphylococcus aureus* nosocomial pneumonia in critically ill patients. Am Rev Respir Dis 1990;142:1320--4.
56. McWhinney PHM, Kibbler CC, Hamon MD, et al. Progress in the diagnosis and management of aspergillosis in bone marrow transplantation: 13 years' experience. Clin Infect Dis 1993;17:397--404.
57. Pannuti CS, Gingrich RD, Pfaller MA, Wenzel RP. Nosocomial pneumonia in adult patients undergoing bone marrow transplantation: a 9-year study. J Clin Oncol 1991;9:77--84.
58. Wingard JR, Beals SU, Santos GW, Mertz WG, Saral R. *Aspergillus* infections in bone marrow transplant recipients. Bone Marrow Transplant 1987;2:175--81.
59. Gerson SL, Talbot GH, Hurwitz S, Strom BL, Lusk EJ, Cassileth PA. Prolonged granulocytopenia: the major risk factor for invasive pulmonary aspergillosis in patients with acute leukemia. Ann Intern Med 1984;100:345--51.

60. Lentino JR, Rosenkranz MA, Michaels JA, Kurup VP, Rose HD, Rytel MW. Nosocomial aspergillosis: a retrospective review of airborne disease secondary to road construction and contaminated air conditioners. *Am J Epidemiol* 1982;116:430--7.
61. Streifel AJ, Lauer JL, Vesley D, Juni B, Rhame FS. *Aspergillus fumigatus* and other thermotolerant fungi generated by hospital building demolition. *Appl Environ Microbiol* 1983;46:375--8.
62. Thio CL, Smith D, Merz WG, et al. Refinements of environmental assessment during an outbreak investigation of invasive aspergillosis in a leukemia and bone marrow transplant unit. *Infect Control Hosp Epidemiol* 2000;21:18--23.
63. Mermel LA, Josephson SL, Giorgio CH, Dempsey J, Parenteau S. Association of Legionnaires' disease with construction: contamination of potable water? *Infect Control Hosp Epidemiol* 1995;16:76--81.
64. Arnow PM, Anderson RL, Mainous PD, Smith EJ. Pulmonary aspergillosis during hospital renovation. *Am Rev Respir Dis* 1978;118:49--53.
65. Kuehn TH, Gacek B, Yang CH, et al. Identification of contaminants, exposures, effects, and control options for construction/renovation activities (RP-804). *ASHRAE Transactions: Research*, 1995.
66. Opal SM, Asp AA, Cannady PB Jr, Morse PL, Burton LJ, Hammer PG II. Efficacy of infection control measures during a nosocomial outbreak of disseminated aspergillosis associated with hospital construction. *J Infect Dis* 1986;153:634--7.
67. Association for Professionals in Infection Control and Epidemiology, Education Committee 1998--99. Infection control tool kit series --- construction and renovation. Bartley J, ed. Washington DC: Association for Professionals in Infection Control and Epidemiology, 1999.
68. Ottney TC. Particle management for HVAC systems. *ASHRAE J* 1993;35:26--34.
69. Finkelstein LE, Mendelson MH. Infection control challenges during hospital renovation. *Am J Nursing* 1997;97:60--1.
70. Overberger PA, Wadowsky RM, Schaper MM. Evaluation of airborne particulates and fungi during hospital renovation. *Am Ind Hyg Assoc J* 1995;56:706--12.
71. Streifel AJ, Marshall JW. Parameters for ventilation controlled environments in hospitals. In: Design, construction, and operation of healthy buildings (IAQ/1997). Atlanta, GA: ASHRAE Press, 1998.
72. American Society of Heating, Refrigerating, and Air-Conditioning Engineers (ASHRAE). The HVAC commissioning process. *ASHRAE Guideline 1-1996*. Atlanta, GA: ASHRAE Press, 1996.
73. Morey R, Williams C. Porous insulation in buildings: a potential source of microorganisms. In: Proceedings of Indoor Air '90, 5th International Conference. Toronto, Canada: International Society of Indoor Air Quality and Climate, 1990.
74. Aisner J, Murillo J, Schimpff SC, Steere AC. Invasive aspergillosis in acute leukemia: correlation with nose cultures and antibiotic use. *Ann Intern Med* 1979;90:4--9.
75. McCarty JM, Flam MS, Pullen G, Jones R, Kassel SH. Outbreak of primary cutaneous aspergillosis related to intravenous arm boards. *J Pediatr* 1986;108(Pt.1):721--4.
76. Klimowski LL, Rotstein C, Cummings KM. Incidence of nosocomial aspergillosis in patients with leukemia over a twenty-year period. *Infect Control Hosp Epidemiol* 1989;10:299--305.
77. Pfundstein J. *Aspergillus* infection among solid organ transplant recipients: a case study. *J Transpl Coord* 1997;7:187--9.
78. Rhame FS, Streifel A, Stevens P, et al. Endemic *Aspergillus* airborne spore levels are a major risk factor for aspergillosis in bone marrow transplant (BMT) patients [Abstract]. In: Program and abstracts of the 25th Interscience Conference on Antimicrobial Agents and Chemotherapy. Minneapolis, MN: American Society for Microbiology, 1985.
79. Walmsley S, Devi S, King S, Schneider R, Richardson S, Ford-Jones L. Invasive *Aspergillus* infections in a pediatric hospital: a ten-year review. *Pediatr Infect Dis J* 1993;12:673--82.
80. Kyriakides GK, Zinneman HH, Hall WH, et al. Immunologic monitoring and aspergillosis in renal transplant patients. *Am J Surg* 1976;131:246--52.
81. Abzug MJ, Gardner S, Glode MP, Cymanski M, Roe MH, Odom LF. Heliport-associated nosocomial mucormycoses [Letter]. *Infect Control Hosp Epidemiol* 1992;13:325--6.
82. Sherertz RJ, Belani A, Kramer BS, et al. Impact of air filtration on nosocomial *Aspergillus* infections: unique risk of bone marrow transplant recipients. *Am J Med* 1987;83:709--18.
83. Aisner J, Schimpff SC, Bennett JE, Young VM, Wiernik PH. *Aspergillus* infections in cancer patients: association with fireproofing materials in a new hospital. *JAMA* 1976;235:411--2.
84. Fox BC, Chamberlin L, Kulich P, Rae EJ, Webster LR. Heavy contamination of operating room air by *Penicillium* species: identification of the source and attempts at decontamination. *Am J Infect*

- Control 1990;18:300--6.
85. Barnes RA, Rogers TR. Control of an outbreak of nosocomial aspergillosis by laminar air-flow isolation. *J Hosp Infect* 1989;14:89--94.
 86. Leenders A, VanBelkum A, Janssen S, et al. Molecular epidemiology of apparent outbreaks of invasive aspergillosis in a hematology ward. *J Clin Microbiol* 1996;34:345--51.
 87. Yeager CC. Copper and zinc preservatives [Chapter 21]. In: Block SS, ed. *Disinfection, sterilization, and preservation*. 4th ed. Philadelphia, PA: Lea and Febiger, 1991.
 88. Allo MD, Miller J, Townsend T, Tan C. Primary cutaneous aspergillosis associated with Hickman intravenous catheters. *N Engl J Med* 1987;317:1105--8.
 89. Schleupner CJ, Hamilton JR. A pseudoepidemic of pulmonary fungal infections related to fiberoptic bronchoscopy. *Infect Control* 1980;1:38--42.
 90. Denning DW, Clemons KV, Hanson LH, Stevens DA. Restriction endonuclease analysis of total cellular DNA of *Aspergillus fumigatus* isolates of geographically and epidemiologically diverse origin. *J Infect Dis* 1990;162:1151--8.
 91. James MJ, Lasker BA, McNeil MM, Shelton M, Warnock DW, Reiss E. Use of a repetitive DNA probe to type clinical and environmental isolates of *Aspergillus flavus* from a cluster of cutaneous infections in a neonatal intensive care unit. *J Clin Microbiol* 2000;38:3612--8.
 92. Skladny H, Buchheidt D, Baust C, et al. Specific detection of *Aspergillus* species in blood and bronchoalveolar lavage samples of immunocompromised patients by two-step PCR. *J Clin Microbiol* 1999;37:3865--71.
 93. Symoens F, Bouchara JP, Heinemann S, Nolard N. Molecular typing of *Aspergillus terreus* isolates by random amplification of polymorphic DNA. *J Hosp Infect* 2000;44:273--80.
 94. Diaz-Guerra TM, Mellado E, Cuenca-Estrella M, Gaztelurrutia L, Navarro JI, Tudela JL. Genetic similarity among one *Aspergillus flavus* strain isolated from a patient who underwent heart surgery and two environmental strains obtained from the operating room. *J Clin Microbiol* 2000;38:2419--22.
 95. Siegler L, Kennedy MJ. *Aspergillus*, *Fusarium*, and other opportunistic moniliaceous fungi. In: Murray PR, Baron EJ, Pfaller MA, Tenover FC, Tenover FC, eds. *Manual of clinical microbiology*. 7th ed. Washington, DC: American Society for Microbiology Press. 1999:1212--41.
 96. Breton P, Germaud P, Morin O, Audouin AF, Milpied N, Harousseau JL. Unusual pulmonary mycoses in patients with hematologic disease [French]. *Rev Pneumol Clin* 1998;54:253--7.
 97. Guarro J, Nucci M, Akiti T, Gené J, Barreiro MD, Gonçalves RT. Fungemia due to *Fusarium sacchari* in an immunosuppressed patient. *J Clin Microbiol* 2000;38:419--21.
 98. Burton JR, Zachery JB, Bessin R, et al. Aspergillosis in four renal transplant patients: diagnosis and effective treatment with amphotericin B. *Ann Intern Med* 1972;77:383--8.
 99. Buckner CD, Clift RA, Sanders JE, et al. Protective environment for marrow transplant recipients: a prospective study. *Ann Intern Med* 1978;89:893--901.
 100. Murray WA, Streifel AJ, O'Dea TJ, Rhame FS. Ventilation for protection of immune compromised patients. *ASHRAE Transactions* 1988;94:1185--91.
 101. Streifel AJ, Vesley D, Rhame FS, Murray B. Control of airborne fungal spores in a university hospital. *Environment International* 1989;15: 221--7.
 102. Rhame FS. Endemic nosocomial filamentous fungal disease: a proposed structure for conceptualizing and studying the environmental hazard. *Infect Control* 1986;7(suppl 2):124--5.
 103. American Society of Heating, Refrigerating, and Air-Conditioning Engineers, Inc. 1999 ASHRAE handbook: heating, ventilating, and air-conditioning applications. Health care facilities [Chapter 7]. Atlanta GA: American Society of Heating, Refrigerating, and Air-Conditioning Engineers, Inc., 1999.
 104. Mahoney DH Jr, Steuber CP, Starling KA, Barrett FF, Goldberg J, Fernbach DJ. An outbreak of aspergillosis in children with acute leukemia. *J Pediatr* 1979;95:70--2.
 105. Ehrenkranz NJ, Kicklighter JL. Tuberculosis outbreak in a general hospital: evidence for airborne spread of infection. *Ann Intern Med* 1972;77:377--82.
 106. Calder RA, Duclos P, Wilder MH, Pryor VL, Scheel, WJ. *Mycobacterium tuberculosis* transmission in a health clinic. *Bull Int Union Tuberc Lung Dis* 1991;66:103--6.
 107. Jereb JA, Burwen DR, Dooley SW, et al. Nosocomial outbreak of tuberculosis in a renal transplant unit: application of a new technique for restriction fragment length polymorphism analysis of *Mycobacterium tuberculosis* isolates. *J Infect Dis* 1993;168:1219--24.
 108. Monath TP. Yellow fever: Victor, Victoria? Conqueror, conquest? Epidemics and research in the last forty years and prospects for the future. *Am J Trop Med Hyg* 1991;45:1--43.

109. [CDC. Update: Management of patients with suspected viral hemorrhagic fever --- United States. MMWR 1995;44:475--9.](#)
110. Weber DJ, Rutala WA. Risks and prevention of nosocomial transmission of rare zoonotic diseases. Clin Infect Dis 2001;32:446--56.
111. Gerberding JL. Nosocomial transmission of opportunistic infections. Infect Control Hosp Epidemiol 1998;19:574--7.
112. Vargas SL, Ponce CA, Gigliotti F, et al. Transmission of *Pneumocystis carinii* DNA from a patient with *P. carinii* pneumonia to immunocompetent contact health care workers. J Clin Microbiol 2000;38:1536--8.
113. Walzer PD. *Pneumocystis carinii* [Chapter 260]. In: Mandell GL, Bennett JE, Dolin R., eds. Principles and practice of infectious diseases. 5th ed. Philadelphia, PA: Churchill Livingstone, 2000:2781--95.
114. Mangram AJ, Horan TC, Pearson ML, Silver LC, Jarvis WR, Hospital Infection Control Practices Advisory Committee. Guideline for prevention of surgical site infection, 1999. Infect Control Hosp Epidemiol 1999;20:247--80.
115. Lidwell OM. Clean air at operation and subsequent sepsis in the joint. Clin Orthop 1986;211:91--102.
116. Nichols RL. The operating room [Chapter 22]. In: Bennett JV, Brachman PS, eds. Hospital infections. 3rd ed. Boston, MA: Little, Brown and Company, 1992:461--73.
117. Clark RP, Reed PJ, Seal DV, Stephenson ML. Ventilation conditions and air-borne bacteria and particles in operating theatres: proposed safe economies. J Hyg (Lond) 1985;95:325--35.
118. Babb JR, Lynam P, Ayliffe GAJ. Risk of airborne transmission in an operating theater containing four ultraclean air units. J Hosp Infect 1995;31:159--68.
119. Laufman H. The operating room [Chapter 20]. In: Bennett JV, Brachman PS, eds. Hospital Infections. 2nd ed. Boston, MA: Little, Brown and Company, 1986:315--23.
120. Ad Hoc Committee of the Committee on Trauma, Division of Medical Sciences, National Academy of Sciences --- National Research Council. Postoperative wound infections: the influence of ultraviolet irradiation of the operating room and of various other factors. Ann Surg 1964;160(suppl):1--192.
121. Charnley J. A clean-air operating enclosure. Br J Surg 1964;51:202--5.
122. Lidwell OM, Lowbury EJ, Whyte W, Blowers R, Stanley SJ, Lowe D. Effect of ultraclean air in operating rooms on deep sepsis in the joint after total hip or knee replacement: a randomised study. Br Med J 1982;285:10--4.
123. Hill C, Flamant R, Mazas F, Evrard J. Prophylactic cefazolin versus placebo in total hip replacement: report of a multicentre double-blind randomised trial. Lancet 1981;1:795--6.
124. Ha'eri GB, Wiley AM. Total hip replacement in a laminar flow environment with special reference to deep infections. Clin Orthop 1980;148:163--8.
125. Collins DK, Steinhaus K. Total hip replacement without deep infection in a standard operating room. J Bone Joint Surg Am 1976;58:446--50.
126. Taylor GJ, Bannister GC, Leeming JP. Wound disinfection with ultraviolet radiation. J Hosp Infect 1995;30:85--93.
127. Ayliffe GA. Role of the environment of the operating suite in surgical wound infection. Rev Infect Dis 1991;13(suppl 10):S800--4.
128. Choux M, Genitori L, Lang D, Lena G. Shunt implantation: reducing the incidence of shunt infection. J Neurosurg 1992;77:875--80.
129. Occupational Safety and Health Administration. 29 CFR 1910.139. Respiratory Protection. Federal Register 1998;63:1152--300.
130. Langevin PB, Rand KH, Layton AJ. The potential for dissemination of *Mycobacterium tuberculosis* through the anesthesia breathing circuit. Chest 1999;115:1107--14.
131. Occupational Safety and Health Administration. 29 CFR 1910. Occupational exposure to tuberculosis proposed rule. Federal Register 1997;62:54159--209.
132. Aranha-Creado H, Prince D, Greene K, Brandwein H. Removal of *Mycobacterium* species by breathing circuit filters. Infect Control Hosp Epidemiol 1997;18:252--4.
133. Burroughs HE. Sick building syndrome: fact, fiction, or facility? In: Hansen W., ed. A guide to managing indoor air quality in health care organizations. Oakbrook Terrace, IL: Joint Commission on Accreditation of Health Care Organizations, 1997:3--13.
134. Anderson K, Morris G, Kennedy H, et al. Aspergillosis in immunocompromised paediatric patients: associations with building hygiene, design, and indoor air. Thorax 1996;51:256--61.

135. National Institute for Occupational Safety and Health. Control of smoke from laser/electric surgical procedures, 1996; DHHS publication no. (NIOSH) 96--128. Available at <http://www.cdc.gov/niosh/hc11.html>.
136. Association of Perioperative Registered Nurses. Recommended practices for laser safety in practice settings. AORN J 1998;67:263--4, 267--9.
137. Hughes PS, Hughes AP. Absence of human papillomavirus DNA in the plume of erbium: YAG laser-treated warts. J Am Acad Dermatol 1998;38:426--8.
138. Capizzi PJ, Clay RP, Battey MJ. Microbiologic activity in laser resurfacing plume and debris. Lasers Surg Med 1998;23:172--4.
139. Emergency Care Research Institute (ECRI). Surgical smoke evacuation systems. Health Devices 1997;26:132--72.
140. ECRI. Update evaluation: surgical smoke evacuation systems. Health Devices 1999;28:333--62.
141. ECRI. Stationary surgical smoke evacuation systems. Health Devices 2001;30:73--86.
142. Villarino ME, Stevens LE, Schable B, et al. Risk factors for epidemic *Xanthomonas maltophilia* infection/colonization in intensive care unit patients. Infect Control Hosp Epidemiol 1992;13:201--6.
143. Seifert H, Strate A, Pulverer G. Nosocomial bacteremia due to *Acinetobacter baumannii*: clinical features, epidemiology, and predictors of mortality. Medicine (Baltimore) 1995;74:340--9.
144. Yu VL. *Serratia marcescens*: historical perspective and clinical review. N Engl J Med 1979;300:887--93.
145. Go ES, Urban C, Burns J, et al. Clinical and molecular epidemiology of *Acinetobacter* infections sensitive only to polymyxin B and sulbactam. Lancet 1994;344:1329--32.
146. Boyce JM, Pittet D. Guideline for hand hygiene in health-care settings: recommendations of the Healthcare Infection Control Practices Advisory Committee and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force. Infect Control Hosp Epidemiol 2002;23 (suppl):S3--40.
147. Burdge DR, Nakielnia EM, Noble MA. Case-control and vector studies of nosocomial acquisition of *Pseudomonas cepacia* in adult patients with cystic fibrosis. Infect Control Hosp Epidemiol 1993;14:127--30.
148. Cox R, deBorja K, Bach MC. A pseudo-outbreak of *Mycobacterium chelonae* infections related to bronchoscopy. Infect Control Hosp Epidemiol 1997;18:136--7.
149. Hoy J, Rolston K, Hopfer RL. Pseudoepidemic of *Mycobacterium fortuitum* in bone marrow cultures. Am J Infect Control 1987;15:268--71.
150. Stine TM, Harris AA, Levin S, Rivera N, Kaplan, RL. A pseudoepidemic due to atypical mycobacteria in a hospital water supply. JAMA 1987;258:809--11.
151. Bennett SN, Peterson DE, Johnson DR, Hall WN, Robinson-Dunn B, Dietrich S. Bronchoscopy-associated *Mycobacterium xenopi* pseudoinfections. Am J Respir Crit Care Med 1994;150:245--50.
152. Hlady WG, Mullen RC, Mintz CS, Shelton BG, Hopkins RS, Daikos GL. Outbreak of Legionnaire's disease linked to a decorative fountain by molecular epidemiology. Am J Epidemiol 1993;138:555--62.
153. American Society of Heating, Refrigerating, and Air-Conditioning Engineers, Inc.. ASHRAE guideline 12--2000: minimizing the risk of legionellosis associated with building water systems. Atlanta, GA: ASHRAE, Inc., 2000:1--6.
154. Snyder MB, Siwicki M, Wireman J, et al. Reduction of *Legionella pneumophila* through heat flushing followed by continuous supplemental chlorination of hospital hot water. J Infect Dis 1990;162:127--32.
155. Ezzeddine H, Van Ossel C, Delmée M, Wauters G. *Legionella* spp. in a hospital hot water system: effect of control measures. J Hosp Infect 1989;13:121--31.
156. Joint Commission on Accreditation of Healthcare Organizations. Comprehensive accreditation manual for hospitals: the official handbook. Oakbrook Terrace, IL: JCAHO Press, 2000.
157. Juranek DD, Addiss DG, Bartlett ME, et al. Cryptosporidiosis and public health: workshop report. Journal of the American Water Works Association 1995;87:69--80.
158. Tokars JJ, Miller ER, Alter MJ, Arduino MJ. National surveillance of dialysis-associated diseases in the United States, 1997. Semin Dial 2000;13:75-85.
159. Vujanovic V, Smoragiewicz W, Krzysztyniak K. Airborne fungal ecological niche determination as one of the possibilities for indirect mycotoxin risk assessment in indoor air. Environ Toxicol 2001;16:1--8.
160. Vesper S, Dearborn DG, Yike I, et al. Evaluation of *Stachybotrys chartarum* in the house of an infant with pulmonary hemorrhage: quantitative assessment before, during, and after remediation. J Urban Health 2000;77:68--85.

161. Best M, Yu VL, Stout J, Goetz A, Muder RR, Taylor F. Legionellaceae in the hospital water-supply: epidemiologic link with disease and evaluation of a method for control of nosocomial Legionnaires' disease and Pittsburgh pneumonia. *Lancet* 1983;2:307--10.
162. Meenhorst PL, Reingold AL, Groothuis DG, et al. Water-related nosocomial pneumonia caused by *Legionella pneumophila* serogroups 1 and 10. *J Infect Dis* 1985;152:356--64.
163. Johnston JM, Latham RH, Meier FA, et al. Nosocomial outbreak of Legionnaires' disease: molecular epidemiology and disease control measures. *Infect Control* 1987;8:53--8.
164. Muraca PW, Yu VL, Goetz A. Disinfection of water distribution systems for *Legionella*: a review of application procedures and methodologies. *Infect Control Hosp Epidemiol* 1990;11:79--88.
165. Johnson JT, Yu VL, Best MG, et al. Nosocomial legionellosis in surgical patients with head and neck cancer: implications for epidemiological reservoir and mode of transmission. *Lancet* 1985;2:298--300.
166. Marrie TJ, MacDonald S, Clarke K, Haldane D. Nosocomial legionnaires' disease: lessons from a four-year prospective study. *Am J Infect Control* 1991;19:79--85.
167. Marrie TJ, Haldane D, Bezanson G, Peppard R. Each water outlet is a unique ecological niche for *Legionella pneumophila*. *Epidemiol Infect* 1992;108:261--70.
168. Department of Health and Social Security and the Welsh Office. The control of *Legionellae* in health care premises: a code of practice. London: Her Majesty's Stationery Office, 1991.
169. Helms CM, Massanari RM, Wenzel RP, et al. Legionnaires' disease associated with a hospital water system: a five-year progress report on continuous hyperchlorination. *JAMA* 1988;259:2423--7.
170. Edelstein PH, Whittaker RE, Kreiling RL, Howell, CL. Efficacy of ozone in eradication of *Legionella pneumophila* from hospital plumbing fixtures. *Appl Environ Microbiol* 1982;44:1330--4.
171. Muraca P, Stout JE, Yu VL. Comparative assessment of chlorine, heat, ozone, and UV light for killing *Legionella pneumophila* within a model plumbing system. *Appl Environ Microbiol* 1987;53:447--53.
172. Domingue EL, Tyndall RL, Mayberry WR, Pancorbo OC. Effects of three oxidizing biocides on *Legionella pneumophila* serogroup 1. *Appl Environ Microbiol* 1988;54:741--7.
173. Landeen LK, Yahya MT, Gerba CP. Efficacy of copper and silver ions and reduced levels of free chlorine in inactivation of *Legionella pneumophila*. *Appl Environ Microbiol* 1989;55:3045--50.
174. Matulonis U, Rosenfeld CS, Shadduck RK. Prevention of *Legionella* infections in bone marrow transplant unit: multifaceted approach to decontamination of a water system. *Infect Control Hosp Epidemiol* 1993;14:571--5.
175. Liu Z, Stout JE, Tedesco L, et al. Controlled evaluation of copper-silver ionization in eradicating *Legionella pneumophila* from a hospital water distribution system. *J Infect Dis* 1994;169:919--22.
176. Margolin AB. Control of microorganisms in source water and drinking water [Chapter 20]. In: Hurst CJ, Knudsen GR, McInerney MJ, Stetzenback LD, Walter MV, eds. *Manual of environmental microbiology*. Washington, DC: American Society for Microbiology Press, 1997:195--202.
177. Freije MR. *Legionella* control in health care facilities: a guide for minimizing risk. Indianapolis, In: HC Information Resources, Inc., 1996:65--75.
178. Lin YE, Vidic RD, Stout JE, Yu VL. *Legionella* in water distribution systems: regular culturing of distribution system samples is the key to successful disinfection. *Journal of the American Water Works Association* 1998;90:112--21.
179. Biurrun A, Caballero L, Pelaz C, León E, Gago A. Treatment of a *Legionella pneumophila*-colonized water distribution system using copper-silver ionization and continuous chlorination. *Infect Control Hosp Epidemiol* 1999;20:426--8.
180. Goetz A, Yu VL. Copper-silver ionization: Cautious optimism for *Legionella* disinfection and implications for environmental culturing. *Am J Infect Control* 1997;25:449--451.
181. Stout JE, Lin EY, Goetz AM, Muder RR. Controlling *Legionella* in hospital water systems: experience with the superheat-and-flush method and copper-silver ionization. *Infect Control Hosp Epidemiol* 1998;19:911--4.
182. Walker JT, Mackerness CW, Mallon D, Makin T, Williets T, Keevil CW. Control of *Legionella pneumophila* in a hospital water system by chlorine dioxide. *J Ind Microbiol* 1995;15:384--90.
183. Hambidge A. Reviewing efficacy of alternative water treatment techniques. *Health Estate Journal* 2001;55:23--5.
184. Rohr U, Senger M, Selenka F, Turley R, Wilhelm M. Four years of experience with silver-copper ionization for control of *Legionella* in a German university hospital hot water plumbing system. *Clin Infect Dis* 1999;29:1507--11.

185. Cunliffe DA. Inactivation of *Legionella pneumophila* by monochloramine. J Appl Bacteriol 1990;68:453--9.
186. Kirmeyer GJ, Foust GW, Pierson GL, Simmler JJ, LeChevalier MW. Optimizing chloramine treatment. Denver, CO; American Water Works Research Foundation, 1993.
187. Kool JL, Carpenter JC, Fields BS. Effect of monochloramine disinfection of municipal drinking water on risk of nosocomial Legionnaires' disease. Lancet 1999;353:272--7.
188. Kool JL, Bergmire-Sweat D, Butler JC, et al. Hospital characteristics associated with colonization of water systems by *Legionella* and risk of nosocomial Legionnaires' disease: a cohort study of 15 hospitals. Infect Control Hosp Epidemiol 1999;20:798--805.
189. Kool JL, Fiore AE, Kioski CM, et al. More than 10 years of unrecognized nosocomial transmission of Legionnaires' disease among transplant patients. Infect Control Hosp Epidemiol 1998;19:898--904.
190. Le Saux NM, Sekla L, McLeod J, et al. Epidemic of nosocomial Legionnaires' disease in renal transplant recipients: a case-control and environmental study. CMAJ 1989;140:1047--53.
191. Kugler JW, Armitage JO, Helms CM, et al. Nosocomial Legionnaires' disease: occurrence in recipients of bone marrow transplants. Am J Med 1983;74:281--8.
192. Marston BJ, Lipman HB, Breiman RF. Surveillance for Legionnaires' disease: risk factors for morbidity and mortality. Arch Intern Med 1994;154:2417--22.
193. Haley CE, Cohen ML, Halter J, Meyer RD. Nosocomial Legionnaires' disease: a continuing common-source epidemic at Wadsworth Medical Center. Ann Intern Med 1979;90:583--6.
194. Jimenez ML, Aspa J, Padilla B, et al. Fiberoptic bronchoscopic diagnosis of pulmonary disease in 151 HIV-infected patients with pneumonitis. Eur J Clin Microbiol Infect Dis 1991; 10:491--7.
195. Bock BV, Kirby BD, Edelstein PH, et al. Legionnaires' disease in renal-transplant recipients. Lancet 1978;1:410--3.
196. Kirby BD, Snyder KM, Meyer RD, Finegold SM. Legionnaires' disease: report of sixty-five nosocomially acquired cases and review of the literature. Medicine (Baltimore) 1980;59:188--205.
197. Brady MT. Nosocomial legionnaires disease in a children's hospital. J Pediatr 1989;115:46--50.
198. Muder RR, Yu VL, McClure JK, Kroboth FJ, Kominos SD, Lumish RM. Nosocomial Legionnaires' disease uncovered in a prospective pneumonia study: implications for underdiagnosis. JAMA 1983;249:3184--8.
199. Garbe PL, Davis BJ, Weisfeld JS, et al. Nosocomial Legionnaires' disease: epidemiologic demonstration of cooling towers as a source. JAMA 1985;254:521--4.
200. Hanrahan JP, Morse DL, Scharf VB, et al. A community hospital outbreak of legionellosis: transmission by potable hot water. Am J Epidemiol 1987;125:639--49.
201. Arnow PM, Chou T, Weil D, Shapiro EN, Kretzschmar C. Nosocomial Legionnaires' disease caused by aerosolized tap water from respiratory devices. J Infect Dis 1982;146:460--7.
202. Mastro TD, Fields BS, Breiman RF, Campbell J, Plikaytis BD, Spika JS. Nosocomial Legionnaires' disease and use of medication nebulizers. J Infect Dis 1991;163:667--70.
203. Dondero TJ Jr, Rendtorff RC, Mallison GF, et al. An outbreak of Legionnaires' disease associated with a contaminated air-conditioning cooling tower. N Engl J Med 1980;302:365--70.
204. O'Mahony MC, Stanwell-Smith RE, Tillett HE, et al. The Stafford outbreak of Legionnaires' disease. Epidemiol Infect 1990;104:361--80.
205. Breiman RF, Fields BS, Sanden G, Volmer L, Meier A, Spika JS. Association of shower use with Legionnaires' disease: possible role of amoebae. JAMA 1990;263:2924--6.
206. Breiman RF, VanLoock FL, Sion JP, et al. Association of "sink bathing" and Legionnaires' disease [Abstract]. In: Program and abstracts of the 91st General Meeting of the American Society for Microbiology. Dallas, TX: American Society for Microbiology, 1991.
207. Struelens MJ, Maes N, Rost F, et al. Genotypic and phenotypic methods for the investigation of a nosocomial *Legionella pneumophila* outbreak and efficacy of control measures. J Infect Dis 1992;166:22--30.
208. Barbaree JM, Gorman GW, Martin WT, Fields BS, Morrill WE. Protocol for sampling environmental sites for Legionellae. Appl Environ Microbiol 1987;53:1454--8.
209. Schoonmaker D, Heimberger T, Birkhead G. Comparison of ribotyping and restriction enzyme analysis using pulsed-field gel electrophoresis for distinguishing *Legionella pneumophila* isolates obtained during a nosocomial outbreak. J Clin Microbiol 1992;30:1491--8.
210. Knirsch CA, Jakob K, Schoonmaker D, et al. An outbreak of *Legionella micdadei* pneumonia in transplant patients: evaluation, molecular epidemiology, and control. Am J Med 2000;108:290--5.

211. [CDC. Sustained transmission of nosocomial Legionnaires Disease --- Arizona and Ohio. MMWR 1997;46:416--21.](#)
212. Alary M, Joly JR. Factors contributing to the contamination of hospital water distribution systems by *Legionellae*. J Infect Dis 1992;165:565--9.
213. Yu VL, Beam TR Jr, Lumish RM, et al. Routine culturing for *Legionella* in the hospital environment may be a good idea: A three-hospital prospective study. Am J Med Sci 1987;294:97--9.
214. Tobin JO, Swann RA, Bartlett CL. Isolation of *Legionella pneumophila* from water systems: Methods and preliminary results. Br Med J 1981;282:515--7.
215. Chow JW, Yu VL. Legionella: a major opportunistic pathogen in transplant recipients. Semin Respir Infect 1998;13:132--9.
216. Mandel AS, Sprauer MA, Sniadack DH, Ostroff SM. State regulation of hospital water temperature. Infect Control Hosp Epidemiol 1993;14:642--5.
217. Hirani NA, Macfarlane JT. Impact of management guidelines on the outcome of severe community acquired pneumonia. Thorax 1997;52:17--21.
218. Patterson WJ, Hay J, Seal DV, McLuckie JC. Colonization of transplant unit water supplies with *Legionella* and protozoa: precautions required to reduce the risk of legionellosis. J Hosp Infect 1997;37:7--17.
219. Marrie TJ, Haldane D, MacDonald S, et al. Control of endemic nosocomial Legionnaires' disease by using sterile potable water for high risk patients. Epidemiol Infect 1991;107:591--605.
220. Zuravleff JJ, Yu VL, Shonnard JW, Rihs JD, Best M. *Legionella pneumophila* contamination of a hospital humidifier: demonstration of aerosol transmission and subsequent subclinical infection in exposed guinea pigs. Am Rev Respir Dis 1983;128:657--61.
221. World Health Organization, Regional Office for Europe. Environmental aspects of the control of legionellosis [German]. Schriftenr Ver Wasser Boden Lufthyg 1993;91:249--52.
222. Bhopal RS, Barr G. Maintenance of cooling towers following two outbreaks of Legionnaires' disease in a city. Epidemiol Infect 1990;104:29--38.
223. World Health Organization. Epidemiology, prevention, and control of legionellosis: memorandum from a WHO meeting. Bull World Health Organ 1990;68:155--64.
224. Bolan G, Reingold AL, Carson LA, et al. Infections with *Mycobacterium chelonae* in patients receiving dialysis and using processed hemodialyzers. J Infect Dis 1985;152:1013--9.
225. Lowry PW, Beck-Saguè CM, Bland LA, et al. *Mycobacterium chelonae* infection among patients receiving high-flux dialysis in a hemodialysis clinic in California. J Infect Dis 1990;161:85--90.
226. Favero MS, Petersen NJ, Boyer KM, Carson LA, Bond WW. Microbial contamination of renal dialysis systems and associated health risks. Trans Am Soc Artif Intern Organs 1974;20:175--83.
227. Favero MS, Petersen NJ, Carson LA, Bond WW, Hindman SH. Gram-negative water bacteria in hemodialysis systems. Health Lab Sci 1975;12:321--34.
228. Favero MS, Petersen NJ. Microbiologic guidelines for hemodialysis systems. Dialysis Transplant 1997;6:34--6.
229. Association for the Advancement of Medical Instrumentation and American National Standards Institute. Hemodialysis systems. ANSI/AAMI RD5-1992. Arlington, VA: 1993.
230. Association for the Advancement of Medical Instrumentation, American National Standards Institute. Reuse of hemodialyzers. ANSI/AAMI RD47-1993. Arlington, VA: 1993.
231. Petersen NJ, Boyer KM, Carson LA, Favero MS. Pyrogenic reactions from inadequate disinfection of a dialysis fluid distribution system. Dialysis Transpl 1978;7:52--7.
232. Dawids SG, Vejlsgaard R. Bacteriological and clinical evaluation of different dialysate delivery systems. Acta Med Scand 1976;199:151--5.
233. Kidd EE. Bacterial contamination of dialyzing fluid of artificial kidney. Br Med J 1964;1:880--2.
234. Klein E, Pass T, Harding GB, Wright R, Million C. Microbial and endotoxin contamination in water and dialysate in the central United States. Artif Organs 1990;14:85--94.
235. Man NK, Degremont A, Darbord JC, Collet M, Vaillant P. Evidence of bacterial biofilm in tubing from hydraulic pathway of hemodialysis system. Artif Organs 1998;22:596--600.
236. Association for the Advancement of Medical Instrumentation. Water treatment equipment for hemodialysis applications. ANSI/AAMI RD62--2001. American National Standards Institute, Inc. Arlington, VA: 2001.
237. Bland LA. Microbiological and endotoxin assays of hemodialysis fluids. Adv Renal Replace Ther 1995;2:70--9.
238. Arduino MJ, Bland LA, Agüero SM, Carson LA, Ridgeway M, Favero MS. Comparison of microbiologic assay methods for hemodialysis fluids. J Clin Microbiol 1991;29:592--4.

239. Bland LA, Ridgeway MR, Aguero SM, Carson LA, Favero MS. Potential bacteriologic and endotoxin hazards associated with liquid bicarbonate concentrate. *ASAIO Trans* 1987;33:542--5.
240. Raij L, Shapiro FL, Michael AF. Endotoxemia in febrile reactions during hemodialysis. *Kidney Int* 1973;4:57--60.
241. Bommer J, Becker KP, Urbaschek R. Potential transfer of endotoxin across high-flux polysulfone membranes. *J Am Soc Nephrol* 1996;7:883--8.
242. Arduino MJ, Favero MS. Microbiologic aspects of hemodialysis. Arlington, VA: Association for the Advancement of Medical Instrumentation, 1998. AAMI monograph WQD--1998.
243. Koepke GH, Christopher RP. Contamination of whirlpool baths during treatment of infected wounds. *Arch Phys Med Rehabil* 1965;46:261--3.
244. CDC. Epidemiologic notes and reports: outbreak of viral gastroenteritis --- Pennsylvania and Delaware. *MMWR* 1987;36:709--11.
245. Crow HE, Corpe RF, Smith CE. Is serious pulmonary disease caused by nonphotochromogenic ("atypical") acid-fast mycobacteria communicable? *Dis Chest* 1961;39:372--81.
246. Stout JE, Yu VL, Muraca P. Isolation of *Legionella pneumophila* from the cold water of hospital ice machines: implications for origin and transmission of the organism. *Infect Control* 1985;6:141--6.
247. Manangan LP, Anderson RL, Arduino MJ, Bond WW. Sanitary care and maintenance of ice-storage chests and ice-making machines in health care facilities. *Am J Infect Control* 1998;26:111--2.
248. Cannon RO, Poliner JR, Hirschhorn RB, et al. A multistate outbreak of Norwalk virus gastroenteritis associated with consumption of commercial ice. *J Infect Dis* 1991;164:860--3.
249. Khan AS, Moe CL, Glass RI, et al. Norwalk virus-associated gastroenteritis traced to ice consumption aboard a cruise ship in Hawaii: comparison and application of molecular method-based assays. *J Clin Microbiol* 1994;32:318--22.
250. Schmidt OW, Cooney MK, Foy HM. Adeno-associated virus in adenovirus type 3 conjunctivitis. *Infect Immun* 1975;11:1362--70.
251. McCandlish R, Renfrew M. Immersion in water during labor and birth: the need for evaluation. *Birth* 1993;20:79--85.
252. White CG. Chemistry of chlorination [Chapter 4]. In: *Handbook of Chlorination and Alternative Disinfectants*. 3rd ed. New York, NY: Van Nostrand Reinhold, 1992:184--249.
253. Muscarella LF. Automatic flexible endoscope reprocessors. *Gastrointest Endosc Clin N Am* 2000;10:245--57.
254. Muscarella LF. Anticipated reliability of liquid chemical sterilants [Letter]. *Am J Infect Control* 1998;26:155--6.
255. Muscarella LF. Déjà vu . . . all over again? The importance of instrument drying [Letter]. *Infect Control Hosp Epidemiol* 2000;21:628--9.
256. Gubler JG, Salfinger M, von Graevenitz A. Pseudoepidemic of nontuberculous mycobacteria due to a contaminated bronchoscope cleaning machine: report of an outbreak and review of the literature. *Chest* 1992;101:1245--9.
257. Fraser VJ, Jones M, Murray PR, Medoff G, Zhang Y, Wallace RJ Jr. Contamination of flexible fiberoptic bronchoscopes with *Mycobacterium chelonae* linked to an automated bronchoscope disinfection machine. *Am Rev Respir Dis* 1992;145:853--5.
258. Muscarella LF. Application of environmental sampling to flexible endoscope reprocessing: the importance of monitoring the rinse water. *Infect Control Hosp Epidemiol* 2002; 23:285--9.
259. Cooke RP, Whyment-Morris A, Umasankar RS, Goddard SV. Bacteria-free water for automatic washer-disinfectors: an impossible dream? *J Hosp Infect* 1998;39:63--5.
260. Allen JJ, Allen MO, Olsen MM, et al. *Pseudomonas* infection of the biliary system resulting from the use of a contaminated endoscope. *Gastroenterology* 1987;92:759--63.
261. Michele TM, Cronin WA, Graham NM, et al. Transmission of *Mycobacterium tuberculosis* by a fiberoptic bronchoscope: identification by DNA fingerprinting. *JAMA* 1997;278:1093--95.
262. US Food and Drug Administration, CDC. Public health advisory: infections from endoscopes inadequately reprocessed by an automated endoscope reprocessing system. September 10, 1999. Available at <http://www.fda.gov/cdrh/safety/endoreprocess.pdf>.
263. Alvarado CJ, Reichelderfer M. APIC guideline for infection prevention and control in flexible endoscopy. *Am J Infect Control* 2000;28:138--55.
264. CDC. Statement from CDC regarding biofilm and dental unit water quality. Atlanta GA: US Department of Health and Human Services, Public Health Service, CDC, 1999.

265. [CDC. Recommended infection-control practices for dentistry, 1993. MMWR 1993;42 \(No. RR-3\):1-12.](#)
266. Office of Safety and Asepsis Procedures Research Foundation. Dental unit waterlines. OSAP position paper. Annapolis, MD: 2000. Available at <http://www.osap.org/issues/pages/water/duwl.htm>.
267. US Environmental Protection Agency. National Primary Drinking Water Regulations, 1999. 40 CFR 1, Part 141, Subpart G. Available at <http://www.epa.gov/safewater/mcl.html>.
268. Bagga BS, Murphy RA, Anderson AW, Punwani I. Contamination of dental unit cooling water with oral microorganisms and its prevention. JADA 1984;109:712--6.
269. Shearer BG. Biofilm and the dental office. JADA 1996;127:181--9.
270. Garner JS, Favero MS. CDC guideline for handwashing and hospital environmental control. Infect Control 1986;7:231--43.
271. US Environmental Protection Agency. Federal Insecticide, Fungicide, and Rodenticide Act, 1972. 7 USC 6 § 136 et seq. Available at <http://www4.law.cornell.edu/uscode/7/ch6schII.html>.
272. Mallison GF. Hospital disinfectants for housekeeping: floors and tables. Infect Control 1984;5:537.
273. Favero MS, Bond WW. Chemical disinfection of medical and surgical materials [Chapter 43]. In: Block SS, ed. Disinfection, sterilization, and preservation. 5th ed. Philadelphia, PA: Lippincott Williams and Wilkins, 2001.
274. Rutala WA. APIC guideline for selection and use of disinfectants. Am J Infect Control 1996;24:313--42.
275. Stingeni L, Lapomarda V, Lisi P. Occupational hand dermatitis in hospital environments. Contact Dermatitis 1995;33:172--6.
276. Ashdown BC, Stricof DD, May ML, Sherman SJ, Carmody RF. Hydrogen peroxide poisoning causing brain infarction: neuroimaging findings. AM J Roentgenol 1998;170:1653--5.
277. Busch A, Werner E. Animal tolerance to peracetic acid: experimental results following the application of peracetic acid solutions on the skin of pigs [German]. Monatshefte für Veterinaermedizin 1974;29:494--8.
278. US Food and Drug Administration. Medical devices: adequate directions for use. [21 CFR Part 801.5, 807.87.e].
279. Favero MS, Bond WW. Sterilization, disinfection, and antisepsis in the hospital [Chapter 24]. In: Balows A, Hausler WJ Jr, Herrmann KL, Isenberg HD, Shadomy HJ, eds. Manual of clinical microbiology. 5th ed. Washington, DC: American Society for Microbiology, 1991:183--200.
280. Chou T. Environmental Services. In: Pfeiffer J, ed. APIC text of infection control and epidemiology. Washington, DC: Association for Professionals in Infection Control and Epidemiology, Inc., 2000;73.1--8.
281. Rutala WA, Weber DJ. Cleaning, disinfection, and sterilization. In: Pfeiffer J, ed. APIC Text of Infection Control and Epidemiology. Washington, DC: Association for Professionals in Infection Control and Epidemiology, Inc., 2000;55.1--6.
282. Ayliffe GA, Collins BJ, Lowbury EJ, Babb JR, Lilly HA. Ward floors and other surfaces as reservoirs of hospital infection. J Hyg (Lond) 1967;65:515--37.
283. Dancer SJ. Mopping up hospital infection. J Hosp Infect 1999;43:85--100.
284. Schmidt EA, Coleman DL, Mallison GF. Improved system for floor cleaning in health care facilities. Appl Environ Microbiol 1984;47:942--6.
285. Mallison GF. Decontamination, disinfection, and sterilization. Nurs Clin North Am 1980;15:757--67.
286. Walter CW, Kundsinn RB. The floor as a reservoir of hospital infections. Surg Gynec Obstet 1960;111:412--22.
287. Scott E, Bloomfield SF. The survival and transfer of microbial contamination via cloths, hands and utensils. J Appl Bacteriol 1990;68:271--8.
288. Scott E, Bloomfield SF. Investigations of the effectiveness of detergent washing, drying and chemical disinfection on contamination of cleaning cloths. J Appl Bacteriol 1990;68:279--83.
289. Brown DG, Schatzle K, Gable T. The hospital vacuum cleaner: mechanism for redistributing microbial contaminants. J Environ Health 1980;42:192--6.
290. Wysowski DK, Flynt JW, Goldfield M, Altman R, Davis AT. Epidemic neonatal hyperbilirubinemia and use of a phenolic disinfectant detergent. Pediatrics 1978;61:165--70.
291. Doan HM, Keith L, Shennan AT. Phenol and neonatal jaundice. Pediatrics 1979;64:324--5.
292. American Academy of Pediatrics, American College of Obstetricians and Gynecologists. Infection control. In: Guidelines for perinatal care. 4th ed. Washington, DC: 1997:269--74.

293. US Department of Labor, Occupational Safety and Health Administration: 29 CFR 1910.1030. Occupational exposure to bloodborne pathogens; final rule. Federal Register 1991;56:64004--182.
294. Spire B, Montagnier L, Barré-Sinoussi F, Chermann JC. Inactivation of lymphadenopathy associated virus by chemical disinfectants. Lancet 1984;2:899--901.
295. Martin LS, McDougal JS, Loskoski SL. Disinfection and inactivation of the human T lymphotropic virus type-III/lymphadenopathy-associated virus. J Infect Dis 1985;152:400--3.
296. Hanson PJ, Gor D, Jeffries DJ, Collins JV. Chemical inactivation of HIV on surfaces. Br Med J 1989;298:862--4.
297. Bloomfield SF, Smith-Burchnell CA, Dalgleish AG. Evaluation of hypochlorite-releasing disinfectants against the human immunodeficiency virus (HIV). J Hosp Infect 1990;15:273--8.
298. Druce JD, Jardine D, Locarnini SA, Birch CJ. Susceptibility of HIV to inactivation by disinfectants and ultraviolet light. J Hosp Infect 1995;30:167--80.
299. Van Bueren J, Simpson RA, Salman H, Farrelly HD, Cookson BD. Inactivation of HIV--1 by chemical disinfectants: sodium hypochlorite. Epidemiol Infect 1995;115:567--79.
300. Prince DL, Prince HN, Thraehart O, et al. Methodological approaches to disinfection of human hepatitis B viruses. J Clin Microbiol 1993;31:3296--3304.
301. CDC. Recommendations for prevention of HIV transmission in health-care settings. MMWR 1987;36(Suppl No. 2S).
302. Sattar SA, Springthorpe VS. Survival and disinfectant inactivation of the human immunodeficiency virus: a critical review. Rev Infect Dis 1991;13:430--47.
303. US Department of Labor, Occupational Safety and Health Administration. EPA-registered disinfectants for HIV/HBV. Memorandum. Washington, D.C.: 1997. Available at http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=INTERPRETATIONS&p_id=22364&p_text_version=FALSE.
304. Weber DJ, Barbee SL, Sobsey MD, Rutala WA. The effect of blood on the antiviral activity of sodium hypochlorite, a phenolic, and a quaternary ammonium compound. Infect Control Hosp Epidemiol 1999;20:821--7.
305. Suzuki A, Namba Y, Matsuura M, Horisawa A. Bacterial contamination of floors and other surfaces in operating rooms: a five-year survey. J Hyg (Lond) 1984;93:559--66.
306. Richet H, McNeil M, Peters W, et al. *Aspergillus flavus* in a bone marrow transplant unit (BMTU): Pseudofungemia traced to hallway carpeting [Abstract F-23]. In: Abstracts of the 89th Annual Meeting of the American Society for Microbiology. New Orleans, LA: American Society for Microbiology, 1989:462.
307. US Department of Labor, Occupational Safety and Health Administration. Decontamination of a plush carpet surface after a spill. Standard interpretations, 1994. Available at http://www.osha.gov/pls/oshaweb/owasrch.search_form?p_doc_type=INTERPRETATIONS&p_toc_level=0&p_keyvalue=I19940610.html.
308. Taplin D, Mertz PM. Flower vases in hospitals as reservoirs for pathogens. Lancet 1973;2:1279--81.
309. Kates SG, McGinley KJ, Larson EL, Leyden JJ. Indigenous multiresistant bacteria from flowers in hospital and nonhospital environments. Am J Infect Control 1991;19:156--61.
310. Bartzokas CA, Holley MP, Sharp CA. Bacteria in flower vase water: incidence and significance in general ward practice. Br J Surg 1975;62:295--7.
311. Siegman-Igra Y, Shalem A, Berger SA, Livio S, Michaeli D. Should potted plants be removed from hospital wards? J Hosp Infect 1986;7:82--5.
312. Lass-Flörl C, Rath P, Niederwieser D, et al. *Aspergillus terreus* infections in haematological malignancies: molecular epidemiology suggests association with in-hospital plants. J Hosp Infect 2000;46:31--5.
313. Burgess NR. Hospital design and cockroach control. Trans R Soc Trop Med Hyg 1984;78:293--4.
314. Lukin LG. Human cutaneous myiasis in Brisbane: a prospective study. Med J Aust 1989;150:237--40.
315. Bruesch J. Institutional pest management: current trends. Exec Housekeep Today 1994;15:6--12.
316. Allen BW. Excretion of viable tubercle bacilli by *Blatta orientalis* (the oriental cockroach) following ingestion of heat-fixed sputum smears: a laboratory investigation. Trans R Soc Trop Med Hyg 1987;81:98--9.
317. Laszlo A. Technical guide: sputum examination for tuberculosis by direct microscopy in low income countries. 5th ed. Paris, France: International Union Against Tuberculosis and Lung Disease, 2000. Available at http://www.ariat.org/pdf/en/guides_publications/microscopy_guide.pdf.

318. [CDC. Recommendations for preventing the spread of vancomycin resistance: recommendations of the Hospital Infection Control Practices Advisory Committee \(HICPAC\). MMWR 1995;44 \(No. RR-12\).](#)
319. Gerding DN, Johnson S, Peterson LR, Mulligan ME, Silva J Jr. *Clostridium difficile*-associated diarrhea and colitis. Infect Control Hosp Epidemiol 1995;16:459--77.
320. Weber DJ, Rutala WA. Role of environmental contamination in the transmission of vancomycin-resistant enterococci. Infect Control Hosp Epidemiol 1997;18:306--9.
321. Lai KK, Kelley AL, Melvin ZS, Belliveau PP, Fontecchio SA. Failure to eradicate vancomycin-resistant enterococci in a university hospital and the cost of barrier precautions. Infect Control Hosp Epidemiol 1998;19:647--52.
322. Byers KE, Durbin LJ, Simonton BM, Anglim AM, Adal KA, Farr BM. Disinfection of hospital rooms contaminated with vancomycin-resistant *Enterococcus faecium*. Infect Control Hosp Epidemiol 1998;19:261--4.
323. Bradley CR, Fraiese AP. Heat and chemical resistance of enterococci. J Hosp Infect 1996;34:191--6.
324. Anderson RL, Carr JH, Bond WW, Favero MS. Susceptibility of vancomycin-resistant enterococci to environmental disinfectants. Infect Control Hosp Epidemiol 1997;18:195--9.
325. Saurina G, Landman D, Quale JM. Activity of disinfectants against vancomycin-resistant *Enterococcus faecium*. Infect Control Hosp Epidemiol 1997;18:345--7.
326. Rutala WA, Stiegel MM, Sarubbi FA, Weber DJ. Susceptibility of antibiotic-susceptible and antibiotic-resistant hospital bacteria to disinfectants. Infect Control Hosp Epidemiol 1997;18:417--21.
327. Sehulster LM, Anderson RL. Susceptibility of glycopeptide-intermediate resistant *Staphylococcus aureus* (GISA) to surface disinfectants, hand washing chemicals, and a skin antiseptic [Abstract Y-3]. In: Abstracts of the 98th General Meeting, American Society for Microbiology. Atlanta, GA: American Society for Microbiology, 1998.
328. Layton MC, Perez M, Heald P, Patterson JE. An outbreak of mupirocin-resistant *Staphylococcus aureus* on a dermatology ward associated with an environmental reservoir. Infect Control Hosp Epidemiol 1993; 14:369--75.
329. Karanfil LV, Murphy M, Josephson A, et al. A cluster of vancomycin-resistant *Enterococcus faecium* in an intensive care unit. Infect Control Hosp Epidemiol 1992;13:195--200.
330. Boyce JM, Opal SM, Chow JW, et al. Outbreak of multidrug-resistant *Enterococcus faecium* with transferable *vanB* class vancomycin resistance. J Clin Microbiol 1994;32:1148--53.
331. Rhinehart E, Smith NE, Wennersten C, et al. Rapid dissemination of beta-lactamase-producing, aminoglycoside-resistant *Enterococcus faecalis* among patients and staff on an infant-toddler surgical ward. N Engl J Med 1990;323:1814--8.
332. Livornese LL Jr, Dias S, Samel C, et al. Hospital-acquired infection with vancomycin-resistant *Enterococcus faecium* transmitted by electronic thermometers. Ann Intern Med 1992;117:112--6.
333. Zervos MJ, Kauffman CA, Therasse PM, Bergman AG, Mikesell TS, Schaberg DR. Nosocomial infection by gentamicin-resistant *Streptococcus faecalis*: an epidemiologic study. Ann Intern Med 1987;106:687--91.
334. Worsley MA. Infection control and prevention of *Clostridium difficile* infection. J Antimicrobial Chemother 1998;41(suppl C):59--66.
335. Lloyd-Evans N, Springthorpe VS, Sattar SA. Chemical disinfection of human rotavirus-contaminated inanimate surfaces. J Hyg (Lond) 1986;97:163--73.
336. Rutala WA, Weber DJ. Creutzfeldt-Jakob disease: recommendations for disinfection and sterilization. Clin Infect Dis 2001;32:1348--56.
337. Kimberlin RH, Walker CA, Millson GC, et al. Disinfection studies with two strains of mouse-passaged scrapie agent: guidelines for Creutzfeldt-Jakob and related agents. J Neurol Sci 1983;59:355--69.
338. Rosenberg RN, White CL, Brown P, et al. Precautions in handling tissues, fluids, and other contaminated materials from patients with documented or suspected Creutzfeldt-Jakob disease. Ann Neurol 1986;19:75--7.
339. Taylor DM. Inactivation of the unconventional agents of scrapie, bovine spongiform encephalopathy, and Creutzfeldt-Jakob disease. J Hosp Infect 1991; 18(suppl A):141--6.
340. Budka H, Aguzzi A, Brown P, et al. Tissue handling in suspected Creutzfeldt-Jakob disease (CJD) and other human spongiform encephalopathies (prion diseases). Brain Pathol 1995;5:319--22.
341. Ironside JW, Bell JE. The 'high-risk' neuropathological autopsy in AIDS and Creutzfeldt-Jakob disease: principles and practice. Neuropathol Appl Neurobiol 1996;22:388--93.

342. World Health Organization. WHO infection control guidelines for transmissible spongiform encephalopathies: report of a WHO consultation. Geneva, Switzerland: World Health Organization, 1999. Available at <http://www.who.int/emc-documents/tse/whocdscsraph2003c.html>.
343. Bond WW, Schulster LM. Microbiological assay of environmental and medical-device surfaces [Section 11]. In: Isenberg HD, ed. Clinical microbiology procedures. Washington, DC: American Society for Microbiology Press, 2003 (in press).
344. Clesceri LS, Greenberg AE, Eaton AD, eds. Standard methods for the examination of water and wastewater. 20th ed. Washington, DC: American Public Health Association, American Water Works Association, Water Environment Foundation, 1998:9-1--9-41.
345. Buttner MP, Willeke K, Grinshpun SA. Sampling and analysis of airborne microorganisms [Chapter 68]. In: Manual of environmental microbiology. Hurst CJ, Knudsen GR, McInerney MJ, Stetzenbach LD, Walter MV, eds. Washington, DC: American Society for Microbiology Press, 1997:629--40.
346. Jensen PA, Schafer MP. Sampling and characterization of bioaerosols. In: NIOSH manual of analytical methods. Cincinnati, OH: US Department of Health and Human Services, National Institute for Occupational Safety and Health, 1998:82--112. Available at <http://www.cdc.gov/niosh/nmam/pdfs/chapter-j.pdf>.
347. International Organization for Standardization. Sterilization of medical devices---microbiological methods [Part 1]. Paramus, NJ: International Organization for Standardization, 1995. ISO Standard 11737-1.
348. Streifel AJ. Air cultures for fungi. In: Isenberg HD, ed. Clinical microbiology procedures handbook. Washington, DC: American Society for Microbiology Press, 1992:11.8.1--7.
349. Wolf HW, Skaliy P, Hall LB, et al. Sampling microbiological aerosols. Washington, DC: US Department of Health, Education and Welfare, Public Health Service, 1964. Public Health Service publication no. 686. (Monograph no. 60).
350. Wagner RA. Partitioned laundry improves bacteria control. Hospitals JAHA 1966;40:148--51.
351. Hambræus A, Malmberg AS. Is a bed centre in a hospital a hygienic hazard? J Hyg (Lond) 1982;88:143--7.
352. McDonald LL, Pugliese G. Textile processing service [Chapter 66]. In: Mayhall CG, ed. Hospital epidemiology and infection control. 2nd ed. Philadelphia, PA: Lippincott Williams and Wilkins, 1999:1031--4.
353. Barrie D, Hoffman PN, Wilson JA, Kramer JM. Contamination of hospital linen by *Bacillus cereus*. Epidemiol Infect 1994;113:297--306.
354. Legnani PP, Leoni E. Factors affecting the bacteriological contamination of commercial washing machines [German]. Zentralbl Hyg 1997;200:319--33.
355. Joint Committee on Healthcare Laundry Guidelines. Guidelines for healthcare linen service. Hallendale, FL: Textile Rental Service Association of America, 1999.
356. Greene VW. Microbiological contamination control in hospitals: part 6 --- roles of central service and the laundry. Hospitals JAHA 1970;44:98--103.
357. Association for the Advancement of Medical Instrumentation. Processing of reusable surgical textiles for use in health care facilities: ANSI/AAMI Recommended Practice ST65:2000; Arlington, VA: Association for the Advancement of Medical Instrumentation, 2000:16.
358. Hughes HG. Chutes in hospitals. Can Hosp 1964;41:56--7,87.
359. Michaelsen GS. Designing linen chutes to reduce spread of infectious organisms. Hospitals JAHA 1965;39:116--9.
360. Hoch KW. Laundry chute cleaning recommendations [Letter]. Infect Control 1982;3:360.
361. Whyte W, Baird G, Annand R. Bacterial contamination on the surface of hospital linen chutes. J Hyg (Lond) 1969;67:427--35.
362. Taylor LJ. Segregation, collection, and disposal of hospital laundry and waste. J Hosp Infect 1988;11(suppl A):57--63.
363. Walter WG, Schillinger JE. Bacterial survival in laundered fabrics. Appl Microbiol 1975; 29:368--73.
364. Belkin NL. Aseptics and aesthetics of chlorine bleach: can its use in laundering be safely abandoned? Am J Infect Control 1998;26:149--51.
365. Blaser MJ, Smith PE, Cody HJ, Wang WL, LaForce FM. Killing of fabric-associated bacteria in hospital laundry by low-temperature washing. J Infect Dis 1984;149:48--57.
366. Jaska JM, Fredell DL. Impact of detergent systems on bacterial survival on laundered fabrics. Appl Environ Microbiol 1980;39:743--8.

367. Battles DR, Vesley D. Wash water temperature and sanitation in the hospital laundry. *J Environ Health* 1981;43:244--50.
368. Christian RR, Manchester JT, Mellor MT. Bacteriological quality of fabrics washed at lower-than-standard temperatures in a hospital laundry facility. *Appl Environ Microbiol* 1983;45:591--7.
369. Smith JA, Neil KR, Davidson CG, Davidson RW. Effect of water temperature on bacterial killing in laundry. *Infect Control* 1987;8:204--9.
370. Tompkins DS, Johnson P, Fittall BR. Low-temperature washing of patients' clothing: effects of detergent with disinfectant and a tunnel drier on bacterial survival. *J Hosp Infect* 1988;12:51--8.
371. Ayliffe GA, Collins BJ, Taylor LJ. Laundering [Chapter 11]. In: *Hospital-acquired infection: principles and prevention*. Bristol, UK: John Wright and Sons, 1982:101--6.
372. Meyer CL, Eitzen HE, Schreiner RL, Gfell MA, Moye L, Kleiman MB. Should linen in newborn intensive care units be autoclaved? *Pediatrics* 1981;67:362--4.
373. Wagg RE. Disinfection of textiles in laundering and dry cleaning. *Chemistry and Industry* 1965;44:1830--4.
374. Bates CJ, Wilcox MH, Smith TL, Spencer RC. The efficacy of a hospital dry cleaning cycle in disinfecting material contaminated with bacteria and viruses. *J Hosp Infect* 1993;23:255--62.
375. Oehnel E. Drycleaning in the hospital laundry. *Can Hosp* 1971;48:66--7.
376. US Environmental Protection Agency. Consumer Products Treated with Pesticides. Office of Pesticide Programs. Available at <http://www.epa.gov/pesticides/factsheets/>.
377. Fujita K, Lilly HA, Kidson A, Ayliffe GA. Gentamicin-resistant *Pseudomonas aeruginosa* infection from mattresses in a burns unit. *Br Med J* 1981;283:219--20.
378. Grubb DJ, Watson KC. *Pseudomonas* septicaemia from plastic mattresses [Letter]. *Lancet* 1982;1:518.
379. Sherertz RJ, Sullivan ML. An outbreak of infections with *Acinetobacter calcoaceticus* in burn patients: contamination of patients' mattresses. *J Infect Dis* 1985;151:252--8.
380. Ndawula EM, Brown L. Mattresses as reservoirs of epidemic methicillin-resistant *Staphylococcus aureus* [Letter]. *Lancet* 1991;337:488.
381. O'Donoghue MA, Allen KD. Costs of an outbreak of wound infections in an orthopaedic ward. *J Hosp Infect* 1992;22:73--9.
382. Weernink A, Severin WP, Tjernberg I, Dijkshoorn L. Pillows, an unexpected source of *Acinetobacter*. *J Hosp Infect* 1995;29:189--99.
383. Scheidt A, Drusin LM. Bacteriologic contamination in an air-fluidized bed. *J Trauma* 1983;23:241--2.
384. Freeman R, Gould FK, Ryan DW, Chamberlain J, Sisson PR. Nosocomial infection due to *Enterococci* attributed to a fluidized microsphere bed. The value of pyrolysis mass spectrometry. *J Hosp Infect* 1994;27:187--93.
385. Clancy MJ. Nosocomial infection and microsphere beds [Letter]. *Lancet* 1993;342:680--1.
386. Clancy MJ. Nosocomial infection due to *Enterococci* attributed to a fluidized microsphere bed [Letter]. *J Hosp Infect* 1994;28:324--5.
387. Jacobsen E, Gurevich I, Cunha BA. Air-fluidized beds and negative-pressure isolation rooms [Letter]. *Am J Infect Control* 1993;21:217--8.
388. American Academy of Allergy, Asthma, and Immunology. Tips to remember: indoor allergens. Milwaukee, WI: American Academy of Allergy, Asthma, and Immunology. Available at <http://www.aaaai.org/patients/publicedmat/tips/indoorallergens.stm>.
389. Duncan SL, APIC Guideline Committee. APIC state-of-the-art report: the implications of service animals in healthcare settings. *Am J Infect Control* 2000;28:170--80.
390. Murray AB, Ferguson AC, Morrison BJ. The frequency and severity of cat allergy vs. dog allergy in atopic children. *J Allergy Clin Immunol* 1983;72:145--9.
391. Delta Society. Standards of practice for animal-assisted activities and animal-assisted therapy. Renton, WA: Delta Society, 1996.
392. Fox JG. Transmissible drug resistance in *Shigella* and *Salmonella* isolated from pet monkeys and their owners. *J Med Primatol* 1975;4:165--71.
393. Ostrowski SR, Leslie MJ, Parrott T, Abelt S, Piercy PE. B-virus from pet macaque monkeys: an emerging threat in the United States? *Emerg Infect Dis* 1998;4:117--21.
394. Saylor K. Pet visitation program. *J Gerontol Nurs* 1998;24:36--8.
395. Draper RJ, Gerber GJ, Layng EM. Defining the role of pet animals in psychotherapy. *Psychiatr J Univ Ottawa* 1990;15:169--72.
396. [CDC. USPHS/IDSA guidelines for the prevention of opportunistic infections in persons infected with human immunodeficiency virus. MMWR 1999;48\(No. RR-10\).](#)

397. [CDC. Reptile-associated salmonellosis --- selected states, 1996--1998. MMWR 1999;48:1009--13.](#)
398. US Department of Justice. Americans With Disabilities Act. Nondiscrimination on the basis of disability by public accommodations and in commercial facilities. Public Law 101-336. Title III, Public accomodations operated by private entities, Sect. 302. Prohibition of discrimination by public accomodations, 42 USC 12101 et seq., 1990.
399. US Department of Agriculture. Public Law 99-198. Food Security Act of 1985, Subtitle F --- Animal Welfare. Title 7, United States Code, Chapter 54, Section 2131.
400. CDC, National Institutes of Health. Biosafety in microbiological and biomedical laboratories. 4th ed. Washington, DC: US Department of Health and Human Services, Public Health Service, CDC; DHHS publication no. (CDC) 93-8395.
401. US Department of Labor, Occupational Safety and Health Administration. Personal protective equipment for general industry; final rule. 29 CFR 1910 § 1910.132, 1910.138. Federal Register 1994;59:16334--64.
402. US Department of Transportation. Hazardous Materials Regulations. 49 CFR Parts 171--180, Division 6.2; and Hazardous materials: revision to standards for infectious substances and genetically-modified microorganisms; proposed rule. Federal Register 1998;63:46843--59.
403. US Postal Service. C 023.8.0 Hazardous materials: infectious substances (hazard class 6, division 6.2). Washington, D.C.: US Government Printing Office. Available at <http://pe.usps.gov/text/dmm/c023.htm>.
404. Greene R, Miele DJ, Slavik NS. Technical assistance manual: state regulatory oversight of medical waste treatment technologies, 2nd ed. State and Territorial Association on Alternative Treatment Technologies, 1994.
405. National Institute for Occupational Safety and Health. NIOSH alert: preventing needlestick injuries in health care settings. Cincinnati, OH: US Department of Health and Human Services, National Institute for Occupational Safety and Health, 1999. DHHS (NIOSH) publication no. 2000-108.
406. Weber AM, Boudreau Y, Mortimer VD. Health hazard evaluation report: Stericycle, Inc., Morton, WA. Cincinnati, OH: National Institute for Occupational Safety and Health, Hazard Evaluations and Technical Assistance Branch, 1998. HETA 98-0027-2709.
407. Johnson KR, Braden CR, Cairns KL, et al. Transmission of *Mycobacterium tuberculosis* from medical waste. JAMA 2000;284:1683--8.
408. Emery R, Sprau D, Lao YJ, Pryor W. Release of bacterial aerosols during infectious waste compaction: an initial hazard evaluation for healthcare workers. Am Ind Hyg Assoc J 1992;53:339--45.
409. US Department of Health and Human Services, CDC. Additional requirements for facilities transferring or receiving select agents; final rule. 42 CFR Part 72. Federal Register 1996;61(207):55189--200.
410. CDC, Office of Biosafety, Hospital Infections Program. Recommendations on infective waste, Atlanta, GA: Department of Health and Human Services, CDC, 1988:1--6.

Table 1

TABLE 1. Air changes/hour (ACH) and time required for airborne-contaminant removal efficiencies of 99% and 99.9%

ACH	Time (min) required for removal efficiency of 99%	Time (min) required for removal efficiency of 99.9%
2 [†]	138	207
4	69	104
6	46	69
8	35	52
10	28	41
12	23	35
15	18	28
20	14	21
50	6	8

Sources: CDC. Guidelines for preventing the transmission of *Mycobacterium tuberculosis* in health-care facilities. MMWR 1994;43(No. RR-13).

American Conference of Governmental Industrial Hygienists. HVAC components, functions and malfunctions (Topic 8-4). In: Industrial ventilation: a manual of recommended practice. 24th ed. Cincinnati, OH: American Conference of Governmental Industrial Hygienists, 2001.

Mutchler JE. Principles of ventilation. In: NIOSH. The industrial environment — its evaluation and control. Washington, DC: US Department of Health, Education, and Welfare, Public Health Service, 1973. DHHS publication no. (NIOSH) 74-117. Available at: <http://www.cdc.gov/niosh/74-117.html>.

Note: Bold entries denote frequently cited ACH for patient-care areas.

*Values were derived from the formula

$$t_2 - t_1 = -[\ln(C_2 / C_1) / (Q / V)] \times 60, \text{ with } t_1 = 0$$

where

t_1 = initial timepoint (min)

t_2 = final timepoint (min)

C_1 = initial concentration of contaminant

C_2 = final concentration of contaminant

$C_2 / C_1 = 1 - (\text{removal efficiency}/100)$

Q = air flow rate in cubic feet/hour

V = room volume in cubic feet

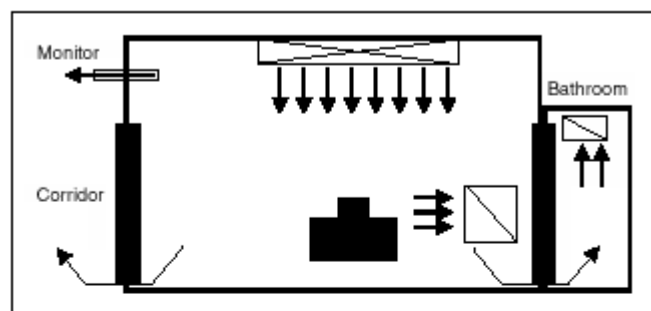
Q / V = ACH

[†]Values apply to an empty room with no aerosol-generating source. With a person present and generating aerosol, this table would not apply. Other equations are available that include a constant generating source. However, certain diseases (e.g., infectious tuberculosis) are not likely to be aerosolized at a constant rate. The times given assume perfect mixing of the air within the space (i.e., mixing factor = 1). However, perfect mixing usually does not occur. Removal times will be longer in rooms or areas with imperfect mixing or air stagnation. Caution should be exercised in using this table in such situations. For booths or other local ventilation enclosures, manufacturers' instructions should be consulted.

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Figure 1

FIGURE 1. Example of positive-pressure room control for protection from airborne environmental microbes*†



Source: Adapted from Heating/Piping/Air Conditioning (HPAC) Engineering, October 2000, Penton Media, Inc.

Note: Stacked black boxes represent patient's bed. Long open box with cross-hatch represents supply air. Open boxes with single, diagonal slashes represent air exhaust registers. Arrows indicate directions of airflow.

*Possible uses include immunocompromised patient rooms (e.g., hematopoietic stem cell transplant or solid organ transplant procedure rooms) and orthopedic operating rooms.

†Positive-pressure room engineering features include

- positive pressure (greater supply than exhaust air volume);
- pressure differential range of 2.5–8 Pa (0.01–0.03-in. water gauge), ideal at 8 Pa;
- airflow differential >125-cfm supply versus exhaust;
- sealed room, approximately 0.5-sq. ft. leakage;
- clean to dirty airflow;
- monitoring;
- ≥ 12 air changes/hr (ACH); and
- return air if refiltered.

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Box 1

BOX 1. Potential sampling sites for *Legionella* spp. in health-care facilities
Potable water system

- incoming water main
- water softener
- holding tanks, cisterns
- water heater tanks (at the inflows and outflows)

Potable water outlets, especially those in or near patient rooms

- faucets or taps
- showers

Cooling tower, evaporative condenser

- makeup water (e.g., added to replace water lost because of evaporation, drift, leakage)
- basin (i.e., area under the tower for collection of cooled water)
- sump (i.e., section of basin from which cooled water returns to heat source)
- heat sources (e.g., chillers)

Humidifiers (e.g., nebulizers)

- bubblers for oxygen
- water used for respiratory therapy equipment

Other sources

- decorative fountains
- irrigation equipment
- fire sprinkler system (if recently used)
- whirlpools, spas

Source: Barbaree JM, Gorman GW, Martin WT, Fields BS, Morrill WE. Protocol for sampling environmental sites for legionellae. *Appl Environ Microbiol* 1987;53:1454–8.

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Table 2

TABLE 2. Microbiologic limits for hemodialysis fluids

Hemodialysis fluid	Maximum total heterotrophs (CFU/mL [*])	Maximum endotoxin level (EU/mL [†])
Present standards		
Product water [§]		
Used to prepare dialysate	200	No standard
Used to reprocess dialyzers	200	5
Dialysate	2,000	No standard
Proposed standards[¶]		
Product water	200	2
Dialysate	200	2

Sources: American National Standards Institute, Association for the Advancement of Medical Instrumentation. Hemodialysis Systems. ANSI/AAMI RD5-1992. Arlington, VA: Association for the Advancement of Medical Instrumentation, 1993.

American National Standards Institute, Association for the Advancement of Medical Instrumentation. Reuse of hemodialyzers. ANSI/AAMI RD47-1993. Arlington, VA: Association for the Advancement of Medical Instrumentation, 1993.

* Colony forming units/milliliter.

† Endotoxin units/milliliter.

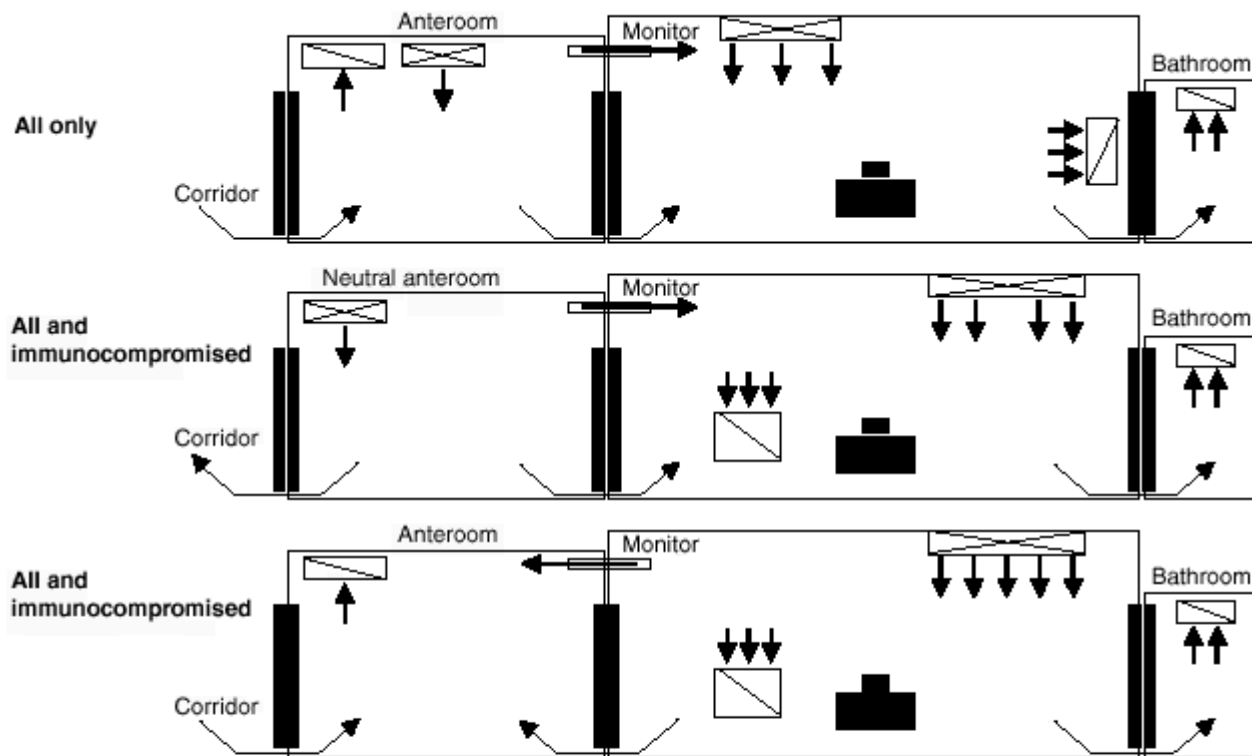
§ Product water presently includes water used to prepare dialysate and water used for reprocessing dialyzers.

¶ Dialysate for hemodialysis, RD52, under development, American National Standards Institute, Association for the Advancement of Medical Instrumentation (AAMI).

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Figure 2

FIGURE 2. Example of airborne infection isolation (All) room with anteroom and neutral anteroom*



Source: Used with permission from Andrew J. Streifel, M.P.H., University of Minnesota.

Note: Top diagram indicates airflow patterns when patient with only airborne infectious disease occupies room. Middle and bottom diagrams indicate recommended airflow patterns when room is occupied by immunocompromised patient with airborne infectious disease. Stacked black boxes represent patient beds. Long open boxes with cross-hatches represent supply air. Open boxes with single, diagonal slashes represent air exhaust registers. Arrows indicate directions of airflow.

*All isolation room with anteroom engineering features include

- pressure differential of 2.5 Pa (0.01-in. water gauge);
- airflow differential >125 cfm supply versus exhaust;
- sealed room with approximately 0.5-sq. ft. leakage;
- clean to dirty airflow;
- monitoring;
- ≥ 12 air exchanges/hr (ACH) new or renovation, 6 ACH existing; and
- anteroom airflow patterns

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Box 2

BOX 2. Procedures for collecting and processing environmental specimens for *Legionella* spp

1. Collect water (1-liter samples, if possible) in sterile, screw-top bottles.
2. Collect culture swabs of internal surfaces of faucets, aerators, and shower heads in a sterile, screw-top container (e.g., 50 mL plastic centrifuge tube). Submerge each swab in 5–10 mL of sample water taken from the same device from which the sample was obtained.
3. Transport samples and process in a laboratory proficient at culturing water specimens for *Legionella* spp, as soon as possible after collection.*
4. Test samples for the presence of *Legionella* spp. by using semiselective culture media using procedures specific to the cultivation and detection of *Legionella* spp.^{†§}

Sources: Barbaree JM, Gorman GW, Martin WT, Fields BS, Morrill WE. Protocol for sampling environmental sites for legionellae. *Appl Environ Microbiol* 1987;53:1454–8.

CDC. Procedures for the recovery of *Legionella* from the environment. Atlanta GA: US Department of Health and Human Services, Public Health Service, 1992:1–13.

Alary MA, Joly JR. Comparison of culture methods and an immunofluorescence assay for the detection of *Legionella pneumophila* in domestic hot water devices. *Curr Microbiol* 1992;24:19–25.

Vickers RM, Stout JE, Yu VL. Failure of a diagnostic monoclonal immunofluorescent reagent to detect *Legionella pneumophila* in environmental samples. *Appl Environ Microbiol* 1990;56:2912–4.

Flournoy DJ, Belobraydic KA, Silberg SL, Lawrence CH, Guthrie PJ. False positive *Legionella pneumophila* direct immunofluorescence monoclonal antibody test caused by *Bacillus cereus* spores. *Diag Microbiol Infect Dis* 1988;9:123–5.

Bej AK, Majbubani MH, Atlas RM. Detection of viable *Legionella pneumophila* in water by polymerase chain reaction and gene probe methods. *Appl Environ Microbiol* 1991;57:597–600.

* Samples may be transported at room temperature but must be protected from temperature extremes. Samples not processed within 24 hours of collection should be refrigerated.

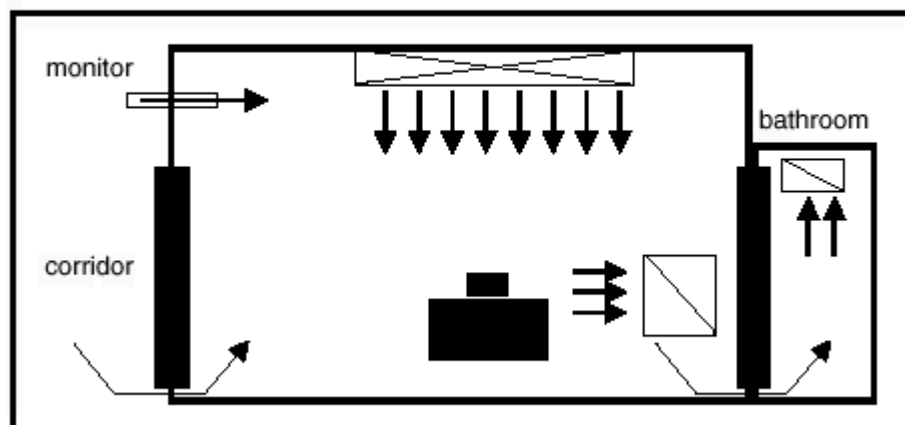
† Detection of *Legionella* spp. antigen by the direct fluorescent antibody technique is not suitable for environmental samples.

§ Use of polymerase chain reaction for identification of *Legionella* spp. is not recommended until more data regarding the sensitivity and specificity of this procedure are available.

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Figure 3

FIGURE 3. Example of negative-pressure room control for airborne infection isolation (AII)*†



Source: Adapted from Heating/Piping/Air Conditioning (HPAC) Engineering, October 2000, Penton Media, Inc.

Note: Stacked black boxes represent patient's bed. Long open box with cross-hatch represents supply air. Open boxes with single, diagonal slashes represent air exhaust registers. Arrows indicate direction of airflow.

* Possible uses include treatment or procedure rooms, bronchoscopy rooms, and autopsy.

† Negative-pressure room engineering features include

- negative pressure (greater exhaust than supply air volume);
- pressure differential of 2.5 Pa (0.01-in. water gauge);
- airflow differential >125-cfm supply versus exhaust;
- sealed room, approximately 0.5-sq. ft. leakage;
- clean to dirty airflow;
- monitoring;
- ≥ 12 air exchanges/hr (ACH) new or renovation, 6 ACH existing; and
- exhaust to outside or HEPA-filtered if recirculated.

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Box 3

BOX 3 . General steps for cleaning and maintaining ice machines, dispensers, and storage chests*

1. Disconnect unit from power supply.
2. Remove and discard ice from bin or storage chest.
3. Allow unit to warm to room temperature.
4. Disassemble removable parts of machine that make contact with water to make ice.
5. Thoroughly clean machine and parts with water and detergent.
6. Dry external surfaces of removable parts before reassembling.
7. Check for any needed repair.
8. Replace feeder lines as appropriate (e.g., when damaged, old, or difficult to clean).
9. Ensure presence of an air space in tubing leading from water inlet into water distribution system of machine.
10. Inspect for rodent or insect infestations under the unit and treat as needed.
11. Check door gaskets (open compartment models) for evidence of leakage or dripping into the storage chest.
12. Clean the ice-storage chest or bin with fresh water and detergent; rinse with fresh tap water.
13. Sanitize machine by circulating a 50–100 parts per million (ppm) solution of sodium hypochlorite (i.e., 4–8 mL sodium hypochlorite/gallon of water) through the ice-making and storage systems for 2 hours (100 ppm solution), or 4 hours (50 ppm solution).
14. Drain sodium hypochlorite solution and flush with fresh tap water.
15. Allow all surfaces of equipment to dry before returning to service.

Source: Adapted from Manangan LP, Anderson RL, Arduino MJ, Bond WW. Sanitary care and maintenance of ice-storage chests and ice-making machines in health care facilities. *Am J Infect Control* 1998;26:111-2.

* These general instructions should be used only where manufacturer-recommended methods and EPA-registered disinfectants are not available.

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Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Settings, 2005

Please note: This report has been corrected and replaces the electronic PDF version that was published on December 30, 2005.

Recommendations and Reports

December 30, 2005 / 54(RR17);1-141

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Summary

In 1994, CDC published the Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health-Care Facilities, 1994. The guidelines were issued in response to 1) a resurgence of tuberculosis (TB) disease that occurred in the United States in the mid-1980s and early 1990s, 2) the documentation of several high-profile health-care-associated (previously termed "nosocomial") outbreaks related to an increase in the prevalence of TB disease and human immunodeficiency virus (HIV) coinfection, 3) lapses in infection-control practices, 4) delays in the diagnosis and treatment of persons with infectious TB disease, and 5) the appearance and transmission of multidrug-resistant (MDR) TB strains. The 1994 guidelines, which followed statements issued in 1982 and 1990, presented recommendations for TB-infection control based on a risk assessment process that classified health-care facilities according to categories of TB risk, with a corresponding series of administrative, environmental, and respiratory-protection control measures.

The TB infection-control measures recommended by CDC in 1994 were implemented widely in health-care facilities in the United States. The result has been a decrease in the number of TB outbreaks in health-care settings reported to CDC and a reduction in health-care-associated transmission of Mycobacterium tuberculosis to patients and health-care workers (HCWs). Concurrent with this success, mobilization of the nation's TB-control programs succeeded in reversing the upsurge in reported cases of TB disease, and case rates have declined in the subsequent 10 years. Findings indicate that although the 2004 TB rate was the lowest recorded in the United States since national reporting began in 1953, the declines in rates for 2003 (2.3%) and 2004 (3.2%) were the smallest since 1993. In addition, TB infection rates greater than the U.S.

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average continue to be reported in certain racial/ethnic populations. The threat of MDR TB is decreasing, and the transmission of *M. tuberculosis* in health-care settings continues to decrease because of implementation of infection-control measures and reductions in community rates of TB.

Given the changes in epidemiology and a request by the Advisory Council for the Elimination of Tuberculosis (ACET) for review and update of the 1994 TB infection-control document, CDC has reassessed the TB infection-control guidelines for health-care settings. This report updates TB control recommendations reflecting shifts in the epidemiology of TB, advances in scientific understanding, and changes in health-care practice that have occurred in the United States during the preceding decade. In the context of diminished risk for health-care–associated transmission of *M. tuberculosis*, this document places emphasis on actions to maintain momentum and expertise needed to avert another TB resurgence and to eliminate the lingering threat to HCWs, which is mainly from patients or others with unsuspected and undiagnosed infectious TB disease. CDC prepared the current guidelines in consultation with experts in TB, infection control, environmental control, respiratory protection, and occupational health. The new guidelines have been expanded to address a broader concept; health-care–associated settings go beyond the previously defined facilities. The term "health-care setting" includes many types, such as inpatient settings, outpatient settings, TB clinics, settings in correctional facilities in which health care is delivered, settings in which home-based health-care and emergency medical services are provided, and laboratories handling clinical specimens that might contain *M. tuberculosis*. The term "setting" has been chosen over the term "facility," used in the previous guidelines, to broaden the potential places for which these guidelines apply.

Introduction

Overview

In 1994, CDC published the Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health Care Facilities, 1994 (1). The guidelines were issued in response to 1) a resurgence of tuberculosis (TB) disease that occurred in the United States in the mid-1980s and early 1990s, 2) the documentation of multiple high-profile health-care–associated (previously "nosocomial") outbreaks related to an increase in the prevalence of TB disease and human immunodeficiency virus (HIV) coinfection, 3) lapses in infection-control practices, 4) delays in the diagnosis and treatment of persons with infectious TB disease (2,3), and 5) the appearance and transmission of multidrug-resistant (MDR) TB strains (4,5).

The 1994 guidelines, which followed CDC statements issued in 1982 and 1990 (1,6,7), presented recommendations for TB infection control based on a risk assessment process. In this process, health-care facilities were classified according to categories of TB risk, with a corresponding series of environmental and respiratory-protection control measures.

The TB infection-control measures recommended by CDC in 1994 were implemented widely in health-care facilities nationwide (8–15). As a result, a decrease has occurred in 1) the number of TB outbreaks in health-care settings reported to CDC and 2) health-care–associated transmission of *M. tuberculosis* to patients and health-care workers (HCWs) (9,16–23). Concurrent with this success, mobilization of the nation's TB-control programs succeeded in reversing the upsurge in reported cases of TB disease, and case rates have declined in the subsequent 10 years (4,5). Findings indicate that although the 2004 TB rate was the lowest recorded in the United States since national reporting began in 1953, the declines in rates for 2003 (2.3%) and 2004 (3.2%) were the lowest since 1993. In addition, TB rates higher than the U.S. average continue to be reported in certain racial/ethnic populations (24). The threat of MDR TB is decreasing, and the transmission of *M. tuberculosis* in health-care settings continues to decrease because of implementation of infection-control measures and reductions in community rates of TB (4,5,25).

Despite the general decline in TB rates in recent years, a marked geographic variation in TB case rates persists, which means that HCWs in different areas face different risks (10). In 2004, case rates varied per 100,000 population: 1.0 in Wyoming, 7.1 in New York, 8.3 in California, and 14.6 in the District of Columbia (26). In addition, despite the progress in the United States, the 2004 rate of 4.9

per 100,000 population remained higher than the 2000 goal of 3.5. This goal was established as part of the national strategic plan for TB elimination; the final goal is <1 case per 1,000,000 population by 2010 (4,5,26).

Given the changes in epidemiology and a request by the Advisory Council for the Elimination of Tuberculosis (ACET) for review and updating of the 1994 TB infection-control document, CDC has reassessed the TB infection-control guidelines for health-care settings. This report updates TB-control recommendations, reflecting shifts in the epidemiology of TB (27), advances in scientific understanding, and changes in health-care practice that have occurred in the United States in the previous decade (28). In the context of diminished risk for health-care–associated transmission of *M. tuberculosis*, this report emphasizes actions to maintain momentum and expertise needed to avert another TB resurgence and eliminate the lingering threat to HCWs, which is primarily from patients or other persons with unsuspected and undiagnosed infectious TB disease.

CDC prepared the guidelines in this report in consultation with experts in TB, infection control, environmental control, respiratory protection, and occupational health. This report replaces all previous CDC guidelines for TB infection control in health-care settings (1,6,7). Primary references citing evidence-based science are used in this report to support explanatory material and recommendations. Review articles, which include primary references, are used for editorial style and brevity.

The following changes differentiate this report from previous guidelines:

- The risk assessment process includes the assessment of additional aspects of infection control.
- The term "tuberculin skin tests" (TSTs) is used instead of purified protein derivative (PPD).
- The whole-blood interferon gamma release assay (IGRA), QuantiFERON(r)-TB Gold test (QFT-G) (Cellestis Limited, Carnegie, Victoria, Australia), is a Food and Drug Administration (FDA)–approved in vitro cytokine-based assay for cell-mediated immune reactivity to *M. tuberculosis* and might be used instead of TST in TB screening programs for HCWs. This IGRA is an example of a blood assay for *M. tuberculosis* (BAMT).
- The frequency of TB screening for HCWs has been decreased in various settings, and the criteria for determination of screening frequency have been changed.
- The scope of settings in which the guidelines apply has been broadened to include laboratories and additional outpatient and nontraditional facility-based settings.
- Criteria for serial testing for *M. tuberculosis* infection of HCWs are more clearly defined. In certain settings, this change will decrease the number of HCWs who need serial TB screening.
- These recommendations usually apply to an entire health-care setting rather than areas within a setting.
- New terms, airborne infection precautions (airborne precautions) and airborne infection isolation room (AII room), are introduced.
- Recommendations for annual respirator training, initial respirator fit testing, and periodic respirator fit testing have been added.
- The evidence of the need for respirator fit testing is summarized.
- Information on ultraviolet germicidal irradiation (UVGI) and room-air recirculation units has been expanded.
- Additional information regarding MDR TB and HIV infection has been included.

In accordance with relevant local, state, and federal laws, implementation of all recommendations must safeguard the confidentiality and civil rights of all HCWs and patients who have been infected with *M. tuberculosis* and who develop TB disease.

The 1994 CDC guidelines were aimed primarily at hospital-based facilities, which frequently refer to a physical building or set of buildings. The 2005 guidelines have been expanded to address a broader concept. Setting has been chosen instead of "facility" to expand the scope of potential places for which these guidelines apply ([Appendix A](#)). "Setting" is used to describe any relationship (physical or organizational) in which HCWs might share air space with persons with TB disease or in which HCWs might be in contact with clinical specimens. Various setting types might be present in a single facility. Health-care settings include inpatient settings, outpatient settings, and nontraditional facility-based settings.

- Inpatient settings include patient rooms, emergency departments (EDs), intensive care units (ICUs), surgical suites, laboratories, laboratory procedure areas, bronchoscopy suites, sputum induction or inhalation therapy rooms, autopsy suites, and embalming rooms.
- Outpatient settings include TB treatment facilities, medical offices, ambulatory-care settings, dialysis units, and dental-care settings.
- Nontraditional facility-based settings include emergency medical service (EMS), medical settings in correctional facilities (e.g., prisons, jails, and detention centers), home-based health-care and outreach settings, long-term-care settings (e.g., hospices, skilled nursing facilities), and homeless shelters. Other settings in which suspected and confirmed TB patients might be encountered might include cafeterias, general stores, kitchens, laundry areas, maintenance shops, pharmacies, and law enforcement settings.

HCWs Who Should Be Included in a TB Surveillance Program

HCWs refer to all paid and unpaid persons working in health-care settings who have the potential for exposure to *M. tuberculosis* through air space shared with persons with infectious TB disease. Part time, temporary, contract, and full-time HCWs should be included in TB screening programs. All HCWs who have duties that involve face-to-face contact with patients with suspected or confirmed TB disease (including transport staff) should be included in a TB screening program.

The following are HCWs who might be included in a TB screening program:

- Administrators or managers
- Bronchoscopy staff
- Chaplains
- Clerical staff
- Computer programmers
- Construction staff
- Correctional officers
- Craft or repair staff
- Dental staff
- Dietician or dietary staff
- ED staff
- Engineers
- Food service staff
- Health aides
- Health and safety staff
- Housekeeping or custodial staff
- Homeless shelter staff
- Infection-control staff
- ICU staff
- Janitorial staff
- Laboratory staff
- Maintenance staff
- Morgue staff
- Nurses
- Outreach staff
- Pathology laboratory staff
- Patient transport staff, including EMS
- Pediatric staff
- Pharmacists
- Phlebotomists
- Physical and occupational therapists
- Physicians (assistant, attending, fellow, resident, or intern), including
 - anesthesiologists
 - pathologists
 - psychiatrists
 - psychologists
- Public health educators or teachers
- Public safety staff

- Radiology staff
- Respiratory therapists
- Scientists
- Social workers
- Students (e.g., medical, nursing, technicians, and allied health)
- Technicians (e.g., health, laboratory, radiology, and animal)
- Veterinarians
- Volunteers

In addition, HCWs who perform any of the following activities should also be included in the TB screening program.

- entering patient rooms or treatment rooms whether or not a patient is present;
- participating in aerosol-generating or aerosol-producing procedures (e.g., bronchoscopy, sputum induction, and administration of aerosolized medications) (29);
- participating in suspected or confirmed *M. tuberculosis* specimen processing; or
- installing, maintaining, or replacing environmental controls in areas in which persons with TB disease are encountered.

Pathogenesis, Epidemiology, and Transmission of *M. tuberculosis*

M. tuberculosis is carried in airborne particles called droplet nuclei that can be generated when persons who have pulmonary or laryngeal TB disease cough, sneeze, shout, or sing (30,31). The particles are approximately 1–5 µm; normal air currents can keep them airborne for prolonged periods and spread them throughout a room or building (32). *M. tuberculosis* is usually transmitted only through air, not by surface contact. After the droplet nuclei are in the alveoli, local infection might be established, followed by dissemination to draining lymphatics and hematogenous spread throughout the body (33). Infection occurs when a susceptible person inhales droplet nuclei containing *M. tuberculosis*, and the droplet nuclei traverse the mouth or nasal passages, upper respiratory tract, and bronchi to reach the alveoli. Persons with TB pleural effusions might also have concurrent unsuspected pulmonary or laryngeal TB disease.

Usually within 2–12 weeks after initial infection with *M. tuberculosis*, the immune response limits additional multiplication of the tubercle bacilli, and immunologic test results for *M. tuberculosis* infection become positive. However, certain bacilli remain in the body and are viable for multiple years. This condition is referred to as latent tuberculosis infection (LTBI). Persons with LTBI are asymptomatic (they have no symptoms of TB disease) and are not infectious.

In the United States, LTBI has been diagnosed traditionally based on a PPD-based TST result after TB disease has been excluded. In vitro cytokine-based immunoassays for the detection of *M. tuberculosis* infection have been the focus of intense research and development. One such blood assay for *M. tuberculosis* (or BAMT) is an IGRA, the QuantiFERON(r)-TB test (QFT), and the subsequently developed version, QFT-G. The QFT-G measures cell-mediated immune responses to peptides from two *M. tuberculosis* proteins that are not present in any Bacille Calmette-Guérin (BCG) vaccine strain and that are absent from the majority of nontuberculous mycobacteria (NTM), also known as mycobacteria other than TB (MOTT). QFT-G was approved by FDA in 2005 and is an available option for detecting *M. tuberculosis* infection. CDC recommendations for the United States regarding QFT and QFT-G have been published (34,35). Because this field is rapidly evolving, in this report, BAMT will be used generically to refer to the test currently available in the United States.

Additional cytokine-based immunoassays are under development and might be useful in the diagnosis of *M. tuberculosis* infection. Future FDA-licensed products in combination with CDC-issued recommendations might provide additional diagnostic alternatives. The latest CDC recommendations for guidance on diagnostic use of these and related technologies are available at http://www.cdc.gov/nchstp/tb/pubs/mmwr/html/Maj_guide/Diagnosis.htm.

Typically, approximately 5%–10% of persons who become infected with *M. tuberculosis* and who are not treated for LTBI will develop TB disease during their lifetimes (1). The risk for progression of

Persons at Highest Risk for Exposure to and Infection with *M. tuberculosis*

Characteristics of persons exposed to *M. tuberculosis* that might affect the risk for infection are not as well defined. The probability that a person who is exposed to *M. tuberculosis* will become infected depends primarily on the concentration of infectious droplet nuclei in the air and the duration of exposure to a person with infectious TB disease. The closer the proximity and the longer the duration of exposure, the higher the risk is for being infected.

Close contacts are persons who share the same air space in a household or other enclosed environment for a prolonged period (days or weeks, not minutes or hours) with a person with pulmonary TB disease (39). A suspect TB patient is a person in whom a diagnosis of TB disease is being considered, whether or not antituberculosis treatment has been started. Persons generally should not remain a suspect TB patient for >3 months (30,39).

In addition to close contacts, the following persons are also at higher risk for exposure to and infection with *M. tuberculosis*. Persons listed who are also close contacts should be top priority.

- Foreign-born persons, including children, especially those who have arrived to the United States within 5 years after moving from geographic areas with a high incidence of TB disease (e.g., Africa, Asia, Eastern Europe, Latin America, and Russia) or who frequently travel to countries with a high prevalence of TB disease.
- Residents and employees of congregate settings that are high risk (e.g., correctional facilities, long-term-care facilities [LTCFs], and homeless shelters).
- HCWs who serve patients who are at high risk.
- HCWs with unprotected exposure to a patient with TB disease before the identification and correct airborne precautions of the patient.
- Certain populations who are medically underserved and who have low income, as defined locally.
- Populations at high risk who are defined locally as having an increased incidence of TB disease.
- Infants, children, and adolescents exposed to adults in high-risk categories.

Persons Whose Condition is at High Risk for Progression From LTBI to TB Disease

The following persons are at high risk for progressing from LTBI to TB disease:

- persons infected with HIV;
- persons infected with *M. tuberculosis* within the previous 2 years;
- infants and children aged <4 years;
- persons with any of the following clinical conditions or other immunocompromising conditions
 - silicosis,
 - diabetes mellitus,
 - chronic renal failure,
 - certain hematologic disorders (leukemias and lymphomas),
 - other specific malignancies (e.g., carcinoma of the head, neck, or lung),
 - body weight $\geq 10\%$ below ideal body weight,
 - prolonged corticosteroid use,
 - other immunosuppressive treatments (including tumor necrosis factor-alpha [TNF- α] antagonists),
 - organ transplant,
 - end-stage renal disease (ESRD), and
 - intestinal bypass or gastrectomy; and
- persons with a history of untreated or inadequately treated TB disease, including persons with chest radiograph findings consistent with previous TB disease.

Persons who use tobacco or alcohol (40,41), illegal drugs, including injection drugs and crack cocaine (42–47), might also be at increased risk for infection and disease. However, because of multiple other potential risk factors that commonly occur among such persons, use of these substances has been difficult to identify as separate risk factors.

HIV infection is the greatest risk factor for progression from LTBI to TB disease (22,39,48,49). Therefore, voluntary HIV counseling, testing, and referral should be routinely offered to all persons at risk for LTBI (1,50,51). Health-care settings should be particularly aware of the need for preventing transmission of *M. tuberculosis* in settings in which persons infected with HIV might be encountered or might work (52).

All HCWs should be informed regarding the risk for developing TB disease after being infected with *M. tuberculosis* (1). However, the rate of TB disease among persons who are HIV-infected and untreated for LTBI in the United States is substantially higher, ranging from 1.7–7.9 TB cases per 100 person-years (53). Persons infected with HIV who are already severely immunocompromised and who become newly infected with *M. tuberculosis* have a greater risk for developing TB disease, compared with newly infected persons without HIV infection (39,53–57).

The percentage of patients with TB disease who are HIV-infected is decreasing in the United States because of improved infection-control practices and better diagnosis and treatment of both HIV infection and TB. With increased voluntary HIV counseling and testing and the increasing use of treatment for LTBI, TB disease will probably continue to decrease among HIV-infected persons in the United States (58). Because the risk for disease is particularly high among HIV-infected persons with *M. tuberculosis* infection, HIV-infected contacts of persons with infectious pulmonary or laryngeal TB disease must be evaluated for *M. tuberculosis* infection, including the exclusion of TB disease, as soon as possible after learning of exposure (39,49,53).

Vaccination with BCG probably does not affect the risk for infection after exposure, but it might decrease the risk for progression from infection with *M. tuberculosis* to TB disease, preventing the development of miliary and meningeal disease in infants and young children (59,60). Although HIV infection increases the likelihood of progression from LTBI to TB disease (39,49), whether HIV infection increases the risk for becoming infected if exposed to *M. tuberculosis* is not known.

Characteristics of a Patient with TB Disease That Increase the Risk for Infectiousness

The following characteristics exist in a patient with TB disease that increases the risk for infectiousness:

- presence of cough;
- cavitation on chest radiograph;
- positive acid-fast bacilli (AFB) sputum smear result;
- respiratory tract disease with involvement of the larynx (substantially infectious);
- respiratory tract disease with involvement of the lung or pleura (exclusively pleural involvement is less infectious);
- failure to cover the mouth and nose when coughing;
- incorrect, lack of, or short duration of antituberculosis treatment; and
- undergoing cough-inducing or aerosol-generating procedures (e.g., bronchoscopy, sputum induction, and administration of aerosolized medications) (29).

Environmental Factors That Increase the Risk for Probability of Transmission of *M. tuberculosis*

The probability of the risk for transmission of *M. tuberculosis* is increased as a result of various environmental factors.

- Exposure to TB in small, enclosed spaces.
- Inadequate local or general ventilation that results in insufficient dilution or removal of infectious droplet nuclei.
- Recirculation of air containing infectious droplet nuclei.
- Inadequate cleaning and disinfection of medical equipment.
- Improper procedures for handling specimens.

Risk for Health-Care–Associated Transmission of *M. tuberculosis*

Transmission of *M. tuberculosis* is a risk in health-care settings (57,61–79). The magnitude of the risk varies by setting, occupational group, prevalence of TB in the community, patient population, and effectiveness of TB infection-control measures. Health-care–associated transmission of *M. tuberculosis* has been linked to close contact with persons with TB disease during aerosol-generating or aerosol-producing procedures, including bronchoscopy (29,63,80–82), endotracheal intubation, suctioning (66), other respiratory procedures (8,9,83–86), open abscess irrigation (69,83), autopsy (71,72,77), sputum induction, and aerosol treatments that induce coughing (87–90).

Of the reported TB outbreaks in health-care settings, multiple outbreaks involved transmission of MDR TB strains to both patients and HCWs (56,57,70,87,91–94). The majority of the patients and certain HCWs were HIV-infected, and progression to TB and MDR TB disease was rapid. Factors contributing to these outbreaks included delayed diagnosis of TB disease, delayed initiation and inadequate airborne precautions, lapses in AII practices and precautions for cough-inducing and aerosol-generating procedures, and lack of adequate respiratory protection. Multiple studies suggest that the decline in health-care–associated transmission observed in specific institutions is associated with the rigorous implementation of infection-control measures (11,12,18–20,23,95–97). Because various interventions were implemented simultaneously, the effectiveness of each intervention could not be determined.

After the release of the 1994 CDC infection-control guidelines, increased implementation of recommended infection-control measures occurred and was documented in multiple national surveys (13,15,98,99). In a survey of approximately 1,000 hospitals, a TST program was present in nearly all sites, and 70% reported having an AII room (13). Other surveys have documented improvement in the proportion of AII rooms meeting CDC criteria and proportion of HCWs using CDC-recommended respiratory protection and receiving serial TST (15,98). A survey of New York City hospitals with high caseloads of TB disease indicated 1) a decrease in the time that patients with TB disease spent in EDs before being transferred to a hospital room, 2) an increase in the proportion of patients initially placed in AII rooms, 3) an increase in the proportion of patients started on recommended antituberculosis treatment and reported to the local or state health department, and 4) an increase in the use of recommended respiratory protection and environmental controls (99). Reports of increased implementation of recommended TB infection controls combined with decreased reports of outbreaks of TB disease in health-care settings suggest that the recommended controls are effective in reducing and preventing health-care–associated transmission of *M. tuberculosis* (28).

Less information is available regarding the implementation of CDC-recommended TB infection-control measures in settings other than hospitals. One study identified major barriers to implementation that contribute to the costs of a TST program in health departments and hospitals, including personnel costs, HCWs' time off from work for TST administration and reading, and training and education of HCWs (100). Outbreaks have occurred in outpatient settings (i.e., private physicians' offices and pediatric settings) where the guidelines were not followed (101–103). CDC-recommended TB infection-control measures are implemented in correctional facilities, and certain variations might relate to resources, expertise, and oversight (104–106).

Fundamentals of TB Infection Control

One of the most critical risks for health-care–associated transmission of *M. tuberculosis* in health-care settings is from patients with unrecognized TB disease who are not promptly handled with appropriate airborne precautions (56,57,93,104) or who are moved from an AII room too soon (e.g., patients with unrecognized TB and MDR TB) (94). In the United States, the problem of MDR TB, which was amplified by health-care–associated transmission, has been substantially reduced by the use of standardized antituberculosis treatment regimens in the initial phase of therapy, rapid drug-susceptibility testing, directly observed therapy (DOT), and improved infection-control practices (1). DOT is an adherence-enhancing strategy in which an HCW or other specially trained health professional watches a patient swallow each dose of medication and records the dates that the administration was observed. DOT is the standard of care for all patients with TB disease and should be used for all doses during the course of therapy for TB disease and for LTBI whenever feasible.

All health-care settings need a TB infection-control program designed to ensure prompt detection, airborne precautions, and treatment of persons who have suspected or confirmed TB disease (or prompt referral of persons who have suspected TB disease for settings in which persons with TB disease are not expected to be encountered). Such a program is based on a three-level hierarchy of controls, including administrative, environmental, and respiratory protection (86,107,108).

Administrative Controls

The first and most important level of TB controls is the use of administrative measures to reduce the risk for exposure to persons who might have TB disease. Administrative controls consist of the following activities:

- assigning responsibility for TB infection control in the setting;
- conducting a TB risk assessment of the setting;
- developing and instituting a written TB infection-control plan to ensure prompt detection, airborne precautions, and treatment of persons who have suspected or confirmed TB disease;
- ensuring the timely availability of recommended laboratory processing, testing, and reporting of results to the ordering physician and infection-control team;
- implementing effective work practices for the management of patients with suspected or confirmed TB disease;
- ensuring proper cleaning and sterilization or disinfection of potentially contaminated equipment (usually endoscopes);
- training and educating HCWs regarding TB, with specific focus on prevention, transmission, and symptoms;
- screening and evaluating HCWs who are at risk for TB disease or who might be exposed to *M. tuberculosis* (i.e., TB screening program);
- applying epidemiologic-based prevention principles, including the use of setting-related infection-control data;
- using appropriate signage advising respiratory hygiene and cough etiquette; and
- coordinating efforts with the local or state health department.

HCWs with TB disease should be allowed to return to work when they 1) have had three negative AFB sputum smear results (109–112) collected 8–24 hours apart, with at least one being an early morning specimen because respiratory secretions pool overnight; and 2) have responded to antituberculosis treatment that will probably be effective based on susceptibility results. In addition, HCWs with TB disease should be allowed to return to work when a physician knowledgeable and experienced in managing TB disease determines that HCWs are noninfectious (see Treatment Procedures for LTBI and TB Disease). Consideration should also be given to the type of setting and the potential risk to patients (e.g., general medical office versus HIV clinic) (see Supplements, Estimating the Infectiousness of a TB Patient; Diagnostic Procedures for LTBI and TB Disease; and Treatment Procedures for LTBI and TB Disease).

Environmental Controls

The second level of the hierarchy is the use of environmental controls to prevent the spread and reduce the concentration of infectious droplet nuclei in ambient air.

Primary environmental controls consist of controlling the source of infection by using local exhaust ventilation (e.g., hoods, tents, or booths) and diluting and removing contaminated air by using general ventilation.

Secondary environmental controls consist of controlling the airflow to prevent contamination of air in areas adjacent to the source (AII rooms) and cleaning the air by using high efficiency particulate air (HEPA) filtration or UVGI.

Respiratory-Protection Controls

The first two control levels minimize the number of areas in which exposure to *M. tuberculosis* might occur and, therefore, minimize the number of persons exposed. These control levels also reduce, but do not eliminate, the risk for exposure in the limited areas in which exposure can still occur. Because

persons entering these areas might be exposed to *M. tuberculosis*, the third level of the hierarchy is the use of respiratory protective equipment in situations that pose a high risk for exposure. Use of respiratory protection can further reduce risk for exposure of HCWs to infectious droplet nuclei that have been expelled into the air from a patient with infectious TB disease (see Respiratory Protection). The following measures can be taken to reduce the risk for exposure:

- implementing a respiratory-protection program,
- training HCWs on respiratory protection, and
- training patients on respiratory hygiene and cough etiquette procedures.

Relevance to Biologic Terrorism Preparedness

MDR *M. tuberculosis* is classified as a category C agent of biologic terrorism (113). Implementation of the TB infection-control guidelines described in this document is essential for preventing and controlling transmission of *M. tuberculosis* in health-care settings. Additional information is at <http://www.bt.cdc.gov> and <http://www.idsociety.org/bt/toc.htm> (114).

Recommendations for Preventing Transmission of *M. tuberculosis* in Health-Care Settings

TB Infection-Control Program

Every health-care setting should have a TB infection-control plan that is part of an overall infection-control program. The specific details of the TB infection-control program will differ, depending on whether patients with suspected or confirmed TB disease might be encountered in the setting or whether patients with suspected or confirmed TB disease will be transferred to another health-care setting. Administrators making this distinction should obtain medical and epidemiologic consultation from state and local health departments.

TB Infection-Control Program for Settings in Which Patients with Suspected or Confirmed TB Disease Are Expected To Be Encountered

The TB infection-control program should consist of administrative controls, environmental controls, and a respiratory-protection program. Every setting in which services are provided to persons who have suspected or confirmed infectious TB disease, including laboratories and nontraditional facility-based settings, should have a TB infection-control plan. The following steps should be taken to establish a TB infection-control program in these settings:

1. Assign supervisory responsibility for the TB infection-control program to a designated person or group with expertise in LTBI and TB disease, infection control, occupational health, environmental controls, and respiratory protection. Give the supervisor or supervisory body the support and authority to conduct a TB risk assessment, implement and enforce TB infection-control policies, and ensure recommended training and education of HCWs.
 - Train the persons responsible for implementing and enforcing the TB infection-control program.
 - Designate one person with a back-up as the TB resource person to whom questions and problems should be addressed, if supervisory responsibility is assigned to a committee.
2. Develop a written TB infection-control plan that outlines a protocol for the prompt recognition and initiation of airborne precautions of persons with suspected or confirmed TB disease, and update it annually.
3. Conduct a problem evaluation (see Problem Evaluation) if a case of suspected or confirmed TB disease is not promptly recognized and appropriate airborne precautions not initiated, or if administrative, environmental, or respiratory-protection controls fail.
4. Perform a contact investigation in collaboration with the local or state health department if health-care-associated transmission of *M. tuberculosis* is suspected (115). Implement and monitor corrective action.
5. Collaborate with the local or state health department to develop administrative controls consisting of the risk assessment, the written TB infection-control plan, management of patients with suspected or confirmed TB disease, training and education of HCWs, screening and evaluation of HCWs, problem evaluation, and coordination.

6. Implement and maintain environmental controls, including AII room(s) (see Environmental Controls).
7. Implement a respiratory-protection program.
8. Perform ongoing training and education of HCWs (see Suggested Components of an Initial TB Training and Education Program for HCWs).
9. Create a plan for accepting patients who have suspected or confirmed TB disease if they are transferred from another setting.

TB Infection-Control Program for Settings in Which Patients with Suspected or Confirmed TB Disease Are Not Expected To Be Encountered

Settings in which TB patients might stay before transfer should still have a TB infection-control program in place consisting of administrative, environmental, and respiratory-protection controls. The following steps should be taken to establish a TB infection-control program in these settings:

1. Assign responsibility for the TB infection-control program to appropriate personnel.
2. Develop a written TB infection-control plan that outlines a protocol for the prompt recognition and transfer of persons who have suspected or confirmed TB disease to another health-care setting. The plan should indicate procedures to follow to separate persons with suspected or confirmed infectious TB disease from other persons in the setting until the time of transfer. Evaluate the plan annually, if possible, to ensure that the setting remains one in which persons who have suspected or confirmed TB disease are not encountered and that they are promptly transferred.
3. Conduct a problem evaluation (see Problem Evaluation) if a case of suspected or confirmed TB disease is not promptly recognized, separated from others, and transferred.
4. Perform an investigation in collaboration with the local or state health department if health-care–associated transmission of *M. tuberculosis* is suspected.
5. Collaborate with the local or state health department to develop administrative controls consisting of the risk assessment and the written TB infection-control plan.

TB Risk Assessment

Every health-care setting should conduct initial and ongoing evaluations of the risk for transmission of *M. tuberculosis*, regardless of whether or not patients with suspected or confirmed TB disease are expected to be encountered in the setting. The TB risk assessment determines the types of administrative, environmental, and respiratory-protection controls needed for a setting and serves as an ongoing evaluation tool of the quality of TB infection control and for the identification of needed improvements in infection-control measures. Part of the risk assessment is similar to a program review that is conducted by the local TB-control program (42). The TB Risk Assessment Worksheet ([Appendix B](#)) can be used as a guide for conducting a risk assessment. This worksheet frequently does not specify values for acceptable performance indicators because of the lack of scientific data.

TB Risk Assessment for Settings in Which Patients with Suspected or Confirmed TB Disease Are Expected To Be Encountered

The initial and ongoing risk assessment for these settings should consist of the following steps:

1. Review the community profile of TB disease in collaboration with the state or local health department.
2. Consult the local or state TB-control program to obtain epidemiologic surveillance data necessary to conduct a TB risk assessment for the health-care setting.
3. Review the number of patients with suspected or confirmed TB disease who have been encountered in the setting during at least the previous 5 years.
4. Determine if persons with unrecognized TB disease have been admitted to or were encountered in the setting during the previous 5 years.
5. Determine which HCWs need to be included in a TB screening program and the frequency of screening (based on risk classification) ([Appendix C](#)).
6. Ensure the prompt recognition and evaluation of suspected episodes of health-care–associated transmission of *M. tuberculosis*.
7. Identify areas in the setting with an increased risk for health-care–associated transmission of *M. tuberculosis*, and target them for improved TB infection controls.

8. Assess the number of AII rooms needed for the setting. The risk classification for the setting should help to make this determination, depending on the number of TB patients examined. At least one AII room is needed for settings in which TB patients stay while they are being treated, and additional AII rooms might be needed, depending on the magnitude of patient-days of cases of suspected or confirmed TB disease. Additional AII rooms might be considered if options are limited for transferring patients with suspected or confirmed TB disease to other settings with AII rooms.
9. Determine the types of environmental controls needed other than AII rooms (see TB Airborne Precautions).
10. Determine which HCWs need to be included in the respiratory-protection program.
11. Conduct periodic reassessments (annually, if possible) to ensure
 - proper implementation of the TB infection-control plan,
 - prompt detection and evaluation of suspected TB cases,
 - prompt initiation of airborne precautions of suspected infectious TB cases,
 - recommended medical management of patients with suspected or confirmed TB disease (31),
 - functional environmental controls,
 - implementation of the respiratory-protection program, and
 - ongoing HCW training and education regarding TB.
12. Recognize and correct lapses in infection control.

TB Risk Assessment for Settings in Which Patients with Suspected or Confirmed TB Disease Are Not Expected To Be Encountered

The initial and ongoing risk assessment for these settings should consist of the following steps:

1. Review the community profile of TB disease in collaboration with the local or state health department.
2. Consult the local or state TB-control program to obtain epidemiologic surveillance data necessary to conduct a TB risk assessment for the health-care setting.
3. Determine if persons with unrecognized TB disease were encountered in the setting during the previous 5 years.
4. Determine if any HCWs need to be included in the TB screening program.
5. Determine the types of environmental controls that are currently in place, and determine if any are needed in the setting (Appendices A and D).
6. Document procedures that ensure the prompt recognition and evaluation of suspected episodes of health-care–associated transmission of *M. tuberculosis*.
7. Conduct periodic reassessments (annually, if possible) to ensure 1) proper implementation of the TB infection-control plan; 2) prompt detection and evaluation of suspected TB cases; 3) prompt initiation of airborne precautions of suspected infectious TB cases before transfer; 4) prompt transfer of suspected infectious TB cases; 5) proper functioning of environmental controls, as applicable; and 6) ongoing TB training and education for HCWs.
8. Recognize and correct lapses in infection control.

Use of Risk Classification to Determine Need for TB Screening and Frequency of Screening HCWs

Risk classification should be used as part of the risk assessment to determine the need for a TB screening program for HCWs and the frequency of screening ([Appendix C](#)). A risk classification usually should be determined for the entire setting. However, in certain settings (e.g., health-care organizations that encompass multiple sites or types of services), specific areas defined by geography, functional units, patient population, job type, or location within the setting might have separate risk classifications. Examples of assigning risk classifications have been provided (see Risk Classification Examples).

TB Screening Risk Classifications

The three TB screening risk classifications are low risk, medium risk, and potential ongoing transmission. The classification of low risk should be applied to settings in which persons with TB disease are not expected to be encountered, and, therefore, exposure to *M. tuberculosis* is unlikely. This classification should also be applied to HCWs who will never be exposed to persons with TB disease or to clinical specimens that might contain *M. tuberculosis*.

The classification of medium risk should be applied to settings in which the risk assessment has determined that HCWs will or will possibly be exposed to persons with TB disease or to clinical specimens that might contain *M. tuberculosis*.

The classification of potential ongoing transmission should be temporarily applied to any setting (or group of HCWs) if evidence suggestive of person-to-person (e.g., patient-to-patient, patient-to-HCW, HCW-to-patient, or HCW-to-HCW) transmission of *M. tuberculosis* has occurred in the setting during the preceding year. Evidence of person-to-person transmission of *M. tuberculosis* includes 1) clusters of TST or BAMT conversions, 2) HCW with confirmed TB disease, 3) increased rates of TST or BAMT conversions, 4) unrecognized TB disease in patients or HCWs, or 5) recognition of an identical strain of *M. tuberculosis* in patients or HCWs with TB disease identified by deoxyribonucleic acid (DNA) fingerprinting.

If uncertainty exists regarding whether to classify a setting as low risk or medium risk, the setting typically should be classified as medium risk.

TB Screening Procedures for Settings (or HCWs) Classified as Low Risk

- All HCWs should receive baseline TB screening upon hire, using two-step TST or a single BAMT to test for infection with *M. tuberculosis*.
- After baseline testing for infection with *M. tuberculosis*, additional TB screening is not necessary unless an exposure to *M. tuberculosis* occurs.
- HCWs with a baseline positive or newly positive test result for *M. tuberculosis* infection (i.e., TST or BAMT) or documentation of treatment for LTBI or TB disease should receive one chest radiograph result to exclude TB disease (or an interpretable copy within a reasonable time frame, such as 6 months). Repeat radiographs are not needed unless symptoms or signs of TB disease develop or unless recommended by a clinician (39,116).

TB Screening Procedures for Settings (or HCWs) Classified as Medium Risk

- All HCWs should receive baseline TB screening upon hire, using two-step TST or a single BAMT to test for infection with *M. tuberculosis*.
- After baseline testing for infection with *M. tuberculosis*, HCWs should receive TB screening annually (i.e., symptom screen for all HCWs and testing for infection with *M. tuberculosis* for HCWs with baseline negative test results).
- HCWs with a baseline positive or newly positive test result for *M. tuberculosis* infection or documentation of previous treatment for LTBI or TB disease should receive one chest radiograph result to exclude TB disease. Instead of participating in serial testing, HCWs should receive a symptom screen annually. This screen should be accomplished by educating the HCW about symptoms of TB disease and instructing the HCW to report any such symptoms immediately to the occupational health unit. Treatment for LTBI should be considered in accordance with CDC guidelines (39).

TB Screening Procedures for Settings (or HCWs) Classified as Potential Ongoing Transmission

- Testing for infection with *M. tuberculosis* might need to be performed every 8–10 weeks until lapses in infection control have been corrected, and no additional evidence of ongoing transmission is apparent.
- The classification of potential ongoing transmission should be used as a temporary classification only. It warrants immediate investigation and corrective steps. After a determination that ongoing transmission has ceased, the setting should be reclassified as medium risk. Maintaining the classification of medium risk for at least 1 year is recommended.

Settings Adopting BAMT for Use in TB Screening

Settings that use TST as part of TB screening and want to adopt BAMT can do so directly (without any overlapping TST) or in conjunction with a period of evaluation (e.g., 1 or 2 years) during which time both TST and BAMT are used. Baseline testing for BAMT would be established as a single step test. As with the TST, BAMT results should be recorded in detail. The details should include date of blood

draw, result in specific units, and the laboratory interpretation (positive, negative, or indeterminate—and the concentration of cytokine measured, for example, interferon-gamma [IFN- γ]).

Risk Classification Examples

Inpatient Settings with More Than 200 Beds

If less than six TB patients for the preceding year, classify as low risk. If greater than or equal to six TB patients for the preceding year, classify as medium risk.

Inpatient Settings with Less Than 200 Beds

If less than three TB patients for the preceding year, classify as low risk. If greater than or equal to three TB patients for the preceding year, classify as medium risk.

Outpatient, Outreach, and Home-Based Health-Care Settings

If less than three TB patients for the preceding year, classify as low risk. If greater than or equal to three TB patients for the preceding year, classify as medium risk.

Hypothetical Risk Classification Examples

The following hypothetical situations illustrate how assessment data are used to assign a risk classification. The risk classifications are for settings in which patients with suspected or confirmed infectious TB disease are expected to be encountered.

Example A. The setting is a 150-bed hospital located in a small city. During the preceding year, the hospital admitted two patients with a diagnosis of TB disease. One was admitted directly to an AII room, and one stayed on a medical ward for 2 days before being placed in an AII room. A contact investigation of exposed HCWs by hospital infection-control personnel in consultation with the state or local health department did not identify any health-care–associated transmission. Risk classification: low risk.

Example B. The setting is an ambulatory-care site in which a TB clinic is held 2 days per week. During the preceding year, care was delivered to six patients with TB disease and approximately 50 persons with LTBI. No instances of transmission of *M. tuberculosis* were noted. Risk classification: medium risk (because it is a TB clinic).

Example C. The setting is a large publicly funded hospital in a major metropolitan area. The hospital admits an average of 150 patients with TB disease each year, comprising 35% of the city burden. The setting has a strong TB infection-control program (i.e., annually updates infection-control plan, fully implements infection-control plan, and has enough AII rooms [see Environmental Controls]) and an annual conversion rate (for tests for *M. tuberculosis* infection) among HCWs of 0.5%. No evidence of health-care–associated transmission is apparent. The hospital has strong collaborative linkages with the state or local health department. Risk classification: medium risk (with close ongoing surveillance for episodes of transmission from unrecognized cases of TB disease, test conversions for *M. tuberculosis* infection in HCWs as a result of health-care–associated transmission, and specific groups or areas in which a higher risk for health-care–associated transmission exists).

Example D. The setting is an inpatient area of a correctional facility. A proportion of the inmates were born in countries where TB disease is endemic. Two cases of TB disease were diagnosed in inmates during the preceding year. Risk classification: medium risk (Correctional facilities should be classified as at least medium risk).

Example E. A hospital located in a large city admits 35 patients with TB disease per year, uses QFT-G to measure *M. tuberculosis* infection, and has an overall HCW *M. tuberculosis* infection test conversion rate of 1.0%. However, on annual testing, three of the 20 respiratory therapists tested had QFT-G conversions, for a rate of 15%. All of the respiratory therapists who tested positive received medical evaluations, had TB disease excluded, were diagnosed with LTBI, and were offered and completed a course of treatment for LTBI. None of the respiratory therapists had known exposures to

M. tuberculosis outside the hospital. The problem evaluation revealed that 1) the respiratory therapists who converted had spent part of their time in the pulmonary function laboratory where induced sputum specimens were collected, and 2) the ventilation in the laboratory was inadequate. Risk classification: potential ongoing transmission for the respiratory therapists (because of evidence of health-care–associated transmission). The rest of the setting was classified as medium risk. To address the problem, booths were installed for sputum induction. On subsequent testing for *M. tuberculosis* infection, no conversions were noted at the repeat testing 3 months later, and the respiratory therapists were then reclassified back to medium risk.

Example F. The setting is an ambulatory-care center associated with a large health maintenance organization (HMO). The patient volume is high, and the HMO is located in the inner city where TB rates are the highest in the state. During the preceding year, one patient who was known to have TB disease was evaluated at the center. The person was recognized as a TB patient on his first visit and was promptly triaged to an ED with an AII room capacity. While in the ambulatory-care center, the patient was held in an area separate from HCWs and other patients and instructed to wear a surgical or procedure mask, if possible. QFT-G was used for infection-control surveillance purposes, and a contact investigation was conducted among exposed staff, and no QFT-G conversions were noted. Risk classification: low risk.

Example G. The setting is a clinic for the care of persons infected with HIV. The clinic serves a large metropolitan area and a patient population of 2,000. The clinic has an AII room and a TB infection-control program. All patients are screened for TB disease upon enrollment, and airborne precautions are promptly initiated for anyone with respiratory complaints while the patient is being evaluated. During the preceding year, seven patients who were encountered in the clinic were subsequently determined to have TB disease. All patients were promptly put into an AII room, and no contact investigations were performed. The local health department was promptly notified in all cases. Annual TST has determined a conversion rate of 0.3%, which is low compared with the rate of the hospital with which the clinic is associated. Risk classification: medium risk (because persons infected with HIV might be encountered).

Example H. A home health-care agency employs 125 workers, many of whom perform duties, including nursing, physical therapy, and basic home care. The agency did not care for any patients with suspected or confirmed TB disease during the preceding year. Approximately 30% of the agency's workers are foreign-born, many of whom have immigrated within the previous 5 years. At baseline two-step testing, four had a positive initial TST result, and two had a positive second-step TST result. All except one of these workers was foreign-born. Upon further screening, none were determined to have TB disease. The home health-care agency is based in a major metropolitan area and delivers care to a community where the majority of persons are poor and medically underserved and TB case rates are higher than the community as a whole. Risk classification: low risk (because HCWs might be from populations at higher risk for LTBI and subsequent progression to TB disease because of foreign birth and recent immigration or HIV-infected clients might be overrepresented, medium risk could be considered).

Screening HCWs Who Transfer to Other Health-Care Settings

All HCWs should receive baseline TB screening, even in settings considered to be low risk. Infection-control plans should address HCWs who transfer from one health-care setting to another and consider that the transferring HCWs might be at an equivalent or higher risk for exposure in different settings. Infection-control plans might need to be customized to balance the assessed risks and the efficacy of the plan based on consideration of various logistical factors. Guidance is provided based on different scenarios.

Because some institutions might adopt BAMT for the purposes of testing for *M. tuberculosis* infection, infection-control programs might be confronted with interpreting historic and current TST and BAMT results when HCWs transfer to a different setting. On a case-by-case basis, expert medical opinion might be needed to interpret results and refer patients with discordant BAMT and TST baseline results. Therefore, infection-control programs should keep all records when documenting

previous test results. For example, an infection-control program using a BAMT strategy should request and keep historic TST results of a HCW transferring from a previous setting. Even if the HCW is transferring from a setting that used BAMT to a setting that uses BAMT, historic TST results might be needed when in the future the HCW transfers to a setting that uses TST. Similarly, historic BAMT results might be needed when the HCW transfers from a setting that used TST to a setting that uses BAMT.

HCWs transferring from low-risk to low-risk settings. After a baseline result for infection with *M. tuberculosis* is established and documented, serial testing for *M. tuberculosis* infection is not necessary.

HCWs transferring from low-risk to medium-risk settings. After a baseline result for infection with *M. tuberculosis* is established and documented, annual TB screening (including a symptom screen and TST or BAMT for persons with previously negative test results) should be performed.

HCWs transferring from low- or medium-risk settings to settings with a temporary classification of potential ongoing transmission. After a baseline result for infection with *M. tuberculosis* is established, a decision should be made regarding follow-up screening on an individual basis. If transmission seems to be ongoing, consider including the HCW in the screenings every 8–10 weeks until a determination has been made that ongoing transmission has ceased. When the setting is reclassified back to medium-risk, annual TB screening should be resumed.

Calculation and Use of Conversion Rates for *M. tuberculosis* Infection

The *M. tuberculosis* infection conversion rate is the percentage of HCWs whose test result for *M. tuberculosis* infection has converted within a specified period. Timely detection of *M. tuberculosis* infection in HCWs not only facilitates treatment for LTBI, but also can indicate the need for a source case investigation and a revision of the risk assessment for the setting. Conversion in test results for *M. tuberculosis*, regardless of the testing method used, is usually interpreted as presumptive evidence of new *M. tuberculosis* infection, and recent infections are associated with an increased risk for progression to TB disease.

For administrative purposes, a TST conversion is ≥ 10 mm increase in the size of the TST induration during a 2-year period in 1) an HCW with a documented negative (< 10 mm) baseline two-step TST result or 2) a person who is not an HCW with a negative (< 10 mm) TST result within 2 years.

In settings conducting serial testing for *M. tuberculosis* infection (medium-risk settings), use the following steps to estimate the risk for test conversion in HCWs.

- Calculate a conversion rate by dividing the number of conversions among HCWs in the setting in a specified period (numerator) by the number of HCWs who received tests in the setting over the same period (denominator) multiplied by 100 (see Use of Conversion Test Data for *M. tuberculosis* Infection To Identify Lapses in Infection Control).
- Identify areas or groups in the setting with a potentially high risk for *M. tuberculosis* transmission by comparing conversion rates in HCWs with potential exposure to patients with TB disease to conversion rates in HCWs for whom health-care–associated exposure to *M. tuberculosis* is not probable.

Use of Conversion Test Data for *M. tuberculosis* Infection To Identify Lapses in Infection Control

- Conversion rates above the baseline level (which will be different in each setting) should instigate an investigation to evaluate the likelihood of health-care–associated transmission. When testing for *M. tuberculosis* infection, if conversions are determined to be the result of well-documented community exposure or probable false-positive test results, then the risk classification of the setting does not need to be adjusted.
- For settings that no longer perform serial testing for *M. tuberculosis* infection among HCWs, reassessment of the risk for the setting is essential to ensure that the infection-control program is effective. The setting should have ongoing communication with the local or state health department regarding incidence and epidemiology of TB in the population served and should

ensure that timely contact investigations are performed for HCWs or patients with unprotected exposure to a person with TB disease.

Example Calculation of Conversion Rates

Medical Center A is classified as medium risk and uses TST for annual screening. At the end of 2004, a total of 10,051 persons were designated as HCWs. Of these, 9,246 had negative baseline test results for *M. tuberculosis* infection. Of the HCWs tested, 10 experienced an increase in TST result by ≥ 10 mm. The overall setting conversion rate for 2004 is 0.11%. If five of the 10 HCWs whose test results converted were among the 100 HCWs employed in the ICU of Hospital X (in Medical Center A), then the ICU setting-specific conversion rate for 2004 is 5%.

Evaluation of HCWs for LTBI should include information from a serial testing program, but this information must be interpreted as only one part of a full assessment. TST or BAMT conversion criteria for administrative (surveillance) purposes are not applicable for medical evaluation of HCWs for the diagnosis of LTBI (see Supplement, Surveillance and Detection of *M. tuberculosis* Infections in Health-Care Workers [HCWs]).

Evaluation of TB Infection-Control Procedures and Identification of Problems

Annual evaluations of the TB infection-control plan are needed to ensure the proper implementation of the plan and to recognize and correct lapses in infection control. Previous hospital admissions and outpatient visits of patients with TB disease should be noted before the onset of TB symptoms.

Medical records of a sample of patients with suspected and confirmed TB disease who were treated or examined at the setting should be reviewed to identify possible problems in TB infection control. The review should be based on the factors listed on the TB Risk Assessment Worksheet ([Appendix B](#)).

- Time interval from suspicion of TB until initiation of airborne precautions and antituberculosis treatment to:
 - suspicion of TB disease and patient triage to proper AII room or referral center for settings that do not provide care for patients with suspected or confirmed TB disease;
 - admission until TB disease was suspected;
 - admission until medical evaluation for TB disease was performed;
 - admission until specimens for AFB smears and polymerase chain reaction (PCR)–based nucleic acid amplification (NAA) tests for *M. tuberculosis* were ordered;
 - admission until specimens for mycobacterial culture were ordered;
 - ordering of AFB smears, NAA tests, and mycobacterial culture until specimens were collected;
 - collection of specimens until performance and AFB smear results were reported;
 - collection of specimens until performance and culture results were reported;
 - collection of specimens until species identification was reported;
 - collection of specimens until drug-susceptibility test results were reported;
 - admission until airborne precautions were initiated; and
 - admission until antituberculosis treatment was initiated.
- Duration of airborne precautions.
- Measurement of meeting criteria for discontinuing airborne precautions. Certain patients might be correctly discharged from an AII room to home.
- Patient history of previous admission.
- Adequacy of antituberculosis treatment regimens.
- Adequacy of procedures for collection of follow-up sputum specimens.
- Adequacy of discharge planning.
- Number of visits to outpatient setting from the start of symptoms until TB disease was suspected (for outpatient settings).

Work practices related to airborne precautions should be observed to determine if employers are enforcing all practices, if HCWs are adhering to infection-control policies, and if patient adherence to airborne precautions is being enforced. Data from the case reviews and observations in the annual risk assessment should be used to determine the need to modify 1) protocols for identifying and initiating prompt airborne precautions for patients with suspected or confirmed infectious TB disease, 2) protocols for patient management, 3) laboratory procedures, or 4) TB training and education programs for HCWs.

- Data from the most recent environmental evaluation should be reviewed to determine if recommended environmental controls are in place (see Suggested Components of an Initial TB Training and Education Program for HCWs).
- Environmental control maintenance procedures and logs should be reviewed to determine if maintenance is conducted properly and regularly.
- Environmental control design specifications should be compared with guidelines from the American Institute of Architects (AIA) and other ventilation guidelines (117,118) (see Risk Classification Examples) and the installed system performance.
- Environmental data should be used to assist building managers and engineers in evaluating the performance of the installed system.
- The number and types of aerosol-generating or aerosol-producing procedures (e.g., specimen processing and manipulation, bronchoscopy, sputum induction, and administration of aerosolized medications) performed in the setting should be assessed.
- The number of AII rooms should be suitable for the setting based on AIA Guidelines and the setting risk assessment. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) has adapted the AIA guidelines when accrediting facilities (118).

Suggested Components of an Initial TB Training and Education Program for HCWs

The following are suggested components of an initial TB training and education program:

1. Clinical Information

Basic concepts of *M. tuberculosis* transmission, pathogenesis, and diagnosis, including the difference between LTBI and TB disease and the possibility of reinfection after previous infection with *M. tuberculosis* or TB disease.

- Symptoms and signs of TB disease and the importance of a high index of suspicion for patients or HCWs with these symptoms.
- Indications for initiation of airborne precautions of inpatients with suspected or confirmed TB disease.
- Policies and indications for discontinuing airborne precautions.
- Principles of treatment for LTBI and for TB disease (indications, use, effectiveness, and potential adverse effects).

2. Epidemiology of TB

- Epidemiology of TB in the local community, the United States, and worldwide.
- Risk factors for TB disease.

3. Infection-Control Practices to Prevent and Detect *M. tuberculosis* Transmission in Health-Care Settings

- Overview of the TB infection-control program.
- Potential for occupational exposure to infectious TB disease in health-care settings.
- Principles and practices of infection control to reduce the risk for transmission of *M. tuberculosis*, including the hierarchy of TB infection-control measures, written policies and procedures, monitoring, and control measures for HCWs at increased risk for exposure to *M. tuberculosis*.
- Rationale for infection-control measures and documentation evaluating the effect of these measures in reducing occupational TB risk exposure and *M. tuberculosis* transmission.
- Reasons for testing for *M. tuberculosis* infection, importance of a positive test result for *M. tuberculosis* infection, importance of participation in a TB screening program, and importance of retaining documentation of previous test result for *M. tuberculosis* infection, chest radiograph results, and treatment for LTBI and TB disease.
- Efficacy and safety of BCG vaccination and principles of screening for *M. tuberculosis* infection and interpretation in BCG recipients.

- Procedures for investigating an *M. tuberculosis* infection test conversion or TB disease occurring in the workplace.
- Joint responsibility of HCWs and employers to ensure prompt medical evaluation after *M. tuberculosis* test conversion or development of symptoms or signs of TB disease in HCWs.
- Role of HCW in preventing transmission of *M. tuberculosis*.
- Responsibility of HCWs to promptly report a diagnosis of TB disease to the setting's administration and infection-control program.
- Responsibility of clinicians and the infection-control program to report to the state or local health department a suspected case of TB disease in a patient (including autopsy findings) or HCW.
- Responsibilities and policies of the setting, the local health department, and the state health department to ensure confidentiality for HCWs with TB disease or LTBI.
- Responsibility of the setting to inform EMS staff who transported a patient with suspected or confirmed TB disease.
- Responsibilities and policies of the setting to ensure that an HCW with TB disease is noninfectious before returning to duty.
- Importance of completing therapy for LTBI or TB disease to protect the HCW's health and to reduce the risk to others.
- Proper implementation and monitoring of environmental controls (see Environmental Controls).
- Training for safe collection, management, and disposal of clinical specimens.
- Required Occupational Safety and Health Administration (OSHA) record keeping on HCW test conversions for *M. tuberculosis* infection.
- Record-keeping and surveillance of TB cases among patients in the setting.
- Proper use of (see Respiratory Protection) and the need to inform the infection-control program of factors that might affect the efficacy of respiratory protection as required by OSHA.
- Success of adherence to infection-control practices in decreasing the risk for transmission of *M. tuberculosis* in health-care settings.

4. TB and Immunocompromising Conditions

- Relationship between infection with *M. tuberculosis* and medical conditions and treatments that can lead to impaired immunity.
- Available tests and counseling and referrals for persons with HIV infection, diabetes, and other immunocompromising conditions associated with an increased risk for progression to TB disease.
- Procedures for informing employee health or infection-control personnel of medical conditions associated with immunosuppression.
- Policies on voluntary work reassignment options for immunocompromised HCWs.
- Applicable confidentiality safeguards of the health-care setting, locality, and state.

5. TB and Public Health

- Role of the local and state health department's TB-control program in screening for LTBI and TB disease, providing treatment, conducting contact investigations and outbreak investigations, and providing education, counseling, and responses to public inquiries.
- Roles of CDC and of OSHA.
- Availability of information, advice, and counseling from community sources, including universities, local experts, and hotlines.
- Responsibility of the setting's clinicians and infection-control program to promptly report to the state or local health department a case of suspected TB disease or a cluster of TST or BAMT conversions.
- Responsibility of the setting's clinicians and infection-control program to promptly report to the state or local health department a person with suspected or confirmed TB disease who leaves the setting against medical advice.

Managing Patients Who Have Suspected or Confirmed TB Disease: General Recommendations

The primary TB risk to HCWs is the undiagnosed or unsuspected patient with infectious TB disease. A high index of suspicion for TB disease and rapid implementation of precautions are essential to

prevent and interrupt transmission. Specific precautions will vary depending on the setting.

Prompt Triage

Within health-care settings, protocols should be implemented and enforced to promptly identify, separate from others, and either transfer or manage persons who have suspected or confirmed infectious TB disease. When patients' medical histories are taken, all patients should be routinely asked about 1) a history of TB exposure, infection, or disease; 2) symptoms or signs of TB disease; and 3) medical conditions that increase their risk for TB disease (see Supplements, Diagnostic Procedures for LTBI and TB Disease; and Treatment Procedures for LTBI and TB Disease). The medical evaluation should include an interview conducted in the patient's primary language, with the assistance of a qualified medical interpreter, if necessary. HCWs who are the first point of contact should be trained to ask questions that will facilitate detection of persons who have suspected or confirmed infectious TB disease. For assistance with language interpretation, contact the local and state health department. Interpretation resources are also available (119) at <http://www.atanet.org> ; <http://www.languageine.com> ; and <http://www.ncihc.org> .

A diagnosis of respiratory TB disease should be considered for any patient with symptoms or signs of infection in the lung, pleura, or airways (including larynx), including coughing for ≥ 3 weeks, loss of appetite, unexplained weight loss, night sweats, bloody sputum or hemoptysis, hoarseness, fever, fatigue, or chest pain. The index of suspicion for TB disease will vary by geographic area and will depend on the population served by the setting. The index of suspicion should be substantially high for geographic areas and groups of patients characterized by high TB incidence (26).

Special steps should be taken in settings other than TB clinics. Patients with symptoms suggestive of undiagnosed or inadequately treated TB disease should be promptly referred so that they can receive a medical evaluation. These patients should not be kept in the setting any longer than required to arrange a referral or transfer to an AII room. While in the setting, symptomatic patients should wear a surgical or procedure mask, if possible, and should be instructed to observe strict respiratory hygiene and cough etiquette procedures (see Glossary) (120–122).

Immunocompromised persons, including those who are HIV-infected, with infectious TB disease should be physically separated from other persons to protect both themselves and others. To avoid exposing HIV-infected or otherwise severely immunocompromised persons to *M. tuberculosis*, consider location and scheduling issues to avoid exposure.

TB Airborne Precautions

Within health-care settings, TB airborne precautions should be initiated for any patient who has symptoms or signs of TB disease, or who has documented infectious TB disease and has not completed antituberculosis treatment. For patients placed in AII rooms because of suspected infectious TB disease of the lungs, airway, or larynx, airborne precautions may be discontinued when infectious TB disease is considered unlikely and either 1) another diagnosis is made that explains the clinical syndrome or 2) the patient has three consecutive, negative AFB sputum smear results (109–112,123). Each of the three sputum specimens should be collected in 8–24-hour intervals (124), and at least one specimen should be an early morning specimen because respiratory secretions pool overnight. Generally, this method will allow patients with negative sputum smear results to be released from airborne precautions in 2 days.

The classification of the risk assessment of the health-care setting is used to determine how many AII rooms each setting needs, depending on the number of TB patients examined. At least one AII room is needed for settings in which TB patients stay while they are being treated, and additional AII rooms might be needed depending on the magnitude of patient-days of persons with suspected or confirmed TB disease (118). Additional rooms might be considered if options are limited for transferring patients with suspected or confirmed TB disease to other settings with AII rooms. For example, for a hospital with 120 beds, a minimum of one AII room is needed, possibly more, depending on how many TB patients are examined in 1 year.

TB Airborne Precautions for Settings in Which Patients with Suspected or Confirmed TB Disease Are Expected To Be Encountered

Settings that plan to evaluate and manage patients with TB disease should have at least one AII room or enclosure that meets AII requirements (see Environmental Controls; and Supplement, Environmental Controls). These settings should develop written policies that specify 1) indications for airborne precautions, 2) persons authorized to initiate and discontinue airborne precautions, 3) specific airborne precautions, 4) AII room-monitoring procedures, 5) procedures for managing patients who do not adhere to airborne precautions, and 6) criteria for discontinuing airborne precautions.

A high index of suspicion should be maintained for TB disease. If a patient has suspected or confirmed TB disease, airborne precautions should be promptly initiated. Persons with suspected or confirmed TB disease who are inpatients should remain in AII rooms until they are determined to be noninfectious and have demonstrated a clinical response to a standard multidrug antituberculosis treatment regimen or until an alternative diagnosis is made. If the alternative diagnosis cannot be clearly established, even with three negative sputum smear results, empiric treatment of TB disease should strongly be considered (see Supplement, Estimating the Infectiousness of a TB Patient). Outpatients with suspected or confirmed infectious TB disease should remain in AII rooms until they are transferred or until their visit is complete.

TB Airborne Precautions for Settings in Which Patients with Suspected or Confirmed TB Disease Are Not Expected To Be Encountered

Settings in which patients with suspected or confirmed TB disease are not expected to be encountered do not need an AII room or a respiratory-protection program for the prevention of transmission of *M. tuberculosis*. However, follow these steps in these settings.

A written protocol should be developed for referring patients with suspected or confirmed TB disease to a collaborating referral setting in which the patient can be evaluated and managed properly. The referral setting should provide documentation of intent to collaborate. The protocol should be reviewed routinely and revised as needed.

Patients with suspected or confirmed TB disease should be placed in an AII room, if available, or in a room that meets the requirements for an AII room, or in a separate room with the door closed, apart from other patients and not in an open waiting area. Adequate time should elapse to ensure removal of *M. tuberculosis*–contaminated room air before allowing entry by staff or another patient ([Tables 1 and 2](#)).

If an AII room is not available, persons with suspected or confirmed infectious TB disease should wear a surgical or procedure mask, if possible. Patients should be instructed to keep the mask on and to change the mask if it becomes wet. If patients cannot tolerate a mask, they should observe strict respiratory hygiene and cough etiquette procedures.

AII Room Practices

AII rooms should be single-patient rooms in which environmental factors and entry of visitors and HCWs are controlled to minimize the transmission of *M. tuberculosis*. All HCWs who enter an AII room should wear at least N95 disposable respirators (see Respiratory Protection). Visitors may be offered respiratory protection (i.e., N95) and should be instructed by HCWs on the use of the respirator before entering an AII room. AII rooms have specific requirements for controlled ventilation, negative pressure, and air filtration (118) (see Environmental Controls). Each inpatient AII room should have a private bathroom.

Settings with AII Rooms

Health-care personnel settings with AII rooms should

- keep doors to AII rooms closed except when patients, HCWs, or others must enter or exit the room (118);

- maintain enough AII rooms to provide airborne precautions of all patients who have suspected or confirmed TB disease. Estimate the number of AII rooms needed based on the results of the risk assessment for the setting;
- monitor and record direction of airflow (i.e., negative pressure) in the room on a daily basis, while the room is being used for TB airborne precautions. Record results in an electronic or readily retrievable document;
- consider grouping AII rooms in one part of the health-care setting to limit costs, reduce the possibility of transmitting *M. tuberculosis* to other patients, facilitate the care of TB patients, and facilitate the installation and maintenance of optimal environmental controls (particularly ventilation). Depending on the architecture and the environmental control systems of a particular setting, AII rooms might be grouped either horizontally (e.g., a wing of a facility) or vertically (e.g., the last few rooms of separate floors of a facility);
- perform diagnostic and treatment procedures (e.g., sputum collection and inhalation therapy) in an AII room.
- ensure patient adherence to airborne precautions. In their primary language, with the assistance of a qualified medical interpreter, if necessary, educate patients (and family and visitors) who are placed in an AII room about *M. tuberculosis* transmission and the reasons for airborne precautions. For assistance with language interpretation, contact the local and state health department. Interpretation resources are available (119) at <http://www.atanet.org>; <http://www.languageine.com>; and <http://www.ncihc.org>. Facilitate patient adherence by using incentives (e.g., provide telephones, televisions, or radios in AII rooms; and grant special dietary requests) and other measures. Address problems that could interfere with adherence (e.g., management of withdrawal from addictive substances, including tobacco); and
- ensure that patients with suspected or confirmed infectious TB disease who must be transported to another area of the setting or to another setting for a medically essential procedure bypass the waiting area and wear a surgical or procedure mask, if possible. Drivers, HCWs, and other staff who are transporting persons with suspected or confirmed infectious TB disease might consider wearing an N95 respirator. Schedule procedures on patients with TB disease when a minimum number of HCWs and other patients are present and as the last procedure of the day to maximize the time available for removal of airborne contamination (Tables 1 and 2).

Diagnostic Procedures

Diagnostic procedures should be performed in settings with appropriate infection-control capabilities. The following recommendations should be applied for diagnosing TB disease and for evaluating patients for potential infectiousness.

Clinical Diagnosis

A complete medical history should be obtained, including symptoms of TB disease, previous TB disease and treatment, previous history of infection with *M. tuberculosis*, and previous treatment of LTBI or exposure to persons with TB disease. A physical examination should be performed, including chest radiograph, microscopic examination, culture, and, when indicated, NAA testing of sputum (39,53,125,126). If possible, sputum induction with aerosol inhalation is preferred, particularly when the patient cannot produce sputum. Gastric aspiration might be necessary for those patients, particularly children, who cannot produce sputum, even with aerosol inhalation (127–130). Bronchoscopy might be needed for specimen collection, especially if sputum specimens have been nondiagnostic and doubt exists as to the diagnosis (90,111,127,128,131–134).

All patients with suspected or confirmed infectious TB disease should be placed under airborne precautions until they have been determined to be noninfectious (see Supplement, Estimating the Infectiousness of a TB Patient). Adult and adolescent patients who might be infectious include persons who are coughing; have cavitation on chest radiograph; have positive AFB sputum smear results; have respiratory tract disease with involvement of the lung, pleura or airways, including larynx, who fail to cover the mouth and nose when coughing; are not on antituberculosis treatment or are on incorrect antituberculosis treatment; or are undergoing cough-inducing or aerosol-generating procedures (e.g., sputum induction, bronchoscopy, and airway suction) (30,135).

Persons diagnosed with extrapulmonary TB disease should be evaluated for the presence of concurrent pulmonary TB disease. An additional concern in infection control with children relates to adult household members and visitors who might be the source case (136). Pediatric patients,

including adolescents, who might be infectious include those who have extensive pulmonary or laryngeal involvement, prolonged cough, positive sputum AFB smears results, cavitary TB on chest radiograph (as is typically observed in immunocompetent adults with TB disease), or those for whom cough-inducing or aerosol-generating procedures are performed (136,137).

Although children are uncommonly infectious, pediatric patients should be evaluated for infectiousness by using the same criteria as for adults (i.e., on the basis of pulmonary or laryngeal involvement). Patients with suspected or confirmed TB disease should be immediately reported to the local public health authorities so that arrangements can be made for tracking their treatment to completion, preferably through a case management system, so that DOT can be arranged and standard procedures for identifying and evaluating TB contacts can be initiated. Coordinate efforts with the local or state health department to arrange treatment and long-term follow-up and evaluation of contacts.

Laboratory Diagnosis

To produce the highest quality laboratory results, laboratories performing mycobacteriologic tests should be skilled in both the laboratory and the administrative aspects of specimen processing. Laboratories should use or have prompt access to the most rapid methods available: 1) fluorescent microscopy and concentration for AFB smears; 2) rapid NAA testing for direct detection of *M. tuberculosis* in patient specimens (125); 3) solid and rapid broth culture methods for isolation of mycobacteria; 4) nucleic acid probes or high pressure liquid chromatography (HPLC) for species identification; and 5) rapid broth culture methods for drug susceptibility testing. Laboratories should incorporate other more rapid or sensitive tests as they become available, practical, and affordable (see Supplement, Diagnostic Procedures for LTBI and TB Disease) (138,139).

In accordance with local and state laws and regulations, a system should be in place to ensure that laboratories report any positive results from any specimens to clinicians within 24 hours of receipt of the specimen (139,140). Certain settings perform AFB smears on-site for rapid results (and results should be reported to clinicians within 24 hours) and then send specimens or cultures to a referral laboratory for identification and drug-susceptibility testing. This referral practice can speed the receipt of smear results but delay culture identification and drug-susceptibility results. Settings that cannot provide the full range of mycobacteriologic testing services should contract with their referral laboratories to ensure rapid results while maintaining proficiency for on-site testing. In addition, referral laboratories should be instructed to store isolates in case additional testing is necessary.

All drug susceptibility results on *M. tuberculosis* isolates should be reported to the local or state health department as soon as these results are available. Laboratories that rarely receive specimens for mycobacteriologic analysis should refer specimens to a laboratory that performs these tests routinely. The reference laboratory should provide rapid testing and reporting. Out-of-state reference laboratories should provide all results to the local or state health department from which the specimen originated.

Special Considerations for Persons Who Are at High Risk for TB Disease or in Whom TB Disease Might Be Difficult to Diagnose

The probability of TB disease is higher among patients who 1) previously had TB disease or were exposed to *M. tuberculosis*, 2) belong to a group at high risk for TB disease or, 3) have a positive TST or BAMT result. TB disease is strongly suggested if the diagnostic evaluation reveals symptoms or signs of TB disease, a chest radiograph consistent with TB disease, or AFB in sputum or from any other specimen. TB disease can occur simultaneously in immunocompromised persons who have pulmonary infections caused by other organisms (e.g., *Pneumocystis jirovecii* [formerly *P. carinii*] and *M. avium* complex) and should be considered in the diagnostic evaluation of all such patients with symptoms or signs of TB disease (53).

TB disease can be difficult to diagnose in persons who have HIV infection (49) (or other conditions associated with severe suppression of cell mediated immunity) because of nonclassical or normal radiographic presentation or the simultaneous occurrence of other pulmonary infections (e.g., *P.*

jaroveci or *M. avium* complex) (2). Patients who are HIV-infected are also at greater risk for having extrapulmonary TB (2). The difficulty in diagnosing TB disease in HIV-infected can be compounded by the possible lower sensitivity and specificity of sputum smear results for detecting AFB (53,141) and the overgrowth of cultures with *M. avium* complex in specimens from patients infected with both *M. tuberculosis* and *M. avium* complex. The TST in patients with advanced HIV infection is unreliable and cannot be used in clinical decision making (35,53,142).

For immunocompromised patients who have respiratory symptoms or signs that are attributed initially to infections or conditions other than TB disease, conduct an evaluation for coexisting TB disease. If the patient does not respond to recommended treatment for the presumed cause of the pulmonary abnormalities, repeat the evaluation (see Supplement, Diagnostic Procedures for LTBI and TB Disease). In certain settings in which immunocompromised patients and patients with TB disease are examined, implementing airborne precautions might be prudent for all persons at high risk. These persons include those infected with HIV who have an abnormal chest radiograph or respiratory symptoms, symptomatic foreign-born persons who have immigrated within the previous 5 years from TB-endemic countries, and persons with pulmonary infiltrates on chest radiograph, or symptoms or signs of TB disease.

Initiation of Treatment

For patients who have confirmed TB disease or who are considered highly probable to have TB disease, promptly start antituberculosis treatment in accordance with current guidelines (see Supplements, Diagnostic Procedures for LTBI and TB Disease; and Treatment Procedures for LTBI and TB Disease) (31). In accordance with local and state regulations, local health departments should be notified of all cases of suspected TB.

DOT is the standard of care for all patients with TB disease and should be used for all doses during the course of therapy for treatment of TB disease. All inpatient medication should be administered by DOT and reported to the state or local health department. Rates of relapse and development of drug-resistance are decreased when DOT is used (143–145). All patients on intermittent (i.e., once or twice per week) treatment for TB disease or LTBI should receive DOT. Settings should collaborate with the local or state health department on decisions concerning inpatient DOT and arrangements for outpatient DOT (31).

Managing Patients Who Have Suspected or Confirmed TB Disease: Considerations for Special Circumstances and Settings

The recommendations for preventing transmission of *M. tuberculosis* are applicable to all health-care settings, including those that have been described ([Appendix A](#)). These settings should each have independent risk assessments if they are stand-alone settings, or each setting should have a detailed section written as part of the risk assessment for the overall setting.

Minimum Requirements

The specific precautions for the settings included in this section vary, depending on the setting.

Inpatient Settings

Emergency Departments (EDs)

The symptoms of TB disease are usually symptoms for which patients might seek treatment in EDs. Because TB symptoms are common and nonspecific, infectious TB disease could be encountered in these settings. The use of ED-based TB screening has not been demonstrated to be consistently effective (146).

The amount of time patients with suspected or confirmed infectious TB disease spend in EDs and urgent-care settings should be minimized. Patients with suspected or confirmed infectious TB disease should be promptly identified, evaluated, and separated from other patients. Ideally, such patients should be placed in an AII room. When an AII room is not available, use a room with effective general ventilation, and use air cleaning technologies (e.g., a portable HEPA filtration system), if available, or

transfer the patient to a setting or area with recommended infection-control capacity. Facility engineering personnel with expertise in heating, ventilation, and air conditioning (HVAC) and air handlers have evaluated how this option is applied to ensure no over pressurization of return air or unwanted deviations exists in design of air flow in the zone.

EDs with a high volume of patients with suspected or confirmed TB disease should have at least one AII room (see TB Risk Assessment). Air-cleaning technologies (e.g., HEPA filtration and UVGI) can be used to increase equivalent air changes per hour (ACH) in waiting areas ([Table 1](#)). HCWs entering an AII room or any room with a patient with infectious TB disease should wear at least an N95 disposable respirator. After a patient with suspected or confirmed TB disease exits a room, allow adequate time to elapse to ensure removal of *M. tuberculosis*-contaminated room air before allowing entry by staff or another patient ([Tables 1](#) and [2](#)).

Before a patient leaves an AII room, perform an assessment of 1) the patient's need to discontinue airborne precautions, 2) the risk for transmission and the patient's ability to observe strict respiratory hygiene, and 3) cough etiquette procedures. Patients with suspected or confirmed infectious TB who are outside an AII room should wear a surgical or procedure mask, if possible. Patients who cannot tolerate masks because of medical conditions should observe strict respiratory hygiene and cough etiquette procedures.

Intensive Care Units (ICUs)

Patients with infectious TB disease might become sick enough to require admission to an ICU. Place ICU patients with suspected or confirmed infectious TB disease in an AII room, if possible. ICUs with a high volume of patients with suspected or confirmed TB disease should have at least one AII room ([Appendix B](#)). Air-cleaning technologies (e.g., HEPA filtration and UVGI) can be used to increase equivalent ACH in waiting areas (see Environmental Controls).

HCWs entering an AII room or any room with a patient with infectious TB disease should wear at least an N95 disposable respirator. To help reduce the risk for contaminating a ventilator or discharging *M. tuberculosis* into the ambient air when mechanically ventilating (i.e., with a ventilator or manual resuscitator) a patient with suspected or confirmed TB disease, place a bacterial filter on the patient's endotracheal tube (or at the expiratory side of the breathing circuit of a ventilator) (147–151). In selecting a bacterial filter, give preference to models specified by the manufacturer to filter particles 0.3 μm in size in both the unloaded and loaded states with a filter efficiency of $\geq 95\%$ (i.e., filter penetration of $< 5\%$) at the maximum design flow rates of the ventilator for the service life of the filter, as specified by the manufacturer.

Surgical Suites

Surgical suites require special infection-control considerations for preventing transmission of *M. tuberculosis*. Normally, the direction of airflow should be from the operating room (OR) to the hallway (positive pressure) to minimize contamination of the surgical field. Certain hospitals have procedure rooms with reversible airflow or pressure, whereas others have positive-pressure rooms with a negative pressure anteroom. Surgical staff, particularly those close to the surgical field, should use respiratory protection (e.g., a valveless N95 disposable respirator) to protect themselves and the patient undergoing surgery.

When possible, postpone non-urgent surgical procedures on patients with suspected or confirmed TB disease until the patient is determined to be noninfectious or determined to not have TB disease. When surgery cannot be postponed, procedures should be performed in a surgical suite with recommended ventilation controls. Procedures should be scheduled for patients with suspected or confirmed TB disease when a minimum number of HCWs and other patients are present in the surgical suite, and at the end of the day to maximize the time available for removal of airborne contamination ([Tables 1](#) and [2](#)).

If a surgical suite or an OR has an anteroom, the anteroom should be either 1) positive pressure compared with both the corridor and the suite or OR (with filtered supply air) or 2) negative pressure

compared with both the corridor and the suite or OR. In the usual design in which an OR has no anteroom, keep the doors to the OR closed, and minimize traffic into and out of the room and in the corridor. Using additional air-cleaning technologies (e.g., UVGI) should be considered to increase the equivalent ACH. Air-cleaning systems can be placed in the room or in surrounding areas to minimize contamination of the surroundings after the procedure (114) (see Environmental Controls).

Ventilation in the OR should be designed to provide a sterile environment in the surgical field while preventing contaminated air from flowing to other areas in the health-care setting. Personnel steps should be taken to reduce the risk for contaminating ventilator or anesthesia equipment or discharging tubercle bacilli into the ambient air when operating on a patient with suspected or confirmed TB disease (152). A bacterial filter should be placed on the patient's endotracheal tube (or at the expiratory side of the breathing circuit of a ventilator or anesthesia machine, if used) (147–151). When selecting a bacterial filter, give preference to models specified by the manufacturer to filter particles 0.3 μm in size in both the unloaded and loaded states with a filter efficiency of $\geq 95\%$ (i.e., filter penetration of $< 5\%$) at the maximum design flow rates of the ventilator for the service life of the filter, as specified by the manufacturer.

When surgical procedures (or other procedures that require a sterile field) are performed on patients with suspected or confirmed infectious TB, respiratory protection should be worn by HCWs to protect the sterile field from the respiratory secretions of HCWs and to protect HCWs from the infectious droplet nuclei generated from the patient. When selecting respiratory protection, do not use valved or positive-pressure respirators, because they do not protect the sterile field. A respirator with a valveless filtering facepiece (e.g., N95 disposable respirator) should be used.

Postoperative recovery of a patient with suspected or confirmed TB disease should be in an AII room in any location where the patient is recovering (118). If an AII or comparable room is not available for surgery or postoperative recovery, air-cleaning technologies (e.g., HEPA filtration and UVGI) can be used to increase the number of equivalent ACH (see Environmental Controls); however, the infection-control committee should be involved in the selection and placement of these supplemental controls.

Laboratories

Staff who work in laboratories that handle clinical specimens encounter risks not typically present in other areas of a health-care setting (153–155). Laboratories that handle TB specimens include 1) pass-through facilities that forward specimens to reference laboratories for analysis; 2) diagnostic laboratories that process specimens and perform acid-fast staining and primary culture for *M. tuberculosis*; and 3) facilities that perform extensive identification, subtyping, and susceptibility studies.

Procedures involving the manipulation of specimens or cultures containing *M. tuberculosis* introduce additional substantial risks that must be addressed in an effective TB infection-control program. Personnel who work with mycobacteriology specimens should be thoroughly trained in methods that minimize the production of aerosols and undergo periodic competency testing to include direct observation of their work practices. Risks for transmission of *M. tuberculosis* in laboratories include aerosol formation during any specimen or isolate manipulation and percutaneous inoculation from accidental exposures. Biosafety recommendations for laboratories performing diagnostic testing for TB have been published (74,75,138,156,157).

In laboratories affiliated with a health-care setting (e.g., a hospital) and in free-standing laboratories, the laboratory director, in collaboration with the infection-control staff for the setting, and in consultation with the state TB laboratory, should develop a risk-based infection-control plan for the laboratory that minimizes the risk for exposure to *M. tuberculosis*. Consider factors including 1) incidence of TB disease (including drug-resistant TB) in the community and in patients served by settings that submit specimens to the laboratory, 2) design of the laboratory, 3) level of TB diagnostic service offered, 4) number of specimens processed, and 5) whether or not aerosol-generating or aerosol-producing procedures are performed and the frequency at which they are performed. Referral laboratories should store isolates in case additional testing is necessary.

Biosafety level (BSL)-2 practices and procedures, containment equipment, and facilities are required for nonaerosol-producing manipulations of clinical specimens (e.g., preparing direct smears for acid-fast staining when done in conjunction with training and periodic checking of competency) (138). All specimens suspected of containing *M. tuberculosis* (including specimens processed for other microorganisms) should be handled in a Class I or II biological safety cabinet (BSC) (158,159). Conduct all aerosol-generating activities (e.g., inoculating culture media, setting up biochemical and antimicrobial susceptibility tests, opening centrifuge cups, and performing sonication) in a Class I or II BSC (158).

For laboratories that are considered at least medium risk ([Appendix C](#)), conduct testing for *M. tuberculosis* infection at least annually among laboratorians who perform TB diagnostics or manipulate specimens from which *M. tuberculosis* is commonly isolated (e.g., sputum, lower respiratory secretions, or tissues) ([Appendix D](#)). More frequent testing for *M. tuberculosis* is recommended in the event of a documented conversion among laboratory staff or a laboratory accident that poses a risk for exposure to *M. tuberculosis* (e.g., malfunction of a centrifuge leading to aerosolization of a sample).

Based on the risk assessment for the laboratory, employees should use personal protective equipment (including respiratory protection) recommended by local regulations for each activity. For activities that have a low risk for generating aerosols, standard personal protective equipment consists of protective laboratory coats, gowns, or smocks designed specifically for use in the laboratory. Protective garments should be left in the laboratory before going to nonlaboratory areas.

For all laboratory procedures, disposable gloves should be worn. Gloves should be disposed of when work is completed, the gloves are overtly contaminated, or the integrity of the glove is compromised. Local or state regulations should determine procedures for the disposal of gloves. Face protection (e.g., goggles, full-facepiece respirator, face shield, or other splatter guard) should also be used when manipulating specimens inside or outside a BSC. Use respiratory protection when performing procedures that can result in aerosolization outside a BSC. The minimum level of respiratory protection is an N95 filtering facepiece respirator. Laboratory workers who use respiratory protection should be provided with the same training on respirator use and care and the same fit testing as other HCWs.

After documented laboratory accidents, conduct an investigation of exposed laboratory workers. Laboratories in which specimens for mycobacteriologic studies (e.g., AFB smears and cultures) are processed should follow the AIA and CDC/National Institute of Health guidelines (118,159) (see Environmental Controls). BSL-3 practices, containment equipment, and facilities are recommended for the propagation and manipulation of cultures of *M. tuberculosis* complex (including *M. bovis*) and for animal studies in which primates that are experimentally or naturally infected with *M. tuberculosis* or *M. bovis* are used. Animal studies in which guinea pigs or mice are used can be conducted at animal BSL-2. Aerosol infection methods are recommended to be conducted at BSL-3 (159).

Bronchoscopy Suites

Because bronchoscopy is a cough-inducing procedure that might be performed on patients with suspected or confirmed TB disease, bronchoscopy suites require special attention (29,81,160,161). Bronchoscopy can result in the transmission of *M. tuberculosis* either through the airborne route (29,63,81,86,162) or a contaminated bronchoscope (80,82,163–170). Closed and effectively filtered ventilatory circuitry and minimizing opening of such circuitry in intubated and mechanically ventilated patients might minimize exposure (see Intensive Care Units) (149).

If possible, avoid bronchoscopy on patients with suspected or confirmed TB disease or postpone the procedure until the patient is determined to be noninfectious, by confirmation of the three negative AFB sputum smear results (109–112). When collection of spontaneous sputum specimen is not adequate or possible, sputum induction has been demonstrated to be equivalent to bronchoscopy for obtaining specimens for culture (110). Bronchoscopy might have the advantage of confirmation of the

diagnosis with histologic specimens, collection of additional specimens, including post bronchoscopy sputum that might increase the diagnostic yield, and the opportunity to confirm an alternate diagnosis. If the diagnosis of TB disease is suspected, consideration should be given to empiric antituberculosis treatment.

A physical examination should be performed, and a chest radiograph, microscopic examination, culture, and NAA testing of sputum or other relevant specimens should also be obtained, including gastric aspirates (125), as indicated (53,126,131,130). Because 15%–20% of patients with TB disease have negative TST results, a negative TST result is of limited value in the evaluation of the patient with suspected TB disease, particularly in patients from high TB incidence groups in whom TST positive rates exceed 30% (31).

Whenever feasible, perform bronchoscopy in a room that meets the ventilation requirements for an AII room (same as the AIA guidelines parameters for bronchoscopy rooms) (see Environmental Controls). Air-cleaning technologies (e.g., HEPA filtration and UVGI) can be used to increase equivalent ACH.

If sputum specimens must be obtained and the patient cannot produce sputum, consider sputum induction before bronchoscopy (111). In a patient who is intubated and mechanically ventilated, minimize the opening of circuitry. At least N95 respirators should be worn by HCWs while present during a bronchoscopy procedure on a patient with suspected or confirmed infectious TB disease. Because of the increased risk for *M. tuberculosis* transmission during the performance of bronchoscopy procedures on patients with TB disease, consider using a higher level of respiratory protection than an N95 disposable respirator (e.g., an elastomeric full-facepiece respirator or a powered air-purifying respirator [PAPR] [29]) (see Respiratory Protection).

After bronchoscopy is performed on a patient with suspected or confirmed infectious TB disease, allow adequate time to elapse to ensure removal of *M. tuberculosis*–contaminated room air before performing another procedure in the same room ([Tables 1](#) and [2](#)). During the period after bronchoscopy when the patient is still coughing, collect at least one sputum for AFB to increase the yield of the procedure. Patients with suspected or confirmed TB disease who are undergoing bronchoscopy should be kept in an AII room until coughing subsides.

Sputum Induction and Inhalation Therapy Rooms

Sputum induction and inhalation therapy induces coughing, which increases the potential for transmission of *M. tuberculosis* (87,88,90). Therefore, appropriate precautions should be taken when working with patients with suspected or confirmed TB disease. Sputum induction procedures for persons with suspected or confirmed TB disease should be considered after determination that self-produced sputum collection is inadequate and that the AFB smear result on other specimens collected is negative. HCWs who order or perform sputum induction or inhalation therapy in an environment without proper controls for the purpose of diagnosing conditions other than TB disease should assess the patient's risk for TB disease.

Cough-inducing or aerosol-generating procedures in patients with diagnosed TB should be conducted only after an assessment of infectiousness has been considered for each patient and should be conducted in an environment with proper controls. Sputum induction should be performed by using local exhaust ventilation (e.g., booths with special ventilation) or alternatively in a room that meets or exceeds the requirements of an AII room (see Environmental Controls) (90). At least an N95 disposable respirator should be worn by HCWs performing sputum inductions or inhalation therapy on a patient with suspected or confirmed infectious TB disease. Based on the risk assessment, consideration should be given to using a higher level of respiratory protection (e.g., an elastomeric full-facepiece respirator or a PAPR) (see Respiratory Protection) (90).

After sputum induction or inhalation therapy is performed on a patient with suspected or confirmed infectious TB disease, allow adequate time to elapse to ensure removal of *M. tuberculosis*–contaminated room air before performing another procedure in the same room ([Tables 1](#) and [2](#)).

Patients with suspected or confirmed TB disease who are undergoing sputum induction or inhalation therapy should be kept in an AII room until coughing subsides.

Autopsy Suites

Autopsies performed on bodies with suspected or confirmed TB disease can pose a high risk for transmission of *M. tuberculosis*, particularly during the performance of aerosol-generating procedures (e.g., median sternotomy). Persons who handle bodies might be at risk for transmission of *M. tuberculosis* (77,78,171–177). Because certain procedures performed as part of an autopsy might generate infectious aerosols, special airborne precautions are required.

Autopsies should not be performed on bodies with suspected or confirmed TB disease without adequate protection for those performing the autopsy procedures. Settings in which autopsies are performed should meet or exceed the requirements of an AII room, if possible (see Environmental Controls), and the drawing in the American Conference of Governmental Industrial Hygienists(r) (ACGIH) Industrial Ventilation Manual VS-99-07 (178). Air should be exhausted to the outside of the building. Air-cleaning technologies (e.g., HEPA filtration or UVGI) can be used to increase the number of equivalent ACH (see Environmental Controls).

As an added administrative measure, when performing autopsies on bodies with suspected or confirmed TB disease, coordination between attending physicians and pathologists is needed to ensure proper infection control and specimen collection. The use of local exhaust ventilation should be considered to reduce exposures to infectious aerosols (e.g., when using a saw, including Striker saw). For HCWs performing an autopsy on a body with suspected or confirmed TB disease, at least N95 disposable respirators should be worn (see Respiratory Protection). Based on the risk assessment, consider using a higher level of respiratory protection than an N95 disposable respirator (e.g., an elastomeric full-facepiece respirator or a PAPR) (see Respiratory Protection).

After an autopsy is performed on a body with suspected or confirmed TB disease, allow adequate time to elapse to ensure removal of *M. tuberculosis*–contaminated room air before performing another procedure in the same room (Tables 1 and 2). If time delay is not feasible, the autopsy staff should continue to wear respirators while they are in the room.

Embalming Rooms

Tissue or organ removal in an embalming room performed on bodies with suspected or confirmed TB disease can pose a high risk for transmission of *M. tuberculosis*, particularly during the performance of aerosol-generating procedures. Persons who handle corpses might be at risk for transmission of *M. tuberculosis* (77,78,171–176). Because certain procedures performed as part of embalming might generate infectious aerosols, special airborne precautions are required.

Embalming involving tissue or organ removal should not be performed on bodies with suspected or confirmed TB disease without adequate protection for the persons performing the procedures. Settings in which these procedures are performed should meet or exceed the requirements of an AII room, if possible (see Environmental Controls), and the drawing in the ACGIH Industrial Ventilation Manual VS-99-07 (178). Air should be exhausted to the outside of the building. Air-cleaning technologies (e.g., HEPA filtration or UVGI) can be used to increase the number of equivalent ACH (see Environmental Controls). The use of local exhaust ventilation should be considered to reduce exposures to infectious aerosols (e.g., when using a saw, including Striker saw) and vapors from embalming fluids.

When HCWs remove tissues or organs from a body with suspected or confirmed TB disease, at least N95 disposable respirators should be worn (see Respiratory Protection). Based on the risk assessment, consider using a higher level of respiratory protection than an N95 disposable respirator (e.g., an elastomeric full-facepiece respirator or a PAPR) (see Respiratory Protection).

After tissue or organ removal is performed on a body with suspected or confirmed TB disease, allow adequate time to elapse to ensure removal of *M. tuberculosis*–contaminated room air before

performing another procedure in the same room (see Environmental Controls). If time delay is not feasible, the staff should continue to wear respirators while in the room.

Outpatient Settings

Outpatient settings might include TB treatment facilities, dental-care settings, medical offices, ambulatory-care settings, and dialysis units. Environmental controls should be implemented based on the types of activities that are performed in the setting.

TB Treatment Facilities

TB treatment facilities might include TB clinics, infectious disease clinics, or pulmonary clinics. TB clinics and other settings in which patients with TB disease and LTBI are examined on a regular basis require special attention. The same principles of triage used in EDs and ambulatory-care settings (see Minimum Requirements) should be applied to TB treatment facilities. These principles include prompt identification, evaluation, and airborne precautions of patients with suspected or confirmed infectious TB disease.

All TB clinic staff, including outreach workers, should be screened for *M. tuberculosis* infection ([Appendix C](#)). Patients with suspected or confirmed infectious TB disease should be physically separated from all patients, but especially from those with HIV infection and other immunocompromising conditions that increase the likelihood of development of TB disease if infected. Immunosuppressed patients with suspected or confirmed infectious TB disease need to be physically separated from others to protect both the patient and others. Appointments should be scheduled to avoid exposing HIV-infected or otherwise severely immunocompromised persons to *M. tuberculosis*. Certain times of the day should be designated for appointments for patients with infectious TB disease or treat them in areas in which immunocompromised persons are not treated.

Persons with suspected or confirmed infectious TB disease should be promptly placed in an AII room to minimize exposure in the waiting room and other areas of the clinic, and they should be instructed to observe strict respiratory hygiene and cough etiquette procedures. Clinics that provide care for patients with suspected or confirmed infectious TB disease should have at least one AII room. The need for additional AII rooms should be based on the risk assessment for the setting.

All cough-inducing and aerosol-generating procedures should be performed using environmental controls (e.g., in a booth or an AII room) (see Environmental Controls). Patients should be left in the booth or AII room until coughing subsides. Another patient or HCW should not be allowed to enter the booth or AII room until sufficient time has elapsed for adequate removal of *M. tuberculosis*-contaminated air (see Environmental Controls). A respiratory-protection program should be implemented for all HCWs who work in the TB clinic and who enter AII rooms, visit areas in which persons with suspected or confirmed TB disease are located, or transport patients with suspected or confirmed TB disease in vehicles. When persons with suspected or confirmed infectious TB disease are in the TB clinic and not in an AII room, they should wear a surgical or procedure mask, if possible.

Medical Offices and Ambulatory-Care Settings

The symptoms of TB disease are usually symptoms for which patients might seek treatment in a medical office. Therefore, infectious TB disease could possibly be encountered in certain medical offices and ambulatory-care settings.

Because of the potential for *M. tuberculosis* transmission in medical offices and ambulatory-care settings, follow the general recommendations for management of patients with suspected or confirmed TB disease and the specific recommendations for EDs (see Intensive Care Units [ICUs]). The risk assessment may be used to determine the need for or selection of environmental controls and the frequency of testing HCWs for *M. tuberculosis* infection.

Dialysis Units

Certain patients with TB disease need chronic dialysis for treatment of ESRD (179–181). The incidence of TB disease and infection in patients with ESRD might be higher than in the general population (181–183) and might be compounded by the overlapping risks for ESRD and TB disease among patients with diabetes mellitus (39). In addition, certain dialysis patients or patients who are otherwise immunocompromised (e.g., patients with organ transplants) might be on immunosuppressive medications (162,183). Patients with ESRD who need chronic dialysis should have at least one test for *M. tuberculosis* infection to determine the need for treatment of LTBI. Annual re-screening is indicated if ongoing exposure of ESRD patients to *M. tuberculosis* is probable.

Hemodialysis procedures should be performed on hospitalized patients with suspected or confirmed TB disease in an AII room. Dialysis staff should use recommended respiratory protection, at least an N95 disposable respirator. Patients with suspected or confirmed TB disease who need chronic hemodialysis might need referral to a hospital or other setting with the ability to perform dialysis procedures in an AII room until the patient is no longer infectious or another diagnosis is made. Certain antituberculosis medications are prescribed differently for hemodialysis patients (31).

Dental-Care Settings

The generation of droplet nuclei containing *M. tuberculosis* as a result of dental procedures has not been demonstrated (184). Nonetheless, oral manipulations during dental procedures could stimulate coughing and dispersal of infectious particles. Patients and dental HCWs share the same air space for varying periods, which contributes to the potential for transmission of *M. tuberculosis* in dental settings (185). For example, during primarily routine dental procedures in a dental setting, MDR TB might have been transmitted between two dental workers (186).

To prevent the transmission of *M. tuberculosis* in dental-care settings, certain recommendations should be followed (187,188). Infection-control policies for each dental health-care setting should be developed, based on the community TB risk assessment ([Appendix B](#)), and should be reviewed annually, if possible. The policies should include appropriate screening for LTBI and TB disease for dental HCWs, education on the risk for transmission to the dental HCWs, and provisions for detection and management of patients who have suspected or confirmed TB disease.

When taking a patient's initial medical history and at periodic updates, dental HCWs should routinely document whether the patient has symptoms or signs of TB disease. If urgent dental care must be provided for a patient who has suspected or confirmed infectious TB disease, dental care should be provided in a setting that meets the requirements for an AII room (see Environmental Controls). Respiratory protection (at least N95 disposable respirator) should be used while performing procedures on such patients.

In dental health-care settings that routinely provide care to populations at high risk for TB disease, using engineering controls (e.g., portable HEPA units) similar to those used in waiting rooms or clinic areas of health-care settings with a comparable community-risk profile might be beneficial.

During clinical assessment and evaluation, a patient with suspected or confirmed TB disease should be instructed to observe strict respiratory hygiene and cough etiquette procedures (122). The patient should also wear a surgical or procedure mask, if possible. Non-urgent dental treatment should be postponed, and these patients should be promptly referred to an appropriate medical setting for evaluation of possible infectiousness. In addition, these patients should be kept in the dental health-care setting no longer than required to arrange a referral.

Nontraditional Facility-Based Settings

Nontraditional facility-based settings include EMS, medical settings in correctional facilities, home-based health-care and outreach settings, long-term-care settings (e.g., hospices and skilled nursing facilities), and homeless shelters. Environmental controls should be implemented based on the types of activities that are performed in the setting.

TB is more common in the homeless population than in the general population (189–192). Because persons who visit homeless shelters frequently share exposure and risk characteristics of TB patients

who are treated in outpatient clinics, homeless shelters with clinics should observe the same TB infection-control measures as outpatient clinics. ACET has developed recommendations to assist health-care providers, health departments, shelter operators and workers, social service agencies, and homeless persons to prevent and control TB in this population (189).

Emergency Medical Services (EMS)

Although the overall risk is low (193), documented transmission of *M. tuberculosis* has occurred in EMS occupational settings (194), and approaches to reduce this risk have been described (193,195). EMS personnel should be included in a comprehensive screening program to test for *M. tuberculosis* infection and provide baseline screening and follow-up testing as indicated by the risk classification of the setting. Persons with suspected or confirmed infectious TB disease who are transported in an ambulance should wear a surgical or procedure mask, if possible, and drivers, HCWs, and other staff who are transporting the patient might consider wearing an N95 respirator.

The ambulance ventilation system should be operated in the nonrecirculating mode, and the maximum amount of outdoor air should be provided to facilitate dilution. If the vehicle has a rear exhaust fan, use this fan during transport. If the vehicle is equipped with a supplemental recirculating ventilation unit that passes air through HEPA filters before returning it to the vehicle, use this unit to increase the number of ACH (188). Air should flow from the cab (front of vehicle), over the patient, and out the rear exhaust fan. If an ambulance is not used, the ventilation system for the vehicle should bring in as much outdoor air as possible, and the system should be set to nonrecirculating. If possible, physically isolate the cab from the rest of the vehicle, and place the patient in the rear seat (194).

EMS personnel should be included in the follow-up contact investigations of patients with infectious TB disease. The Ryan White Comprehensive AIDS Resource Emergency Act of 1990 (Public law 101–381) mandates notification of EMS personnel after they have been exposed to a patient with suspected or confirmed infectious TB disease (Title 42 U.S. Code 1994) (<http://hab.hrsa.gov/data2/adap/introduction.htm>).

Medical Settings in Correctional Facilities

TB is a substantial health concern in correctional facilities; employees and inmates are at high risk (105,196–205). TB outbreaks in correctional facilities can lead to transmission in surrounding communities (201,206,207). ACET recommends that all correctional facilities have a written TB infection-control plan (196), and multiple studies indicate that screening correctional employees and inmates is a vital TB control measure (204,208,209).

The higher risk for *M. tuberculosis* transmission in health-care settings in correctional facilities (including jails and prisons) is a result of the disproportionate number of inmates with risk factors for TB infection and TB disease (203,210). Compared with the general population, TB prevalence is higher among inmates and is associated with a higher prevalence of HIV infection (197), increased illicit substance use, lower socioeconomic status (201), and their presence in settings that are at high risk for transmission of *M. tuberculosis*.

A TB infection-control plan should be developed specifically for that setting, even if the institution is part of a multifacility system (196,211). Medical settings in correctional facilities should be classified as at least medium risk; therefore, all correctional facility health-care personnel and other staff, including correctional officers should be screened for TB at least annually (201,203,208).

Correctional facilities should collaborate with the local or state health department to decide on TB contact investigations and discharge planning (105,212) and to provide TB training and education to inmates and employees (196). Corrections staff should be educated regarding symptoms and signs of TB disease and encouraged to facilitate prompt evaluation of inmates with suspected infectious TB disease (206).

At least one AII room should be available in correctional facilities. Any inmate with suspected or confirmed infectious TB disease should be placed in an AII room immediately or transferred to a

setting with an AII room; base the number of additional AII rooms needed on the risk assessment for the setting. Sputum samples should be collected in sputum induction booths or AII rooms, not in inmates' cells. Sputum collection can also be performed safely outside, away from other persons, windows, and ventilation intakes.

Inmates with suspected or confirmed infectious TB disease who must be transported outside an AII room for medically essential procedures should wear a surgical or procedure mask during transport, if possible. If risk assessment indicates the need for respiratory protection, drivers, medical or security staff, and others who are transporting patients with suspected or confirmed infectious TB disease in an enclosed vehicle should consider wearing an N95 disposable respirator.

A respiratory-protection program, including training, education, and fit-testing in the correctional facility's TB infection-control program should be implemented. Correctional facilities should maintain a tracking system for inmate TB screening and treatment and establish a mechanism for sharing this information with state and local health departments and other correctional facilities (196,201). Confidentiality of inmates should be ensured during screening for symptoms or signs of TB disease and risk factors.

Home-Based Health-Care and Outreach Settings

Transmission of *M. tuberculosis* has been documented in staff who work in home-based health-care and outreach settings (213,214). The setting's infection-control plan should include training that reminds HCWs who provide medical services in the homes of patients or other outreach settings of the importance of early evaluation of symptoms or signs of TB disease for early detection and treatment of TB disease. Training should also include the role of the HCW in educating patients regarding the importance of reporting symptoms or signs of TB disease and the importance of reporting any adverse effects to treatment for LTBI or TB disease.

HCWs who provide medical services in the homes of patients with suspected or confirmed TB disease can help prevent transmission of *M. tuberculosis* by 1) educating patients and other household members regarding the importance of taking medications as prescribed, 2) facilitating medical evaluation of symptoms or signs of TB disease, and 3) administering DOT, including DOT for treatment of LTBI whenever feasible.

HCWs who provide medical services in the homes of patients should not perform cough-inducing or aerosol-generating procedures on patients with suspected or confirmed infectious TB disease, because recommended infection controls probably will not be in place. Sputum collection should be performed outdoors, away from other persons, windows, and ventilation intakes.

HCWs who provide medical services in the homes of patients with suspected or confirmed infectious TB disease should instruct TB patients to observe strict respiratory hygiene and cough etiquette procedures. HCWs who enter homes of persons with suspected or confirmed infectious TB disease or who transport such persons in an enclosed vehicle should consider wearing at least an N95 disposable respirator (see Respiratory Protection).

Long-Term–Care Facilities (LTCFs)

TB poses a health risk to patients, HCWs, visitors, and volunteers in LTCFs (e.g., hospices and skilled nursing facilities) (215,216). Transmission of *M. tuberculosis* has occurred in LTCF (217–220), and pulmonary TB disease has been documented in HIV-infected patients and other immunocompromised persons residing in hospices (218,221,222). New employees and residents to these settings should receive a symptom screen and possibly a test for *M. tuberculosis* infection (see TB Risk Assessment Worksheet).

LTCFs must have adequate administrative and environmental controls, including airborne precautions capabilities and a respiratory-protection program, if they accept patients with suspected or confirmed infectious TB disease. The setting should have 1) a written protocol for the early identification of patients with symptoms or signs of TB disease and 2) procedures for referring these patients to a setting where they can be evaluated and managed. Patients with suspected or confirmed

infectious TB disease should not stay in LTCFs unless adequate administrative and environmental controls and a respiratory-protection program are in place. Persons with TB disease who are determined to be noninfectious can remain in the LTCF and do not need to be in an AII room.

Training and Educating HCWs

HCW training and education regarding infection with *M. tuberculosis* and TB disease is an essential part of administrative controls in a TB surveillance or infection-control program. Training physicians and nurse managers is especially essential because of the leadership role they frequently fulfill in infection control. HCW training and education can increase adherence to TB infection-control measures. Training and education should emphasize the increased risks posed by an undiagnosed person with TB disease in a health-care setting and the specific measures to reduce this risk. HCWs receive various types of training; therefore, combining training for TB infection control with other related trainings might be preferable.

Initial TB Training and Education

The setting should document that all HCWs, including physicians, have received initial TB training relevant to their work setting and additional occupation-specific education. The level and detail of baseline training will vary according to the responsibilities of the HCW and the risk classification of the setting.

Educational materials on TB training are available from various sources at no cost in printed copy, on videotape (223), on compact discs, and the Internet. The local or state health department should have access to additional materials and resources and might be able to help develop a setting-specific TB education program. Suggested components of a baseline TB training program for HCWs have been described previously. CDC's TB website provides information regarding training and education materials (<http://www.cdc.gov/tb>). Additional training and education materials are available on CDC's TB Education and Training Resources website (<http://www.findtbresources.org>) and on other TB-related websites and resources ([Appendix E](#)).

Physicians, trainees, students, and other HCWs who work in a health-care setting but do not receive payment from that setting should receive baseline training in TB infection-control policies and practices, the TB screening program, and procedures for reporting an *M. tuberculosis* infection test conversion or diagnosis of TB disease. Initial TB training should be provided before the HCW starts working.

Follow-Up TB Training and Education

All settings should conduct an annual evaluation of the need for follow-up training and education for HCWs based on the number of untrained and new HCWs, changes in the organization and services of the setting, and availability of new TB infection-control information.

If a potential or known exposure to *M. tuberculosis* occurs in the setting, prevention and control measures should include retraining HCWs in the infection-control procedures established to prevent the recurrence of exposure. If a potential or known exposure results in a newly recognized positive TST or BAMT result, test conversion, or diagnosis of TB disease, education should include information on 1) transmission of *M. tuberculosis*, 2) noninfectiousness of HCWs with LTBI, and 3) potential infectiousness of HCWs with TB disease.

OSHA requires annual respiratory-protection training for HCWs who use respiratory devices (see Respiratory Protection). HCWs in settings with a classification of potential ongoing transmission should receive additional training and education on 1) symptoms and signs of TB disease, 2) *M. tuberculosis* transmission, 3) infection-control policies, 4) importance of TB screening for HCWs, and 5) responsibilities of employers and employees regarding *M. tuberculosis* infection test conversion and diagnosis of TB disease.

TB Infection-Control Surveillance

HCW Screening Programs for TB Support Surveillance and Clinical Care

TB screening programs provide critical information for caring for individual HCWs and information that facilitates detection of *M. tuberculosis* transmission. The screening program consists of four major components: 1) baseline testing for *M. tuberculosis* infection, 2) serial testing for *M. tuberculosis* infection, 3) serial screening for symptoms or signs of TB disease, and 4) TB training and education.

Surveillance data from HCWs can protect both HCWs and patients. Screening can prevent future transmission by identifying lapses in infection control and expediting treatment for persons with LTBI or TB disease. Tests to screen for *M. tuberculosis* infection should be administered, interpreted, and recorded according to procedures in this report (see Supplement, Diagnostic Procedures for LTBI and TB Disease). Protection of privacy and maintenance of confidentiality of HCW test results should be ensured. Methods to screen for infection with *M. tuberculosis* are available (30,31,39).

Baseline Testing for *M. tuberculosis* Infection

Baseline testing for *M. tuberculosis* infection is recommended for all newly hired HCWs, regardless of the risk classification of the setting and can be conducted with the TST or BAMT. Baseline testing is also recommended for persons who will receive serial TB screening (e.g., residents or staff of correctional facilities or LTCFs) (39,224). Certain settings, with the support of the infection-control committee, might choose not to perform baseline or serial TB screening for HCWs who will never be in contact with or have shared air space with patients who have TB disease (e.g., telephone operators who work in a separate building from patients) or who will never be in contact with clinical specimens that might contain *M. tuberculosis*.

Baseline test results 1) provide a basis for comparison in the event of a potential or known exposure to *M. tuberculosis* and 2) facilitate the detection and treatment of LTBI or TB disease in an HCW before employment begins and reduces the risk to patients and other HCWs. If TST is used for baseline testing, two-step testing is recommended for HCWs whose initial TST results are negative (39,224). If the first-step TST result is negative, the second-step TST should be administered 1–3 weeks after the first TST result was read. If either 1) the baseline first-step TST result is positive or 2) the first-step TST result is negative but the second-step TST result is positive, TB disease should be excluded, and if it is excluded, then the HCW should be evaluated for treatment of LTBI. If the first and second-step TST results are both negative, the person is classified as not infected with *M. tuberculosis*.

If the second test result of a two-step TST is not read within 48–72 hours, administer a TST as soon as possible (even if several months have elapsed) and ensure that the result is read within 48–72 hours (39). Certain studies indicate that positive TST reactions might still be measurable from 4–7 days after testing (225,226). However, if a patient fails to return within 72 hours and has a negative test result, the TST should be repeated (42).

A positive result to the second step of a baseline two-step TST is probably caused by boosting as opposed to recent infection with *M. tuberculosis*. These responses might result from remote infections with *M. tuberculosis*, infection with an NTM (also known as MOTT), or previous BCG vaccination. Two-step testing will minimize the possibility that boosting will lead to an unwarranted suspicion of transmission of *M. tuberculosis* with subsequent testing. A second TST is not needed if the HCW has a documented TST result from any time during the previous 12 months (see Baseline Testing for *M. tuberculosis* Infection After TST Within the Previous 12 Months).

A positive TST reaction as a result of BCG wanes after 5 years. Therefore, HCWs with previous BCG vaccination will frequently have a negative TST result (74,227–232). Because HCWs with a history of BCG are frequently from high TB-prevalence countries, positive test results for *M. tuberculosis* infection in HCWs with previous BCG vaccination should be interpreted as representing infection with *M. tuberculosis* (74,227–233). Although BCG reduces the occurrence of severe forms of TB disease in children and overall might reduce the risk for progression from LTBI to TB disease (234,235), BCG is not thought to prevent *M. tuberculosis* infection (236). Test results for *M. tuberculosis* infection for HCWs with a history of BCG should be interpreted by using the same diagnostic cut points used for HCWs without a history of BCG vaccination.

BAMT does not require two-step testing and is more specific than skin testing. BAMT that uses *M. tuberculosis*-specific antigens (e.g., QFT-G) are not expected to result in false-positive results in persons vaccinated with BCG. Baseline test results should be documented, preferably within 10 days of HCWs starting employment.

Baseline Testing for *M. tuberculosis* Infection After TST Within the Previous 12 Months

A second TST is not needed if the HCW has a documented TST result from any time during the previous 12 months. If a newly employed HCW has had a documented negative TST result within the previous 12 months, a single TST can be administered in the new setting ([Box 1](#)). This additional TST represents the second stage of two-step testing. The second test decreases the possibility that boosting on later testing will lead to incorrect suspicion of transmission of *M. tuberculosis* in the setting.

A recent TST (performed in ≤ 12 months) is not a contraindication to a subsequent TST unless the test was associated with severe ulceration or anaphylactic shock, which are substantially rare adverse events (30,237–239). Multiple TSTs are safe and do not increase the risk for a false-positive result or a TST conversion in persons without infection with mycobacteria (39).

Baseline Documentation of a History of TB Disease, a Previously Positive Test Result for *M. tuberculosis* Infection, or Completion of Treatment for LTBI or TB Disease

Additional tests for *M. tuberculosis* infection do not need to be performed for HCWs with a documented history of TB disease, documented previously positive test result for *M. tuberculosis* infection, or documented completion of treatment for LTBI or TB disease. Documentation of a previously positive test result for *M. tuberculosis* infection can be substituted for a baseline test result if the documentation includes a recorded TST result in millimeters (or BAMT result), including the concentration of cytokine measured (e.g., IFN- γ). All other HCWs should undergo baseline testing for *M. tuberculosis* infection to ensure that the test result on record in the setting has been performed and measured using the recommended diagnostic the recommended procedures (see Supplement, Diagnostic Procedures for LTBI and TB Disease).

A recent TST (performed in ≤ 12 months) is not a contraindication to the administration of an additional test unless the TST was associated with severe ulceration or anaphylactic shock, which are substantially rare adverse events (30,237,238). However, the recent test might complicate interpretation of subsequent test results because of the possibility of boosting.

Serial Follow-Up of TB Screening and Testing for *M. tuberculosis* Infection

The need for serial follow-up screening for groups of HCWs with negative test results for *M. tuberculosis* infection is an institutional decision that is based on the setting's risk classification. This decision and changes over time based on updated risk assessments should be official and documented. If a serial follow-up screening program is required, the risk assessment for the setting ([Appendix B](#)) will determine which HCWs should be included in the program and the frequency of screening. Two-step TST testing should not be performed for follow-up testing.

If possible, stagger follow-up screening (rather than testing all HCWs at the same time each year) so that all HCWs who work in the same area or profession are not tested in the same month. Staggered screening of HCWs (e.g., on the anniversary of their employment or on their birthdays) increases opportunities for early recognition of infection-control problems that can lead to conversions in test results for *M. tuberculosis* infection. Processing aggregate analysis of TB screening data on a periodic regular basis is important for detecting problems.

HCWs with a Newly Recognized Positive Test Result for *M. tuberculosis* Infection or Symptoms or Signs of TB Disease

Clinical Evaluation

Any HCW with a newly recognized positive test result for *M. tuberculosis* infection, test conversion, or symptoms or signs of TB disease should be promptly evaluated. The evaluation should be arranged with employee health, the local or state health department, or a personal physician. Any physicians who evaluate HCWs with suspected TB disease should be familiar with current diagnostic and therapeutic guidelines for LTBI and TB disease (31,39).

The definitions for positive test results for *M. tuberculosis* infection and test conversion in HCWs are included in this report (see Supplement, Diagnostic Procedures for LTBI and TB Disease). Symptoms of disease in the lung, pleura, or airways, and the larynx include coughing for ≥ 3 weeks, loss of appetite, unexplained weight loss, night sweats, bloody sputum or hemoptysis, hoarseness, fever, fatigue, or chest pain. The evaluation should include a clinical examination and symptom screen (a procedure used during a clinical evaluation in which patients are asked if they have experienced any symptoms or signs of TB disease), chest radiograph, and collection of sputum specimens.

If TB disease is diagnosed, begin antituberculosis treatment immediately, according to published guidelines (31). The diagnosing clinician (who might not be a physician with the institution's infection-control program) should notify the local or state health department in accordance with disease reporting laws, which generally specify a 24-hour time limit.

If TB disease is excluded, offer the HCW treatment for LTBI in accordance with published guidelines (see Supplements, Diagnostic Procedures for LTBI and TB Disease; and Treatment Procedures for LTBI and TB Disease [39,240]). If the HCW has already completed treatment for LTBI and is part of a TB screening program, instead of participating in serial skin testing, the HCW should be monitored for symptoms of TB disease and should receive any available training, which should include information on the symptoms of TB disease and instructing the HCW to report any such symptoms immediately to occupational health. In addition, annual symptom screens should be performed, which can be administered as part of other HCW screening and education efforts. Treatment for LTBI should be offered to HCWs who are eligible (39).

HCWs with a previously negative test result who have an increase of ≥ 10 mm induration when examined on follow-up testing probably have acquired *M. tuberculosis* infection and should be evaluated for TB disease. When disease is excluded, HCWs should be treated for LTBI unless medically contraindicated (39,240).

Chest Radiography

HCWs with a baseline positive or newly positive TST or BAMT result should receive one chest radiograph to exclude a diagnosis of TB disease (or an interpretable copy within a reasonable time frame, such as 6 months). After this baseline chest radiograph is performed and the result is documented, repeat radiographs are not needed unless symptoms or signs of TB disease develop or a clinician recommends a repeat chest radiograph (39,116). Instead of participating in serial testing for *M. tuberculosis* infection, HCWs with a positive test result for *M. tuberculosis* infection should receive a symptom screen. The frequency of this symptom screen should be determined by the risk classification for the setting.

Serial follow-up chest radiographs are not recommended for HCWs with documentation of a previously positive test result for *M. tuberculosis* infection, treatment for LTBI or TB disease, or for asymptomatic HCWs with negative test results for *M. tuberculosis* infection. HCWs who have a previously positive test result for *M. tuberculosis* infection and who change jobs should carry documentation of a baseline chest radiograph result (and the positive test result for *M. tuberculosis* infection) to their new employers.

Workplace Restrictions

HCWs with a baseline positive or newly positive test result for *M. tuberculosis* infection should receive one chest radiograph result to exclude TB disease (or an interpretable copy within a reasonable time frame, such as 6 months).

HCWs with confirmed infectious pulmonary, laryngeal, endobroncheal, or tracheal TB disease, or a draining TB skin lesion pose a risk to patients, HCWs, and others. Such HCWs should be excluded from the workplace and should be allowed to return to work when the following criteria have been met: 1) three consecutive sputum samples (109–112) collected in 8–24-hour intervals that are negative, with at least one sample from an early morning specimen (because respiratory secretions pool overnight); 2) the person has responded to antituberculosis treatment that will probably be effective (can be based on susceptibility results); and 3) the person is determined to be noninfectious by a physician knowledgeable and experienced in managing TB disease (see Supplements, Estimating the Infectiousness of a TB Patient; Diagnostic Procedures for LTBI and TB Disease; and Treatment Procedures for LTBI and TB Disease).

HCWs with extrapulmonary TB disease usually do not need to be excluded from the workplace as long as no involvement of the respiratory track has occurred. They can be confirmed as noninfectious and can continue to work if documented evidence is available that indicates that concurrent pulmonary TB disease has been excluded.

HCWs receiving treatment for LTBI can return to work immediately. HCWs with LTBI who cannot take or do not accept or complete a full course of treatment for LTBI should not be excluded from the workplace. They should be counseled regarding the risk for developing TB disease and instructed to report any TB symptoms immediately to the occupational health unit.

HCWs who have a documented positive TST or BAMT result and who leave employment should be counseled again, if possible, regarding the risk for developing TB disease and instructed to seek prompt evaluation with the local health department or their primary care physician if symptoms of TB disease develop. Consider mailing letters to former HCWs who have LTBI. This information should be recorded in the HCWs' employee health record when they leave employment.

Asymptomatic HCWs with a baseline positive or newly positive TST or BAMT result do not need to be excluded from the workplace. Treatment for LTBI should be considered in accordance with CDC guidelines (39).

Identification of Source Cases and Recording of Drug-Susceptibility Patterns

If an HCW experiences a conversion in a test result for *M. tuberculosis* infection, evaluate the HCW for a history of suspected or known exposure to *M. tuberculosis* to determine the potential source. When the source case is identified, also identify the drug susceptibility pattern of the *M. tuberculosis* isolate from the source. The drug-susceptibility pattern should be recorded in the HCW's medical or employee health record to guide the treatment of LTBI or TB disease, if indicated.

HCWs with Medical Conditions Associated with Increased Risk for Progression to TB Disease

In settings in which HCWs are severely immunocompromised, additional precautions must be taken. HIV infection is the highest risk factor for progression from LTBI to TB disease (22,39,42,49). Other immunocompromising conditions, including diabetes mellitus, certain cancers, and certain drug treatments, also increase the risk for rapid progression from LTBI to TB disease. TB disease can also adversely affect the clinical course of HIV infection and acquired immunodeficiency syndrome (AIDS) and can complicate HIV treatment (31,39,53).

Serial TB screening beyond that indicated by the risk classification for the setting is not indicated for persons with the majority of medical conditions that suppress the immune system or otherwise increase the risk for infection with *M. tuberculosis* progressing to TB disease (58). However, consideration should be given to repeating the TST for HIV-infected persons whose initial TST result was negative and whose immune function has improved in response to highly active antiretroviral therapy (HAART) (i.e., those whose CD4-T lymphocyte count has increased to >200 cells/mL).

All HCWs should, however, be encouraged during their initial TB training to determine if they have such a medical condition and should be aware that receiving medical treatment can improve cell-mediated immunity. HCWs should be informed concerning the availability of counseling, testing, and

referral for HIV (50,51). In addition, HCWs should know whether they are immunocompromised, and they should be aware of the risks from exposure to *M. tuberculosis* (1). In certain cases, reassignment to areas in which exposure is minimized or nonexistent might be medically advisable or desirable.

Immunocompromised HCWs should have the option of an assignment in an area or activity where the risk for exposure to *M. tuberculosis* is low. This choice is a personal decision for the immunocompromised HCW (241) (<http://www.eeoc.gov/laws/ada.html> ). Health-care settings should provide education and follow infection-control recommendations (70).

Information provided by HCWs regarding their immune status and request for voluntary work assignments should be treated confidentially, according to written procedures on the confidential handling of such information. All HCWs should be made aware of these procedures at the time of employment and during initial TB training and education.

Problem Evaluation

Contact investigations might be initiated in response to 1) conversions in test results in HCWs for *M. tuberculosis* infection, 2) diagnosis of TB disease in an HCW, 3) suspected person-to-person transmission of *M. tuberculosis*, 4) lapses in TB infection-control practices that expose HCWs and patients to *M. tuberculosis*, or 5) possible TB outbreaks identified using automated laboratory systems (242). In these situations, the objectives of a contact investigation might be to 1) determine the likelihood that transmission of *M. tuberculosis* has occurred; 2) determine the extent of *M. tuberculosis* transmission; 3) identify persons who were exposed, and, if possible, the sources of potential transmission; 4) identify factors that could have contributed to transmission, including failure of environmental infection-control measures, failure to follow infection-control procedures, or inadequacy of current measures or procedures; 5) implement recommended interventions; 6) evaluate the effectiveness of the interventions; and 7) ensure that exposure to *M. tuberculosis* has been terminated and that the conditions leading to exposure have been eliminated.

Earlier recognition of a setting in which *M. tuberculosis* transmission has occurred could be facilitated through innovative approaches to TB contact investigations (e.g., network analysis and genetic typing of isolates). Network analysis makes use of information (e.g., shared locations within a setting that might not be collected in traditional TB contact investigations) (45). This type of information might be useful during contact investigations involving hospitals or correctional settings to identify any shared wards, hospital rooms, or cells. Genotyping of isolates is universally available in the United States and is a useful adjunct in the investigation of *M. tuberculosis* transmission (44,89,243,244). Because the situations prompting an investigation are likely to vary, investigations should be tailored to the individual circumstances. Recommendations provide general guidance for conducting contact investigations (34,115).

General Recommendations for Investigating Conversions in Test Results for *M. tuberculosis* Infection in HCWs

A test conversion might need to be reported to the health department, depending on state and local regulations. Problem evaluation during contact investigations should be accomplished through cooperation between infection-control personnel, occupational health, and the local or state TB-control program. If a test conversion in an HCW is detected as a result of serial screening and the source is not apparent, conduct a source case investigation to determine the probable source and the likelihood that transmission occurred in the health-care setting (115).

Lapses in TB infection control that might have contributed to the transmission of *M. tuberculosis* should be corrected. Test conversions and TB disease among HCWs should be recorded and reported, according to OSHA requirements (<http://www.osha.gov/recordkeeping> ). Consult Recording and Reporting Occupational Injuries and Illness (OSHA standard 29 Code of Federal Regulations [CFR], 1904) to determine recording and reporting requirements (245).

Investigating Conversions in Test Results for *M. tuberculosis* Infection in HCWs: Probable Source Outside the Health-Care Setting

If a test conversion in an HCW is detected and exposure outside the health-care setting has been documented by the corresponding local or state health department, terminate the investigation within the health-care setting.

Investigating Conversions in Test Results for *M. tuberculosis* Infection in HCWs: Known Source in the Health-Care Setting

An investigation of a test conversion should be performed in collaboration with the local or state health department. If a conversion in an HCW is detected and the HCW's history does not document exposure outside the health-care setting but does identify a probable source in the setting, the following steps should be taken: 1) identify and evaluate close contacts of the suspected source case, including other patients and visitors; 2) determine possible reasons for the exposure; 3) implement interventions to correct the lapse(s) in infection control; and 4) immediately screen HCWs and patients if they were close contacts to the source case. For exposed HCWs and patients in a setting that has chosen to screen for infection with *M. tuberculosis* by using the TST, the following steps should be taken:

- administer a symptom screen;
- administer a TST to those who had previously negative TST results; baseline two-step TST should not be performed in contact investigations;
- repeat the TST and symptom screen 8–10 weeks after the end of exposure, if the initial TST result is negative (33);
- administer a symptom screen, if the baseline TST result is positive;
- promptly evaluate (including a chest radiograph) the exposed person for TB disease, if the symptom screen or the initial or 8–10-week follow-up TST result is positive; and
- conduct additional medical and diagnostic evaluation (which includes a judgment about the extent of exposure) for LTBI, if TB disease is excluded.

If no additional conversions in the test results for *M. tuberculosis* infection are detected in the follow-up testing, terminate the investigation. If additional conversions in the tests for *M. tuberculosis* infection are detected in the follow-up testing, transmission might still be occurring, and additional actions are needed: 1) implement a classification of potential ongoing transmission for the specific setting or group of HCWs; 2) the initial cluster of test conversions should be reported promptly to the local or state health department; 3) possible reasons for exposure and transmission should be reassessed and 4) the degree of adherence to the interventions implemented should be evaluated.

Testing for *M. tuberculosis* infection should be repeated 8–10 weeks after the end of exposure for HCW contacts who previously had negative test results, and the circle of contacts should be expanded to include other persons who might have been exposed. If no additional TST conversions are detected on the second round of follow-up testing, terminate the investigation. If additional TST conversions are detected on the second round of follow-up testing, maintain a classification of potential ongoing transmission and consult the local or state health department or other persons with expertise in TB infection control for assistance.

The classification of potential ongoing transmission should be used as a temporary classification only. This classification warrants immediate investigation and corrective steps. After determination has been made that ongoing transmission has ceased, the setting should be reclassified as medium risk. Maintaining the classification of medium risk for at least 1 year is recommended.

Investigating a Conversion of a Test Result for *M. tuberculosis* Infection in an HCW with an Unknown Exposure

If a test conversion in an HCW is detected and the HCW's history does not document exposure outside the health-care setting and does not identify a probable source of exposure in the setting, additional investigation to identify a probable source in the health-care setting is warranted.

If no source case is identified, estimate the interval during which the HCW might have been infected. The interval is usually 8–10 weeks before the most recent negative test result through 2 weeks before the first positive test result. Laboratory and infection-control records should be reviewed to identify

all patients (and any HCWs) who have had suspected or confirmed infectious TB disease and who might have transmitted *M. tuberculosis* to the HCW. If the investigation identifies a probable source, identify and evaluate contacts of the suspected source. Close contacts should be the highest priority for screening.

The following steps should be taken in a setting that uses TST or BAMT to screen for *M. tuberculosis*: 1) administer a symptom screen and the test routinely used in the setting (i.e., TST or BAMT) to persons who previously had negative results; 2) if the initial result is negative, the test and symptom screen should be repeated 8–10 weeks after the end of exposure; 3) if the symptom screen, the first test result, or the 8–10-week follow-up test result is positive, the presumed exposed person should be promptly evaluated for TB disease, including the use of a chest radiograph; and 4) if TB disease is excluded, additional medical and diagnostic evaluation for LTBI is needed, which includes a judgment regarding the extent of exposure (see Investigating Conversions in Test Results for *M. tuberculosis* Infection in HCWs: Known Source in the Health-Care Setting).

Investigations That Do Not Identify a Probable Source

If serial TB screening is performed in the setting, review the results of screening of other HCWs in the same area of the health-care setting or same occupational group. If serial TB screening is not performed in the setting or if insufficient numbers of recent results are available, conduct additional TB screening of other HCWs in the same area or occupational group. If the review and screening yield no additional test conversions, and no evidence to indicate health-care–associated transmission exists, then the investigation should be terminated.

Whether HCW test conversions resulted from exposure in the setting or elsewhere or whether true infection with *M. tuberculosis* has even occurred is uncertain. However, the absence of other data implicating health-care–associated transmission suggests that the conversion could have resulted from 1) unrecognized exposure to *M. tuberculosis* outside the health-care setting; 2) cross reactivity with another antigen (e.g., BCG or nontuberculous mycobacteria); or 3) errors in applying, reading, or interpreting the test result for *M. tuberculosis* infection. If the review and screening identify additional test conversions, health-care–associated transmission is more probable.

Evaluation of the patient identification process, TB infection-control policies and practices, and environmental controls to identify lapses that could have led to exposure and transmission should be conducted. If no problems are identified, a classification of potential ongoing transmission should be applied, and the local or state health department or other persons with expertise in TB infection control should be consulted for assistance. If problems are identified, implement recommended interventions and repeat testing for *M. tuberculosis* infection 8–10 weeks after the end of exposure for HCWs with negative test results. If no additional test conversions are detected in the follow-up testing, terminate the investigation.

Conversions in Test Results for *M. tuberculosis* Infection Detected in Follow-Up Testing

In follow-up testing, a classification of potential ongoing transmission should be maintained. Possible reasons for exposure and transmission should be reassessed, and the appropriateness of and degree of adherence to the interventions implemented should be evaluated. For HCWs with negative test results, repeat testing for *M. tuberculosis* infection 8–10 weeks after the end of exposure. The local or state health department or other persons with expertise in TB infection control should be consulted.

If no additional conversions are detected during the second round of follow-up testing, terminate the investigation. If additional conversions are detected, continue a classification of potential ongoing transmission and consult the local or state health department or other persons with expertise in TB infection control.

The classification of potential ongoing transmission should be used as a temporary classification only. This classification warrants immediate investigation and corrective steps. After a determination that

ongoing transmission has ceased, the setting should be reclassified as medium risk. Maintaining the classification of medium risk for at least 1 year is recommended.

Investigating a Case of TB Disease in an HCW

Occupational health services and other physicians in the setting should have procedures for immediately notifying the local administrators or infection-control personnel if an HCW is diagnosed with TB disease so that a problem evaluation can be initiated. If an HCW is diagnosed with TB disease and does not have a previously documented positive test result for *M. tuberculosis* infection, conduct an investigation to identify the probable sources and circumstances for transmission (see General Recommendations for Investigating Conversions in Test Results for *M. tuberculosis* Infection in HCWs). If an HCW is diagnosed with TB disease, regardless of previous test result status, an additional investigation must be conducted to ascertain whether the disease was transmitted from this HCW to others, including other HCWs, patients, and visitors.

The potential infectiousness of the HCW, if potentially infectious, and the probable period of infectiousness (see Contact Investigations) should be determined. For HCWs with suspected or confirmed infectious TB disease, conduct an investigation that includes 1) identification of contacts (e.g., other HCWs, patients, and visitors), 2) evaluation of contacts for LTBI and TB disease, and 3) notification of the local or state health department for consultation and investigation of community contacts who were exposed outside the health-care setting.

M. tuberculosis genotyping should be performed so that the results are promptly available. Genotyping results are useful adjuncts to epidemiologically based public health investigations of contacts and possible source cases (especially in determining the role of laboratory contamination) (89,166,243,246–261). When confidentiality laws prevent the local or state health department from communicating information regarding a patient's identity, health department staff should work with hospital staff and legal counsel, and the HCW to determine how the hospital can be notified without breaching confidentiality.

Investigating Possible Patient-to-Patient Transmission of *M. tuberculosis*

Information concerning TB cases among patients in the setting should be routinely recorded for risk classification and risk assessment purposes. Documented information by location and date should include results of sputum smear and culture, chest radiograph, drug-susceptibility testing, and adequacy of infection-control measures.

Each time a patient with suspected or confirmed TB disease is encountered in a health-care setting, an assessment of the situation should be made and the focus should be on 1) a determination of infectiousness of the patient, 2) confirmation of compliance with local public health reporting requirements (including the prompt reporting of a person with suspected TB disease as required), and 3) assessment of the adequacy of infection control.

A contact investigation should be initiated in situations where infection control is inadequate and the patient is infectious. Patients with positive AFB sputum smear results are more infectious than patients with negative AFB sputum smear results, but the possibility exists that patients with negative sputum smear results might be infectious (262). Patients with negative AFB sputum smear results but who undergo aerosol-generating or aerosol-producing procedures (including bronchoscopy) without adequate infection-control measures create a potential for exposure. All investigations should be conducted in consultation with the local public health department.

If serial surveillance of these cases reveals one of the following conditions, patient-to-patient transmission might have occurred, and a contact investigation should be initiated:

- A high proportion of patients with TB disease were admitted to or examined in the setting during the year preceding onset of their TB disease, especially when TB disease is identified in patients who were otherwise unlikely to be exposed to *M. tuberculosis*.
- An increase occurred in the number of TB patients diagnosed with drug-resistant TB, compared with the previous year.

- Isolates from multiple patients had identical and characteristic drug susceptibility or DNA fingerprint patterns.

Surveillance of TB Cases in Patients Indicates Possible Patient-to-Patient Transmission of *M. tuberculosis*

Health-care settings should collaborate with the local or state health department to conduct an investigation. For settings in which HCWs are serially tested for *M. tuberculosis* infection, review HCW records to determine whether an increase in the number of conversions in test results for *M. tuberculosis* infection has occurred. Patient surveillance data and medical records should be reviewed for additional cases of TB disease. Settings should look for possible exposures from previous or current admissions that might have exposed patients with newly diagnosed TB disease to other patients with TB disease, determining if the patients were admitted to the same room or area, or if they received the same procedure or went to the same treatment area on the same day.

If the investigation suggests that transmission has occurred, possible causes of transmission of *M. tuberculosis* (e.g., delayed diagnosis of TB disease, institutional barriers to implementing timely and correct airborne precautions, and inadequate environmental controls) should be evaluated. Possible exposure to other patients or HCWs should be determined, and if exposure has occurred, these persons should be evaluated for LTBI and TB disease (i.e., test for *M. tuberculosis* infection and administer a symptom screen).

If the local or state health department was not previously contacted, settings should notify the health department so that a community contact investigation can be initiated, if necessary. The possibility of laboratory errors in diagnosis or the contamination of bronchoscopes (82,169) or other equipment should be considered (136).

Contact Investigations

The primary goal of contact investigations is to identify secondary cases of TB disease and LTBI among contacts so that therapy can be initiated as needed (263–265). Contact investigations should be collaboratively conducted by both infection-control personnel and local TB-control program personnel.

Initiating a Contact Investigation

A contact investigation should be initiated when 1) a person with TB disease has been examined at a health-care setting, and TB disease was not diagnosed and reported quickly, resulting in failure to apply recommended TB infection controls; 2) environmental controls or other infection-control measures have malfunctioned while a person with TB disease was in the setting; or 3) an HCW develops TB disease and exposes other persons in the setting.

As soon as TB disease is diagnosed or a problem is recognized, standard public health practice should be implemented to prioritize the identification of other patients, HCWs, and visitors who might have been exposed to the index case before TB infection-control measures were correctly applied (52). Visitors of these patients might also be contacts or the source case.

The following activities should be implemented in collaboration with or by the local or state health department (34,266): 1) interview the index case and all persons who might have been exposed; 2) review the medical records of the index case; 3) determine the exposure sites (i.e., where the index case lived, worked, visited, or was hospitalized before being placed under airborne precautions); and 4) determine the infectious period of the index case, which is the period during which a person with TB disease is considered contagious and most capable of transmitting *M. tuberculosis* to others.

For programmatic purposes, for patients with positive AFB sputum smear results, the infectious period can be considered to begin 3 months before the collection date of the first positive AFB sputum smear result or the symptom onset date (whichever is earlier). The end of the infectious period is the date the patient is placed under airborne precautions or the date of collection of the first of consistently negative AFB sputum smear results (whichever is earlier). For patients with negative

AFB sputum smear results, the infectious period can begin 1 month before the symptom onset date and end when the patient is placed under airborne precautions.

The exposure period, the time during which a person shared the same air space with a person with TB disease for each contact, should be determined as well as whether transmission occurred from the index patient to persons with whom the index patient had intense contact. In addition, the following should be determined: 1) intensity of the exposure based on proximity, 2) overlap with the infectious period of the index case, 3) duration of exposure, 4) presence or absence of infection-control measures, 5) infectiousness of the index case, 6) performance of procedures that could increase the risk for transmission during contact (e.g., sputum induction, bronchoscopy, and airway suction), and 7) the exposed cohort of contacts for TB screening.

The most intensely exposed HCWs and patients should be screened as soon as possible after exposure to *M. tuberculosis* has occurred and 8–10 weeks after the end of exposure if the initial TST result is negative. Close contacts should be the highest priority for screening.

For HCWs and patients who are presumed to have been exposed in a setting that screens for infection with *M. tuberculosis* using the TST, the following activities should be implemented:

- performing a symptom screen;
- administering a TST to those who previously had negative TST results;
- repeating the TST and symptom screen 8–10 weeks after the end of exposure, if the initial TST result is negative;
- promptly evaluating the HCW for TB disease, including performing a chest radiograph, if the symptom screen or the initial or 8–10-week follow-up TST result is positive; and
- providing additional medical and diagnostic evaluation for LTBI, including determining the extent of exposure, if TB disease is excluded.

For HCWs and patients who are presumed to have been exposed in a setting that screens for infection with *M. tuberculosis* using the BAMT, the following activities should be implemented (see Supplement, Surveillance and Detection of *M. tuberculosis* Infections in Health-Care Settings). If the most intensely exposed persons have test conversions or positive test results for *M. tuberculosis* infection in the absence of a previous history of a positive test result or TB disease, expand the investigation to evaluate persons with whom the index patient had less contact. If the evaluation of the most intensely exposed contacts yields no evidence of transmission, expanding testing to others is not necessary.

Exposed persons with documented previously positive test results for *M. tuberculosis* infection do not require either repeat testing for *M. tuberculosis* infection or a chest radiograph (unless they are immunocompromised or otherwise at high risk for TB disease), but they should receive a symptom screen. If the person has symptoms of TB disease, 1) record the symptoms in the HCW's medical chart or employee health record, 2) perform a chest radiograph, 3) perform a full medical evaluation, and 4) obtain sputum samples for smear and culture, if indicated.

The setting should determine the reason(s) that a TB diagnosis or initiation of airborne precautions was delayed or procedures failed, which led to transmission of *M. tuberculosis* in the setting. Reasons and corrective actions taken should be recorded, including changes in policies, procedures, and TB training and education practices.

Collaboration with the Local or State Health Department

For assistance with the planning and implementation of TB-control activities in the health-care setting and for names of experts to help with policies, procedures, and program evaluation, settings should coordinate with the local or state TB-control program. By law, the local or state health department must be notified when TB disease is suspected or confirmed in a patient or HCW so that follow up can be arranged and a community contact investigation can be conducted. The local or state health department should be notified as early as possible before the patient is discharged to facilitate followup and continuation of therapy by DOT (31). For inpatient settings, coordinate a discharge plan

with the patient (including a patient who is an HCW with TB disease) and the TB-control program of the local or state health department.

Environmental Controls

Environmental controls are the second line of defense in the TB infection-control program, after administrative controls. Environmental controls include technologies for the removal or inactivation of airborne *M. tuberculosis*. These technologies include local exhaust ventilation, general ventilation, HEPA filtration, and UVGI. These controls help to prevent the spread and reduce the concentration of infectious droplet nuclei in the air. A summary of environmental controls and their use in prevention of transmission of *M. tuberculosis* is provided in this report (see Supplement, Environmental Controls), including detailed information concerning the application of environmental controls.

Local Exhaust Ventilation

Local exhaust ventilation is a source-control technique used for capturing airborne contaminants (e.g., infectious droplet nuclei or other infectious particles) before they are dispersed into the general environment. In local exhaust ventilation methods, external hoods, enclosing booths, and tents are used. Local exhaust ventilation (e.g., enclosed, ventilated booth) should be used for cough-inducing and aerosol-generating procedures. When local exhaust is not feasible, perform cough-inducing and aerosol-generating procedures in a room that meets the requirements for an AII room.

General Ventilation

General ventilation systems dilute and remove contaminated air and control airflow patterns in a room or setting. An engineer or other professional with expertise in ventilation should be included as part of the staff of the health-care setting or hire a consultant with expertise in ventilation engineering specific to health-care settings. Ventilation systems should be designed to meet all applicable federal, state, and local requirements.

A single-pass ventilation system is the preferred choice in areas in which infectious airborne droplet nuclei might be present (e.g., AII rooms). Use HEPA filtration if recirculation of air is necessary.

AII rooms in health-care settings pre-existing 1994 guidelines should have an airflow of ≥ 6 ACH. When feasible, the airflow should be increased to ≥ 12 ACH by 1) adjusting or modifying the ventilation system or 2) using air-cleaning methods (e.g., room-air recirculation units containing HEPA filters or UVGI systems that increase the equivalent ACH). New construction or renovation of health-care settings should be designed so that AII rooms achieve an airflow of ≥ 12 ACH. Ventilation rates for other areas in health-care settings should meet certain specifications (see Risk Classification Examples). If a variable air volume (VAV) ventilation system is used in an AII room, design the system to maintain the room under negative pressure at all times. The VAV system minimum set point must be adequate to maintain the recommended mechanical and outdoor ACH and a negative pressure ≥ 0.01 inch of water gauge compared with adjacent areas.

Based on the risk assessment for the setting, the required number of AII rooms, other negative-pressure rooms, and local exhaust devices should be determined. The location of these rooms and devices will depend partially on where recommended ventilation conditions can be achieved. Grouping AII rooms in one area might facilitate the care of patients with TB disease and the installation and maintenance of optimal environmental controls.

AII rooms should be checked for negative pressure by using smoke tubes or other visual checks before occupancy, and these rooms should be checked daily when occupied by a patient with suspected or confirmed TB disease. Design, construct, and maintain general ventilation systems so that air flows from clean to less clean (more contaminated) areas. In addition, design general ventilation systems to provide optimal airflow patterns within rooms and to prevent air stagnation or short-circuiting of air from the supply area to the exhaust area.

Health-care settings serving populations with a high prevalence of TB disease might need to improve the existing general ventilation system or use air-cleaning technologies in general-use areas (e.g., waiting rooms, EMS areas, and radiology suites). Applicable approaches include 1) single-pass,

nonrecirculating systems that exhaust air to the outside, 2) recirculation systems that pass air through HEPA filters before recirculating it to the general ventilation system, and 3) room-air recirculation units with HEPA filters and/or UVGI systems.

Air-Cleaning Methods

High-Efficiency Particulate Air (HEPA) Filters

HEPA filters can be used to filter infectious droplet nuclei from the air and must be used 1) when discharging air from local exhaust ventilation booths or enclosures directly into the surrounding room or area and 2) when discharging air from an AII room (or other negative-pressure room) into the general ventilation system (e.g., in settings in which the ventilation system or building configuration makes venting the exhaust to the outside impossible).

HEPA filters can be used to remove infectious droplet nuclei from air that is recirculated in a setting or exhausted directly to the outside. HEPA filters can also be used as a safety measure in exhaust ducts to remove droplet nuclei from air being discharged to the outside. Air can be recirculated through HEPA filters in areas in which 1) no general ventilation system is present, 2) an existing system is incapable of providing sufficient ACH, or 3) air-cleaning (particulate removal) without affecting the fresh-air supply or negative-pressure system is desired. Such uses can increase the number of equivalent ACH in the room or area.

Recirculation of HEPA filtered air can be achieved by exhausting air from the room into a duct, passing it through a HEPA filter installed in the duct, and returning it to the room or the general ventilation system. In addition, recirculation can be achieved by filtering air through HEPA recirculation systems installed on the wall or ceiling of the room or filtering air through portable room-air recirculation units.

To ensure adequate functioning, install HEPA filters carefully and maintain the filters according to the instructions of the manufacturer. Maintain written records of all prefilter and HEPA maintenance and monitoring (114). Manufacturers of room-air recirculation units should provide installation instructions and documentation of the filtration efficiency and of the overall efficiency of the unit (clean air delivery rate) in removing airborne particles from a space of a given size.

UVGI

UVGI is an air-cleaning technology that can be used in a room or corridor to irradiate the air in the upper portion of the room (upper-air irradiation) and is installed in a duct to irradiate air passing through the duct (duct irradiation) or incorporated into room air-recirculation units. UVGI can be used in ducts that recirculate air back into the same room or in ducts that exhaust air directly to the outside. However, UVGI should not be used in place of HEPA filters when discharging air from isolation booths or enclosures directly into the surrounding room or area or when discharging air from an AII room into the general ventilation system. Effective use of UVGI ensures that *M. tuberculosis*, as contained in an infectious droplet nucleus is exposed to a sufficient dose of ultraviolet-C (UV-C) radiation at 253.7 nanometers (nm) to result in inactivation. Because dose is a function of irradiance and time, the effectiveness of any application is determined by its ability to deliver sufficient irradiance for enough time to result in inactivation of the organism within the infectious droplet. Achieving a sufficient dose can be difficult for airborne inactivation because the exposure time can be substantially limited; therefore, attaining sufficient irradiance is essential.

For each system, follow design guidelines to maximize UVGI effectiveness in equivalent ACH. Because air velocity, air mixing, relative humidity, UVGI intensity, and lamp position all affect the efficacy of UVGI systems, consult a UVGI system designer before purchasing and installing a UVGI system. Experts who might be consulted include industrial hygienists, engineers, and health physicists.

To function properly and minimize potential hazards to HCWs and other room occupants, upper-air UVGI systems should be properly installed, maintained, and labeled. A person knowledgeable in the use of ultraviolet (UV) radiometers or actinometers should monitor UV irradiance levels to ensure

that exposures in the work area are within safe exposure levels. UV irradiance levels in the upper-air, where the air disinfection is occurring, should also be monitored to determine that irradiance levels are within the desired effectiveness range.

UVGI tubes should be changed and cleaned according to the instructions of the manufacturer or when irradiance measurements indicate that output is reduced below effective levels. In settings that use UVGI systems, education of HCWs should include 1) basic principles of UVGI systems (mechanism and limitations), 2) potential hazardous effects of UVGI if overexposure occurs, 3) potential for photosensitivity associated with certain medical conditions or use of certain medications, and 4) the importance of maintenance procedures and record-keeping. In settings that use UVGI systems, patients and visitors should be informed of the purpose of UVGI systems and be warned about the potential hazards and safety precautions.

Program Issues

Personnel from engineering, maintenance, safety and infection control, and environmental health should collaborate to ensure the optimal selection, installation, operation, and maintenance of environmental controls. A written maintenance plan should be developed that outlines the responsibility and authority for maintenance of the environmental controls and addresses HCW training needs. Standard operating procedures should include the notification of infection-control personnel before performing maintenance on ventilation systems servicing TB patient-care areas.

Personnel should schedule routine preventive maintenance for all components of the ventilation systems (e.g., fans, filters, ducts, supply diffusers, and exhaust grills) and air-cleaning devices. Quality control (QC) checks should be conducted to verify that environmental controls are operating as designed and that records are current. Provisions for emergency electrical power should be made so that the performance of essential environmental controls is not interrupted during a power failure.

Respiratory Protection

The first two levels of the infection-control hierarchy, administrative and environmental controls, minimize the number of areas in which exposure to *M. tuberculosis* might occur. In addition, these administrative and environmental controls also reduce, but do not eliminate, the risk in the few areas in which exposures can still occur (e.g., AII rooms and rooms where cough-inducing or aerosol-generating procedures are performed). Because persons entering these areas might be exposed to airborne *M. tuberculosis*, the third level of the hierarchy is the use of respiratory protective equipment in situations that pose a high risk for exposure (see Supplement, Respiratory Protection).

On October 17, 1997, OSHA published a proposed standard for occupational exposure to *M. tuberculosis* (267). On December 31, 2003, OSHA announced the termination of rulemaking for a TB standard (268). Previous OSHA policy permitted the use of any Part 84 particulate filter respirator for protection against TB disease (269). Respirator use for TB had been regulated by OSHA under CFR Title 29, Part 1910.139 (29CFR1910.139) (270) and compliance policy directive (CPL) 2.106 (Enforcement Procedures and Scheduling for Occupational Exposure to Tuberculosis). Respirator use for TB is regulated under the general industry standard for respiratory protection (29 CFR 1910.134, <http://www.osha.gov/SLTC/respiratoryprotection/index.html> ) (271). General information concerning respiratory protection for aerosols, including *M. tuberculosis*, has been published (272–274).

Indications for Use

Respiratory protection should be used by the following persons:

- all persons, including HCWs and visitors, entering rooms in which patients with suspected or confirmed infectious TB disease are being isolated;
- persons present during cough-inducing or aerosol-generating procedures performed on patients with suspected or confirmed infectious TB disease; and
- persons in other settings in which administrative and environmental controls probably will not protect them from inhaling infectious airborne droplet nuclei. These persons might also include persons who transport patients with suspected or confirmed infectious TB disease in vehicles

(e.g., EMS vehicles or, ideally, ambulances) and persons who provide urgent surgical or dental care to patients with suspected or confirmed infectious TB disease (see Supplement, Estimating the Infectiousness of a TB Patient).

Laboratorians conducting aerosol-producing procedures might require respiratory protection. A decision concerning use of respiratory protection in laboratories should be made on an individual basis, depending on the type of ventilation in use for the laboratory procedure and the likelihood of aerosolization of viable mycobacteria that might result from the laboratory procedure.

Respiratory-Protection Program

OSHA requires health-care settings in which HCWs use respiratory protection to develop, implement, and maintain a respiratory-protection program. All HCWs who use respiratory protection should be included in the program (see Supplement, Respiratory Protection).

Training HCWs

Annual training regarding multiple topics should be conducted for HCWs, including the nature, extent, and hazards of TB disease in the health-care setting. The training can be conducted in conjunction with other related training regarding infectious disease associated with airborne transmission. In addition, training topics should include the 1) risk assessment process and its relation to the respirator program, including signs and symbols used to indicate that respirators are required in certain areas and the reasons for using respirators; 2) environmental controls used to prevent the spread and reduce the concentration of infectious droplet nuclei; 3) selection of a particular respirator for a given hazard (see Selection of Respirators); 4) operation, capabilities, and limitations of respirators; 5) cautions regarding facial hair and respirator use (275,276); and 6) OSHA regulations regarding respirators, including assessment of employees' knowledge.

Trainees should be provided opportunities to handle and wear a respirator until they become proficient (see Fit Testing). Trainees should also be provided with 1) copies or summaries of lecture materials for use as references and 2) instructions to refer all respirator problems immediately to the respiratory program administrator.

Selection of Respirators

Respiratory protective devices used in health-care settings for protection against *M. tuberculosis* should meet the following criteria (277,278):

- certified by CDC/National Institute for Occupational Safety and Health (NIOSH) as a nonpowered particulate filter respirator (N-, R-, and P-series 95%, 99%, and 100% filtration efficiency), including disposable respirators, or PAPRs with high efficiency filters (279);
- ability to adequately fit respirator wearers (e.g., a fit factor of ≥ 100 for disposable and half facepiece respirators) who are included in a respiratory-protection program; and
- ability to fit the different facial sizes and characteristics of HCWs. (This criterion can usually be met by making respirators available in different sizes and models.)

The fit of filtering facepiece respirators varies because of different facial types and respirator characteristics (10,280–289). Assistance with selection of respirators should be obtained through consultation with respirator fit-testing experts, CDC, occupational health and infection-control professional organizations, peer-reviewed research, respirator manufacturers, and advanced respirator training courses.

Fit Testing

A fit test is used to determine which respirator fits the user adequately and to ensure that the user knows when the respirator fits properly. After a risk assessment is conducted to validate the need for respiratory protection, perform fit testing during the initial respiratory-protection program training and periodically thereafter in accordance with federal, state, and local regulations.

Fit testing provides a means to determine which respirator model and size fits the wearer best and to confirm that the wearer can don the respirator properly to achieve a good fit. Periodic fit testing of

respirators on HCWs can serve as an effective training tool in conjunction with the content included in employee training and retraining. The frequency of periodic fit testing should be determined by the occurrence of 1) risk for transmission of *M. tuberculosis*, 2) a change in facial features of the wearer, 3) medical condition that would affect respiratory function, 4) physical characteristics of respirator (despite the same model number), or 5) a change in the model or size of the assigned respirator (281).

Respirator Options: General Recommendations

In situations that require respiratory protection, the minimum respiratory protection device is a filtering facepiece (nonpowered, air-purifying, half-facepiece) respirator (e.g., an N95 disposable respirator). This CDC/NIOSH-certified respirator meets the minimum filtration performance for respiratory protection in areas in which patients with suspected or confirmed TB disease might be encountered. For situations in which the risk for exposure to *M. tuberculosis* is especially high because of cough-inducing and aerosol-generating procedures, more protective respirators might be needed (see Respirator Options: Special Circumstances).

Respirator Options: Special Circumstances

Visitors to AII rooms and other areas with patients who have suspected or confirmed infectious TB disease may be offered respirators and should be instructed by an HCW on the use of the respirator before entering an AII room (Supplement, Frequently Asked Questions [FAQs] User-Seal Check in Respiratory Protection section). Particulate respirators vary substantially by model, and fit testing is usually not easily available to visitors.

The risk assessment for the setting might identify a limited number of circumstances (e.g., bronchoscopy or autopsy on persons with suspected or confirmed TB disease and selected laboratory procedures) for which a level of respiratory protection that exceeds the minimum level provided by an N95 disposable respirator should be considered. In such circumstances, consider providing HCWs with a level of respiratory protection that both exceeds the minimum criteria and is compatible with patient care delivery. Such protection might include more protective respirators (e.g., full-facepiece respirators or PAPRs) (see Supplement, Respiratory Protection). Detailed information regarding these and other respirators has been published (272,273,278,290).

In certain settings, HCWs might be at risk for both inhalation exposure to *M. tuberculosis* and mucous membrane exposure to bloodborne pathogens. In these situations, the HCW might wear a nonfluid-resistant respirator with a full-face shield or the combination product surgical mask/N95 disposable respirator to achieve both respiratory protection and fluid protection.

When surgical procedures (or other procedures requiring a sterile field) are performed on persons with suspected or confirmed infectious TB disease, respiratory protection worn by HCWs must also protect the surgical field. The patient should be protected from the HCW's respiratory secretions and the HCW from infectious droplet nuclei that might be expelled by the patient or generated by the procedure. Respirators with exhalation valves and PAPRs do not protect the sterile field.

Settings in which patients with suspected or confirmed infectious TB disease will not be encountered do not need a respiratory-protection program for exposure to *M. tuberculosis*. However, these settings should have written protocols for the early identification of persons with symptoms or signs of TB disease and procedures for referring these patients to a setting where they can be evaluated and managed. Filtering facepiece respirators should also be available for emergency use by HCWs who might be exposed to persons with suspected or confirmed TB disease before transfer. In addition, respirators and the associated respiratory-protection program might be needed to protect HCWs from other infectious diseases or exposures to harmful vapors and gases. Their availability or projected need for other exposures should be considered in the selection of respirators for protection against TB to minimize replication of effort.

Surgical or procedure masks are designed to prevent respiratory secretions of the wearer from entering the air. To reduce the expulsion of droplet nuclei into the air, persons with suspected or confirmed TB disease should be instructed to observe respiratory hygiene and cough etiquette

procedures (122) and should wear a surgical or procedure mask, if possible, when they are not in AII rooms. These patients do not need to wear particulate respirators.

Patients with suspected or confirmed TB disease should never wear any kind of respiratory protection that has an exhalation valve. This type of respirator does not prevent droplet nuclei from being expelled into the air.

Cough-Inducing and Aerosol-Generating Procedures

General Recommendations

Procedures that involve instrumentation of the lower respiratory tract or induction of sputum can increase the likelihood that droplet nuclei will be expelled into the air. These cough-inducing procedures include endotracheal intubation, suctioning, diagnostic sputum induction, aerosol treatments (e.g., pentamidine therapy and nebulized treatments), bronchoscopy, and laryngoscopy. Gastric aspiration and nasogastric tube placement can also induce cough in certain patients. Other procedures that can generate aerosols include irrigating TB abscesses, homogenizing or lyophilizing tissue, performing autopsies on cadavers with untreated TB disease, and other processing of tissue that might contain tubercle bacilli and TB laboratory procedures.

If possible, postpone cough-inducing or aerosol-generating procedures on patients with suspected or confirmed infectious TB disease unless the procedure can be performed with recommended precautions. When a cough-inducing or aerosol-generating procedure must be performed on a patient with suspected or confirmed infectious TB disease, use a local exhaust ventilation device (e.g., booth or special enclosure). If using this device is not feasible, perform the procedure in a room that meets the ventilation requirements for an AII room.

After completion of cough-inducing procedures, keep patients in the AII room or enclosure until coughing subsides. Patients should be given tissues and instructed to cover the mouth and nose with tissues when coughing. Tissues should be disposed of in accordance with the infection-control plan.

Before the booth, enclosure, or room is used for another patient, allow enough time for the removal of $\geq 99\%$ of airborne contaminants. This interval will vary based on the efficiency of the ventilation or filtration system ([Table 1](#)).

For postoperative recovery, do not place the patient in a recovery room with other patients; place the patient in a room that meets the ventilation requirements for an AII room. If the room does not meet the ventilation requirements for an AII room, air-cleaning technologies (e.g., HEPA filtration and UVGI) can be used to increase the number of equivalent ACH (see Supplement, Environmental Controls).

Perform all manipulations of suspected or confirmed *M. tuberculosis* specimens that might generate aerosols in a BSC. When in rooms or enclosures in which cough-inducing or aerosol-generating procedures are being performed, respiratory protection should be worn.

Special Considerations for Bronchoscopy

Bronchoscopy can result in the transmission of *M. tuberculosis* either through the airborne route (63,81,86,162) or a contaminated bronchoscope (80,82,163–169). Whenever feasible, perform bronchoscopy in a room that meets the ventilation requirements for an AII room (see Supplement, Environmental Controls). Air-cleaning technologies can be used to increase equivalent ACH. If a bronchoscopy must be performed in a positive-pressure room (e.g., OR), exclude TB disease before performing the procedure. Examine three spontaneous or induced sputum specimens for AFB (if possible) to exclude a diagnosis of TB disease before bronchoscopy is considered as a diagnostic procedure (110,291).

In a patient who is intubated and mechanically ventilated, minimize the opening of circuitry. For HCWs present during bronchoscopic procedures on patients with suspected or confirmed TB disease, a respirator with a level of protection of at least an N95 disposable respirator should be worn.

Protection greater than an N95 disposable respirator (e.g., a full-facepiece elastomeric respirator or PAPR) should be considered.

Special Considerations for Administration of Aerosolized Pentamidine and Other Medications

Patients receiving aerosolized pentamidine (or other aerosolized medications) who are immunocompromised and have a confirmed or suspected pulmonary infection (i.e., pneumocystis pneumonia [PCP] or pneumonia caused by *P. jaroveci*, formerly *P. carinii*) are also at risk for TB disease. Patients receiving other aerosolized medications might have an immunocompromising condition that puts them at greater risk for TB disease. Patients should be screened for TB disease before initiating prophylaxis with aerosolized pentamidine; a medical history, test for infection with *M. tuberculosis*, and a chest radiograph should be performed.

Before each subsequent treatment with aerosolized pentamidine, screen patients for symptoms or signs of TB disease. If symptoms or signs are present, evaluate the patient for TB disease. Patients with suspected or confirmed TB disease should be administered oral prophylaxis for *P. jaroveci* instead of aerosolized pentamidine if clinically practical. Patients receiving other aerosolized medication might have immunocompromising conditions; therefore, if warranted, they should be similarly screened and evaluated, and treatment with oral medications should be considered.

Supplements

Estimating the Infectiousness of a TB Patient

General Principles

Transmission of *M. tuberculosis* is most likely to result from exposure to persons who have 1) unsuspected pulmonary TB disease and are not receiving antituberculosis treatment, 2) diagnosed TB disease and are receiving inadequate therapy, or 3) diagnosed TB disease and are early in the course of effective therapy. Administration of effective antituberculosis treatment has been associated with decreased infectiousness among persons who have TB disease (292). Effective treatment reduces coughing, the amount of sputum produced, the number of organisms in the sputum, and the viability of the organisms in the sputum. However, the duration of therapy required to decrease or eliminate infectiousness varies (293). Certain TB patients are never infectious, whereas those with unrecognized or inadequately treated drug-resistant TB disease might remain infectious for weeks or months (2,3,87,94,162,294–297). In one study, 17% of transmission occurred from persons with negative AFB smear results (262). Rapid laboratory methods, including PCR-based techniques, can decrease diagnostic delay and reduce the duration of infectiousness (298).

The infectiousness of patients with TB correlates with the number of organisms they expel into the air (299). The number of organisms expelled are related to the following factors: 1) presence of cough lasting ≥ 3 weeks; 2) cavitation on chest radiograph; 3) positive AFB sputum smear result; 4) respiratory tract disease with involvement of the lung or airways, including larynx; 5) failure to cover the mouth and nose when coughing; 6) lack of, incorrect, or short duration of antituberculosis treatment (300); or 7) undergoing cough-inducing or aerosol-generating procedures (e.g., sputum induction, bronchoscopy, and airway suction). Closed and effectively filtered ventilatory circuitry and minimized opening of such circuitry in intubated and mechanically ventilated patients might minimize exposure (see Intensive Care Units [ICUs]).

Persons with extrapulmonary TB disease usually are not infectious unless they have concomitant pulmonary disease, nonpulmonary disease located in the oral cavity or the larynx, or extrapulmonary disease that includes an open abscess or lesion in which the concentration of organisms is high, especially if drainage from the abscess or lesion is extensive, or if aerosolization of drainage fluid is performed (69,72,77,83,301). Persons with TB pleural effusions might also have concurrent unsuspected pulmonary or laryngeal TB disease. These patients should be considered infectious until pulmonary TB disease is excluded. Patients with suspected TB pleural effusions or extrapulmonary TB disease should be considered pulmonary TB suspects until concomitant pulmonary disease is excluded (302).

Although children with TB disease usually are less likely than adults to be infectious, transmission from young children can occur (135,137). Therefore, children and adolescents with TB disease should be evaluated for infectiousness by using the majority of the same criteria as for adults. These criteria include presence of cough lasting ≥ 3 weeks; cavitation on chest radiograph; or respiratory tract disease with involvement of lungs, airways, or larynx. Infectiousness would be increased if the patient were on nonstandard or short duration of antituberculosis treatment (300) or undergoing cough-inducing or aerosol-generating procedures (e.g., sputum induction, bronchoscopy, and airway suction). Although gastric lavage is useful in the diagnosis of pediatric TB disease, the grade of the positive AFB smear result does not correlate with infectiousness. Pediatric patients who might be infectious include those who are not on antituberculosis treatment, who have just been started on treatment or are on inadequate treatment, and who have extensive pulmonary or laryngeal involvement (i.e., coughing ≥ 3 weeks, cavitary TB disease, positive AFB sputum smear results, or undergoing cough-inducing or aerosol-generating procedures). Children who have typical primary TB lesions on chest radiograph and do not have any of these indicators of infectiousness might not need to be placed in an AII room.

No data exist on the transmission of *M. tuberculosis* and its association with the collection of gastric aspirate specimens. Children who do not have predictors for infectiousness do not need to have gastric aspirates obtained in an AII room or other special enclosure; however, the procedure should not be performed in an area in which persons infected with HIV might be exposed. Because the source case for pediatric TB patients might be a member of the infected child's family, parents and other visitors of all hospitalized pediatric TB patients should be screened for TB disease as soon as possible to ensure that they do not become sources of health-care–associated transmission of *M. tuberculosis* (303–306).

Patients who have suspected or confirmed TB disease and who are not on antituberculosis treatment usually should be considered infectious if characteristics include

- presence of cough;
- cavitation on chest radiograph;
- positive AFB sputum smear result;
- respiratory tract disease with involvement of the lung or airways, including larynx;
- failure to cover the mouth and nose when coughing; and
- undergoing cough-inducing or aerosol-generating procedures (e.g., sputum induction, bronchoscopy, and airway suction).

If a patient with one or more of these characteristics is on standard multidrug therapy with documented clinical improvement usually in connection with smear conversion over multiple weeks, the risk for infectiousness is reduced.

Suspected TB Disease

For patients placed under airborne precautions because of suspected infectious TB disease of the lungs, airway, or larynx, airborne precautions can be discontinued when infectious TB disease is considered unlikely and either 1) another diagnosis is made that explains the clinical syndrome or 2) the patient has three negative AFB sputum smear results (109–112). Each of the three consecutive sputum specimens should be collected in 8–24-hour intervals (124), and at least one specimen should be an early morning specimen because respiratory secretions pool overnight. Generally, this method will allow patients with negative sputum smear results to be released from airborne precautions in 2 days.

Hospitalized patients for whom the suspicion of TB disease remains after the collection of three negative AFB sputum smear results should not be released from airborne precautions until they are on standard multidrug antituberculosis treatment and are clinically improving. If the patient is believed to not have TB disease because of an alternate diagnosis or because clinical information is not consistent with TB disease, airborne precautions may be discontinued. Therefore, a patient suspected of having TB disease of the lung, airway, or larynx who is symptomatic with cough and not

responding clinically to antituberculosis treatment should not be released from an AII room into a non-AII room, and additional sputum specimens should be collected for AFB examination until three negative AFB sputum smear results are obtained (30,31). Additional diagnostic approaches might need to be considered (e.g., sputum induction) and, after sufficient time on treatment, bronchoscopy.

Confirmed TB Disease

A patient who has drug-susceptible TB of the lung, airway, or larynx, who is on standard multidrug antituberculosis treatment, and who has had a substantial clinical and bacteriologic response to therapy (i.e., reduction in cough, resolution of fever, and progressively decreasing quantity of AFB on smear result) is probably no longer infectious. However, because culture and drug-susceptibility results are not usually known when the decision to discontinue airborne precautions is made, all patients with suspected TB disease should remain under airborne precautions while they are hospitalized until they have had three consecutive negative AFB sputum smear results, each collected in 8–24-hour intervals, with at least one being an early morning specimen; have received standard multidrug antituberculosis treatment (minimum of 2 weeks); and have demonstrated clinical improvement.

Discharge to Home of Patients with Suspected or Confirmed TB Disease

If a hospitalized patient who has suspected or confirmed TB disease is deemed medically stable (including patients with positive AFB sputum smear results indicating pulmonary TB disease), the patient can be discharged from the hospital before converting the positive AFB sputum smear results to negative AFB sputum smear results, if the following parameters have been met:

- a specific plan exists for follow-up care with the local TB-control program;
- the patient has been started on a standard multidrug antituberculosis treatment regimen, and DOT has been arranged;
- no infants and children aged <4 years or persons with immunocompromising conditions are present in the household;
- all immunocompetent household members have been previously exposed to the patient; and
- the patient is willing to not travel outside of the home except for health-care–associated visits until the patient has negative sputum smear results.

Patients with suspected or confirmed infectious TB disease should not be released to health-care settings or homes in which the patient can expose others who are at high risk for progressing to TB disease if infected (e.g., persons infected with HIV or infants and children aged <4 years). Coordination with the local health department TB program is indicated in such circumstances.

Drug-Resistant TB Disease

Because the consequences of transmission of MDR TB are severe, certain infection-control practitioners might choose to keep persons with suspected or confirmed MDR TB disease under airborne precautions during the entire hospitalization or until culture conversion is documented, regardless of sputum smear results. The role of drug resistance in transmission is complex. Transmission of drug-resistant organisms to persons with and without HIV infection has been documented (54,307–309). In certain cases, transmission from patients with TB disease caused by drug-resistant organisms might be extensive because of prolonged infectiousness as a result of delays in diagnosis and delays in initiation of effective therapy (53,94,98,101,255,310,311).

HIV-Associated TB Disease

Although multiple TB outbreaks among HIV-infected persons have been reported (51,52,99), the risk for transmission does not appear to be increased from patients with TB disease and HIV infection, compared with TB patients without HIV infection (54,312–315). Whether persons infected with HIV are more likely to be infected with *M. tuberculosis* if exposed is unclear; however, after infected with *M. tuberculosis*, the risk for progression to TB disease in persons infected with HIV is high (316). Progression to TB disease can be rapid, as soon as 1 month after exposure (51,53,54,101).

Diagnostic Procedures for LTBI and TB Disease

LTBI is a condition that develops after exposure to a person with infectious TB disease, and subsequent infection with *M. tuberculosis* occurs where the bacilli are alive but inactive in the body. Persons who have LTBI but who do not have TB disease are asymptomatic (i.e., have no symptoms), do not feel sick, and cannot spread TB to other persons.

Use of QFT-G for Diagnosing *M. tuberculosis* Infections in Health-Care Workers (HCWs)

In the United States, LTBI has been traditionally diagnosed based on a positive TST result after TB disease has been excluded. In vitro cytokine-based immunoassays for the detection of *M. tuberculosis* infection have been the focus of intense research and development. This document uses the term "BAMT" to refer to blood assay for *M. tuberculosis* infection currently available in the United States.

One such BAMT is QFT (which is PPD-based) and the subsequently developed version, QFT-G. QFT-G measures cell-mediated immune responses to peptides representative of two *M. tuberculosis* proteins that are not present in any BCG vaccine strain and are absent from the majority of nontuberculosis mycobacteria. This assay was approved by FDA in 2005 and is an available option for detecting *M. tuberculosis* infection. CDC recommendations for the United States on QFT and QFT-G have been published (35).

QFT-G is an in vitro test based on measuring interferon-gamma (IFN- γ) released in heparinized whole blood when incubated overnight with mitogen (serving as a positive control), Nil (i.e., all reagents except antigens, which sets a baseline), and peptide simulating ESAT-6 (6-kDa early secretory antigenic target) and CFP-10 (10-kDa culture filtrate protein) (measured independently), two different proteins with similar amino acid sequences specific for *M. tuberculosis* (Box 2). The sequences of ESAT-6 and CFP-10 are not related to each other. The genes encoding these two proteins are usually found next to each other in an operon (i.e., are coexpressed and translated from an mRNA product containing both genes). Although mycobacterial genomes contain multiple copies of each family, QFT-G and Elispot detect immunoreactivity associated only with the ESAT-6 protein and CFP-10 protein encoded by the genes in the region of deletion (RD1). In addition, virulence attributes are associated with the RD1 genes only and not the other homologues.

Specific antigens of these two proteins are found in *M. tuberculosis*–complex organisms (i.e., *M. tuberculosis*, *M. bovis*, *M. africanum*, *M. microti*, *M. canetti*, *M. caprae*, and *M. pinnipedii*), but not in the majority of other mycobacteria or in vaccine-variant *M. bovis*, BCG. Lymphocytes from the majority of persons who have been infected by *M. tuberculosis* complex indicate their sensitivity to ESAT-6 or CFP-10 by releasing IFN- γ , whereas infection by the majority of other mycobacteria, including BCG, does not appear to cause this sensitivity.

The blood tests using IFN- γ methods require one less patient visit, assess responsiveness to *M. tuberculosis* antigens, and do not boost anamnestic immune responses. Interpretation of the BAMT result is less subjective than interpretation of a skin test result, and the BAMT result might be affected less by previous BCG vaccination and sensitization to environmental mycobacteria (e.g., *M. avium* complex) than the PPD-based TST. BAMT might be more efficient and cost effective than TST (35). Screening programs that use BAMT might eliminate the need for two-step testing because this test does not boost sensitization.

Other cytokine-based immunoassays are under development and might be useful in the diagnosis of *M. tuberculosis* infection. Future FDA-approved products, in combination with CDC-issued recommendations, might provide additional diagnostic alternatives. For guidance on the use of these and related technologies, CDC plans to periodically publish recommendations on the diagnosis of *M. tuberculosis* infection. BAMT can be used in both testing and infection-control surveillance programs for HCWs.

Use of Tuberculin Skin Test (TST) for Diagnosing *M. tuberculosis* Infections in HCWs

The TST is frequently the first step of a TB diagnostic evaluation that might lead to diagnosing LTBI. Although currently available preparations of PPD used in TST are <100% sensitive and specific for the detection of LTBI, the TST is currently the most widely used diagnostic test for *M. tuberculosis* infection in the United States. The TST is less sensitive in patients who have TB disease.

The TST, like all medical tests, is subject to variability (74,228,317), but many of the inherent variations in administering and reading TST results can be avoided by training and attention to detail (318). Details of TST administration and TST result reading procedures are suggested in this report to improve the technical aspects of TST placement and reading, thus reducing observer variations and improving test reliability ([Appendix F](#)). These checklists were developed for the National Health and Nutrition Examination Survey (NHANES) to standardize TST placement and reading for research purposes. The suggested TST training recommendations are not mandatory.

Adherence to TST

Operational policies, procedures, and practices at health-care settings can enhance HCW adherence to serial TST. In 2002, one focus group study identified potential barriers and facilitators to adherence with routine TST (319). HCWs identified structural factors (e.g., inconvenient TST screening schedules and locations and long waiting times) that negatively affected adherence. Facilitators to help HCWs adhere to routine TST included active follow-up by supervisors and occupational health staff and work-site visits for TST screening. Misinformation and stigma concerning TB also emerged in the discussions, indicating the need for additional training and education for HCWs.

Administering the TST

For each patient, a risk assessment should be conducted that takes into consideration recent exposure to *M. tuberculosis*, clinical conditions that increase risk for TB disease if infected, and the program's capacity to deliver treatment for LTBI to determine if the TST should be administered.

The recommended method for TST is the Mantoux method ([Appendix F](#)) (223,318,320–322). Mantoux TST training materials supporting the guidance in this report are available at <http://www.cdc.gov/tb> (223,318,320–325). Multipuncture tests (e.g., Tine(r) tests) are not as reliable as the Mantoux method of skin testing and should not be used as a diagnostic test in the United States (30). Contact the state and local health department for TST resources.

Reading the TST Result

The TST result should be read by a designated, trained HCW 48–72 hours after the TST is placed (39,326,327). If the TST was not read between 48–72 hours, ideally, another TST should be placed as soon as possible and read within 48–72 hours (39). Certain studies indicate that positive TST reactions might still be measurable from 4–7 days after testing (225,226,328). However, if a patient fails to return within 72 hours and has a negative test result, the TST should be repeated (42). Patients and HCWs should not be allowed to read their own TST results. HCWs do not typically measure their own TST results reliably (48).

Reading the TST result consists of first determining the presence or absence of induration (hard, dense, and raised formation) and, if induration is present, measuring the diameter of induration transverse (perpendicular) to the long axis of the forearm ([Figure 1](#)) (39,318). Erythema or redness of the skin should not be considered when reading a TST result ([Appendix F](#)).

Interpreting TST Results

The positive-predictive value of a TST is the probability that a person with a positive TST result is actually infected with *M. tuberculosis*. The positive predictive value is dependent on the prevalence of infection with *M. tuberculosis* in the population being tested and the sensitivity and specificity of the test (228,329,330).

In populations with a low prevalence of *M. tuberculosis* infection, the probability that a positive TST result represents true infection with *M. tuberculosis* can be substantially low, especially if the cut

point is set too low (i.e., the test is not adequately specific and a low prevalence exists in the population). In populations with a high prevalence of infection with *M. tuberculosis* and inadequate test specificity, the probability that a positive TST result using the same cut point represents true infection with *M. tuberculosis* is much higher.

Interpreting TST Results in HCWs

TST result interpretation depends on two factors: 1) measured TST induration in millimeters and 2) the person's risk for being infected with *M. tuberculosis* and risk for progression to TB disease if infected.

Interpretations of TST and QFT results vary according to the purpose of testing ([Box 3](#)). A TST result with no induration (0 mm) or a measured induration below the defined cut point for each category is considered to signify absence of infection with *M. tuberculosis*.

In the context of TST screening as part of a TB infection-control program, the interpretation of TST results occurs in two distinct parts. The first is the interpretation by standard criteria, without regard to personal risk factors or setting-specific factors of the TST results for infection control, surveillance, and referral purposes. The second is the interpretation by individualized criteria to determine the need for treatment of LTBI.

Determining the need for treatment of LTBI is a subsequent and separate task. For infection-control and surveillance purposes, TST results should be interpreted and recorded under strict criteria, without considering setting-based or personal risk factors (see Supplement, Diagnostic Procedures for LTBI and TB Disease). Any HCW with a positive TST result from serial TB screening should be referred to a medical provider for an evaluation and to determine the need for treatment of LTBI based on individual risk ([Box 3](#)).

Interpreting the TST Result for Infection Control and Surveillance

On baseline TST testing, a TST result of ≥ 10 mm is considered positive for the majority of HCWs, and a TST result of ≥ 5 mm is considered positive for HCWs who are infected with HIV or who have other immunocompromising conditions ([Box 3](#)). All HCWs with positive baseline TST results should be referred for medical and diagnostic evaluation; additional skin testing does not need to be performed.

On serial screening for the purposes of infection-control surveillance, TST results indicating an increase of ≥ 10 mm within 2 years should be interpreted and recorded as a TST conversion. For the purposes of assessing and monitoring infection control, TST conversion rates should be regularly determined. Health-care settings with a substantial number of HCWs to be tested might have systems in place that can accurately determine the TST conversion rate every month (e.g., from among a group of HCWs tested annually), whereas smaller settings might have imprecise estimates of their TST conversion rate even with annual assessments.

The precision of the setting's TST conversion rate and any analysis assessing change from baseline TST results will depend on the number and frequency of HCWs tested. These factors should be considered when establishing a regular interval for TB screening for HCWs.

After a known exposure in a health-care setting, close HCW contacts who have TST results of ≥ 5 mm should be considered to have positive TST results, which should be interpreted as new infections only in HCWs whose previous TST result is 0 mm. However, HCWs 1) with a baseline or follow-up TST result of > 0 mm but < 10 mm with a health-care-associated exposure to *M. tuberculosis* and 2) who then have an increase of ≥ 10 mm should be considered to have a TST conversion because of a new infection ([Box 3](#)).

In a contact investigation, a follow-up TST should be administered 8–10 weeks after the end of exposure (rather than 1–3 weeks later, as in two-step testing). In this instance, a change from a negative TST result to a positive TST result should not be interpreted as a boosted reaction. The change in the TST result indicates a TST conversion, recent exposure, transmission, and infection.

All HCWs who are immunocompromised should be referred for a medical and diagnostic evaluation for any TST result of ≥ 5 mm on baseline or follow-up screening. Because infection-control staff will usually not know the immune status of the HCWs being tested, HCWs who have TST results of 5–9 mm should be advised that such results can be an indication for referral for medical evaluation for HCWs who have HIV infection or other causes of severe immunosuppression.

After an HCW has met criteria for a positive TST result, including HCWs who will not receive treatment for LTBI, repeat TSTs are not necessary because the results would not provide any additional information (30). This approach applies to HCWs who have positive TST results but who will not receive treatment for LTBI after medical evaluation. For future TB screening in settings that are medium risk, instead of participating in serial skin testing, the HCW should receive a medical evaluation and a symptom screen annually.

Interpreting the TST Result for Medical and Diagnostic Referral and Evaluation

HCWs who have positive TST results and who meet the criteria for referral should have a medical and diagnostic evaluation. For HCWs who are at low risk (e.g., those from low-incidence settings), a baseline result of ≥ 15 mm of induration (instead of ≥ 10 mm) might possibly be the cut point. The criteria used to determine the need for treatment of LTBI has been presented.

When making decisions for the diagnosis and treatment of LTBI, setting-based risk factors (e.g., the prevalence of TB disease and personal risk factors such as having an immunocompromising condition or known contact with a TB case) should be assessed when choosing the cut point for a positive TST result. The medical evaluation can occur in different settings, including an occupational health clinic, local or state health department, or private medical clinic.

When 15 mm is used as the cut point, TST results of 10–14 mm can be considered clinically negative (331). These HCWs should not have repeat TST, and the referring physician might not recommend treatment for LTBI. This issue of false-positive TST results might be especially true in areas of the country where the prevalence of infection with NTM is high.

HCWs who have TST results of 5–9 mm on baseline two-step testing should be advised that such results might be an indication for treatment of LTBI if the HCW is a contact of a person with infectious TB disease, has HIV infection, or has other causes of severe immunosuppression (e.g., organ transplant and receipt of the equivalent of ≥ 15 mg/day of prednisone for ≥ 1 month). The risk for TB disease in persons treated with corticosteroids increases with higher dose and longer duration of corticosteroid use. TNF- α antagonists also substantially increase the risk for progression to TB disease in persons with LTBI (332).

HCWs with negative baseline two-step TST results who are referred for medical evaluation for an increase of ≥ 10 mm induration on follow-up TST screening, including those who are otherwise at low risk for TB disease, probably acquired *M. tuberculosis* infection since receiving the previous TST and should be evaluated for TB disease. If disease is excluded, the HCW should be offered treatment for LTBI if they have no contraindication to treatment.

QC Program for Techniques for TST Administration and Reading TST Results

Random variation (i.e., differences in procedural techniques) in TST administration and reading TST results can cause false-positive or false-negative TST results. Many of the variations in administering and reading TST results can be avoided by conducting training and maintaining attention to details. HCWs who are responsible for TST procedures should be trained to reduce variation by following standardized operational procedures and should be observed by an expert TST trainer. All TST procedures (i.e., administering, reading, and recording the results) should be supervised and controlled to detect and correct variation. Corrective actions might include coaching and demonstration by the TST trainer. Annual re-training is recommended for HCWs responsible for administering and reading TST results.

One strategy to identify TST procedure variation is to use a QC tool ([Appendix F](#)). The expert TST trainer should observe the procedures and indicate procedural variation on the observation checklists. An expert trainer includes persons who have documented training experience.

QC for Administering TST by the Mantoux Method

Ideally, the TST trainer should participate in QC TST administrations with other TST trainers to maintain TST trainer certification. State regulations specify who is qualified to administer the test by injection. The TST trainer should first ensure antigen stability by maintaining the manufacturer's recommended cold chain (i.e., controlling antigen exposure to heat and light from the time it is out of refrigeration until the time it is placed back into refrigeration or until the vial is empty or expired). The TST trainer should prevent infection during an injection by preparing the skin and preventing contamination of solution, needle, and syringe.

The TST trainer should prevent antigen administration errors by controlling the five rights of administration: 1) right antigen; 2) right dose; 3) right patient; 4) right route; and 5) right time for TST administration, reading, and clinical evaluation (333). Finally, the TST trainer should observe and coach the HCW trainee in administering multiple intradermal injections by the Mantoux method. The TST trainer should record procedural variation on the observation checklist ([Appendix F](#)). TST training and coaching should continue until more than 10 correct skin test placements (i.e., ≥ 6 mm wheal) are achieved.

For training purposes, normal saline for injection can be used instead of PPD for intradermal injections. Volunteers are usually other HCWs who agree to be tested. Attempt to recruit volunteers who have known positive TST results so the trainees can practice reading positive TST results. A previous TST is not a contraindication to a subsequent TST unless the test was associated with severe ulceration or anaphylactic shock, which are substantially rare adverse events (30,237,238).

Model TST Training Program

A model TST training program for placing TST and reading TST results has been produced by NHANES (326). The number of hours, sessions, and blinded independent duplicate reading (BIDR) readings should be determined by the setting's TB risk assessment. The following information can be useful for a model TST training program. The suggested TST training recommendations are not mandatory.

Initial training for a TST placer ideally consists of three components.

- Introductory lecture and demonstration by an expert TST placer or trainer. An expert TST trainer is a qualified HCW who has received training on administering multiple TST and reading multiple TST results (consider 3 hours of lecture).
- Supervised practical work using procedural checklists observed and coached by the expert TST trainer ([Appendix F](#)) (consider 9 hours of practical work).
- Administration of more than 10 total skin tests on volunteers by using injectable saline and producing more than 10 wheals that measure 6–10 mm.

TST training should include supervised TST administration, which is a procedure in which an expert TST trainer supervises a TST trainee during all steps on the procedural observation checklist for TST administration ([Appendix F](#)). Wheal size should be checked for all supervised TST administrations, and skin tests should be repeated if wheal size is inadequate (i.e., < 6 mm). TST training and coaching should continue until more than 10 correct skin test placements (i.e., ≥ 6 mm wheal) are achieved.

QC for Reading TST Results by the Palpation Method

The TST trainer should participate in QC readings with other TST trainers to maintain TST trainer certification. When training HCWs to read TST results, providing measurable TST responses is helpful (i.e., attempt to recruit volunteers who have known positive TST results so that the trainees can practice reading positive TST results).

TST readers should correctly read both measurable (>0 mm) and nonmeasurable responses (0 mm) (e.g., consider reading more than 20 TST results [at least 10 measurable and at least 10 nonmeasurable], if possible). The TST trainer should observe and coach the HCW in reading multiple TST results by the Palpation method and should record procedure variation on the observation checklist ([Appendix F](#)).

The TST trainer should conduct BIDRs for comparison with the HCW's reading. BIDRs are performed when two or more consecutive TST readers immediately measure the same TST result by standard procedures, without consulting or observing one another's readings, and record results independently (may use recommended procedural observation checklist; [Appendix F](#)). BIDRs help ensure that TST readers continue to read TST results correctly.

Initial training for a TST reader ideally should consist of multiple components.

- Receiving an introductory lecture and demonstration by an expert TST reader. Training materials are available from CDC (223,318) and CDC-sponsored Regional Model and Training Centers and should also be available at the local or state health department (consider 6 hours for lecture and demonstration).
- Receiving four sessions of supervised practical work using procedural checklists (observed and coached by an expert TST reader) (consider 16 hours of practical work).
- Performing BIDR readings (consider more than 80, if possible). TST trainers should attempt to organize the sessions so that at least 50% of the TST results read have a result of >0 mm according to the expert TST reader.
- Performing BIDR readings on the last day of TST training (consider more than 30 BIDR readings out of the total 80 readings, if possible). TST trainers should attempt to ensure that at least 25% of persons tested have a TST result of >0 mm, according to the expert TST reader.
- Missing no more than two items on the procedural observation checklist ([Appendix F](#)) for three random observations by an expert TST reader.
- Performing all procedures on the checklist correctly during the final observation.

TST training and coaching should continue until the HCW is able to perform all procedures correctly and until a satisfactory measurement is achieved (i.e., the trainer and the trainee read the TST results within 2 mm of each other). For example, if the trainer reads the TST result as 11 mm (this might be considered the gold standard reading), the trainee's reading should be between 9–13 mm to be considered correct. Only a single measurement in millimeters should be recorded (not 11 mm x 11 mm or 11 mm x 15 mm). QC Procedural Observation Checklists ([Appendix F](#)) are recommended by CDC as a tool for use during TST training.

Special Considerations in TST

Anergy. The absence of a reaction to a TST does not exclude a diagnosis of TB disease or infection with *M. tuberculosis*. In immunocompromised persons, delayed-type hypersensitivity (DTH) responses (e.g., tuberculin reactions) can decrease or disappear more rapidly, and a limited number of otherwise healthy persons apparently are incapable of reacting to tuberculin even after diagnosed infection with *M. tuberculosis*. This condition, called anergy, can be caused by multiple factors (e.g., advanced HIV infection, measles infection, sarcoidosis, poor nutrition, certain medications, vaccinations, TB disease itself, and other factors) (307,334–338). However, anergy testing in conjunction with TB skin testing is no longer recommended routinely for screening for *M. tuberculosis* infection (336).

Reconstitution of DTH in HIV-infected persons taking antiretroviral therapy (ART). In one prospective study (340), TB patients who initially had negative TST results had positive TST results after initiation of HAART. HCWs must be aware of the potential public health and clinical implications of restored TST reactivity among persons who have not been diagnosed with TB disease but who might have LTBI. After the initiation of HAART repeat testing for infection with *M. tuberculosis* is recommended for HIV-infected persons previously known to have negative TST results (58). Recommendations on the prevention and treatment of TB in HIV-infected persons have been published (39,53,240).

Pregnancy. Tens of thousands of pregnant women have received TST since the test was developed, and no documented episodes of TST-related fetal harm have been reported (341). No evidence exists that the TST has adverse effects on the pregnant mother or fetus (39). Pregnant HCWs should be included in serial skin testing as part of an infection-control program or a contact investigation because no contraindication for skin testing exists (342). Guidelines issued by the American College of Obstetricians and Gynecologists (ACOG) emphasize that postponement of the diagnosis of infection with *M. tuberculosis* during pregnancy is unacceptable (343).

Booster phenomenon and two-step testing. In certain persons with LTBI, the DTH responsible for TST reactions wanes over time. Repeated TST can elicit a reaction called boosting in which an initial TST result is negative, but a subsequent TST result is positive. For example, a TST administered years after infection with *M. tuberculosis* can produce a false-negative result. This TST might stimulate (or boost) the person's ability to react to tuberculin, resulting in a positive result to a subsequent test (including the second step of a two-step procedure) (36,74,316,342,343). With serial testing, a boosted reaction on a subsequent TST might be misinterpreted as a newly acquired infection, compared with the false-negative result from the initial TST. Misinterpretation of a boosted reaction as a new infection with *M. tuberculosis* or TST conversion might prompt unnecessary investigations to find the source case, unnecessary treatment for the person tested, and unnecessary testing of other HCWs. The booster phenomenon can occur in anyone, but it is more likely to occur in older persons, persons with remote infection with *M. tuberculosis* (i.e., infected years ago), persons infected with NTM, and persons with previous BCG vaccination (39,229,234,344,345).

All newly employed HCWs who will be screened with TST should receive baseline two-step TST upon hire, unless they have documentation of either a positive TST result or treatment for LTBI or TB disease (39,224). Any setting might have HCWs at risk for boosting, and a rate of boosting even as low as 1% can result in unnecessary investigation of transmission. Therefore, two-step TSTs are needed to establish a baseline for persons who will receive serial TST (e.g., residents or staff of correctional facilities or LTCFs). This procedure is especially important for settings that are classified as low risk where testing is indicated only upon exposure. A reliable baseline test result is necessary to detect health-care–associated transmission of *M. tuberculosis*. Guidance for baseline TST for HCWs is included in this report ([Box 3](#)). To estimate the frequency of boosting in a particular setting, a four-appointment schedule of TST administration and reading (i.e., appointments for TST administration and reading both TST results) is necessary, rather than the three-appointment schedule (i.e., appointments for the administration of both tests, with reading of the second-step TST result only) ([196](#)).

Two-step testing should be used only for baseline screening, not in contact investigations. In a contact investigation, for persons with a negative TST, a follow-up test should be administered 8–10 weeks after the end of exposure (rather than 1–3 weeks later, as in a two-step TST). In this instance, a change from a negative to a positive TST result suggests that recent exposure, transmission, and infection occurred and should not be interpreted as a boosted response.

After a known exposure in a health-care setting (close contact to a patient or HCW with infectious TB disease), TST results of ≥ 5 mm should be considered positive and interpreted as a new infection in HCWs whose previous TST result is 0 mm. If an HCW has a baseline or follow-up TST result of >0 mm but ≤ 10 mm, a health-care–associated exposure to *M. tuberculosis*, and an increase in the TST size of ≥ 10 mm, the result should be interpreted as the HCW having a TST conversion because of new infection.

BCG vaccination. In the United States, vaccination with BCG is not recommended routinely for anyone, including HCWs or children ([227](#)). Previous BCG vaccination is not a contraindication to having a TST or two-step skin testing administered. HCWs with previous BCG vaccination should receive baseline and serial skin testing in the same manner as those without BCG vaccination ([233](#)) ([Box 1](#)).

Previous BCG vaccination can lead to boosting in baseline two-step testing in certain persons (74,231,344–346). Distinguishing a boosted TST reaction resulting from BCG vaccination (a false-

positive TST result) and a TST result because of previous infection with *M. tuberculosis* (true positive TST result) is not possible (39). Infection-control programs should refer HCWs with positive TST results for medical evaluation as soon as possible ([Box 3](#)).

Previous BCG vaccination increases the probability of a boosted reaction that will probably be uncovered on initial two-step skin testing. For an HCW with a negative baseline two-step TST result who is a known contact of a patient who has suspected or confirmed infectious TB disease, treatment for LTBI should be considered if the follow-up TST result is ≥ 5 mm, regardless of BCG vaccination status.

PPD preparations for diagnosing infection with *M. tuberculosis*. Two PPD preparations are available in the United States: Tubersol(r) (Aventis Pasteur, Switzwater, Pennsylvania) (237) and APLISOL(r) (Parkdale Pharmaceuticals, Rochester, Michigan) (238). Compared with the U.S. reference PPD, no difference exists in TST interpretation between the two preparations (347). However, when Tubersol and Aplisol were compared with each other, a slight difference in reactivity was observed. Aplisol produced slightly larger reactions than Tubersol, but this difference was not statistically significant (347). The difference in specificity, 98% versus 99%, is limited. However, when applied in large institutional settings that test thousands of workers annually who are at low risk for infection with *M. tuberculosis*, this difference in specificity might affect the rate of positive TST results observed.

TB screening programs should use one antigen consistently and should realize that changes in products might make serial changes in TST results difficult to interpret. In one report, systematic changes in product use resulted in a cluster of pseudoconversions that were believed to have erroneously indicated a health-care-associated outbreak (348). Persons responsible for making decisions about the choice of pharmacy products should seek advice from the local or state health department's TB infection-control program before switching PPD preparations and should inform program staff of any changes.

Chest Radiography

Chest radiographic abnormalities can suggest pulmonary TB disease. Radiographic abnormalities that are consistent with pulmonary TB disease include upper-lobe infiltration, cavitation, and effusion. Infiltrates can be patchy or nodular and observed in the apical (in the top part of the lungs) or subapical posterior upper lobes or superior segment of the lower lobes in the lungs. HCWs who have positive test results for *M. tuberculosis* infection or symptoms or signs of TB disease, regardless of test results for *M. tuberculosis* infection, should have a chest radiograph performed to exclude a diagnosis of TB disease. However, a chest radiograph is not a substitute for tests for *M. tuberculosis* infection in a serial TB screening program for HCWs.

Persons who have LTBI or cured TB disease should not have repeat chest radiographs performed routinely (116). Repeat radiographs are not needed unless symptoms or signs of TB disease develop or a clinician recommends a repeat chest radiograph (39,116).

A chest radiograph to exclude pulmonary TB disease is indicated for all persons being considered for treatment of LTBI. If chest radiographs do not indicate pulmonary TB and if no symptoms or signs of TB disease are present, persons with a positive test result for infection with *M. tuberculosis* might be candidates for treatment of LTBI. In persons with LTBI, the chest radiograph is usually normal, although it might demonstrate abnormalities consistent with previous healed TB disease or other pulmonary conditions. In patients with symptoms or signs of TB disease, pulmonary infiltrates might only be apparent on a computed tomography (CT) scan. Previous, healed TB disease can produce radiographic findings that might differ from those associated with current TB disease, although a substantial overlap might exist. These findings include nodules, fibrotic scars, calcified granulomas, or basal pleural thickening. Nodules and fibrotic scars might contain slowly multiplying tubercle bacilli and pose a high risk for progression to TB disease. Calcified nodular lesions (calcified granulomas) and apical pleural thickening pose a lower risk for progression to TB disease (31).

Chest Radiography and Pregnancy

Because TB disease is dangerous to both mother and fetus, pregnant women who have a positive TST result or who are suspected of having TB disease, as indicated by symptoms or other concerns, should receive chest radiographs (with shielding consistent with safety guidelines) as soon as feasible, even during the first trimester of pregnancy (31,39,341).

Chest Radiography and HIV-Infected Persons

The radiographic presentation of pulmonary TB in persons infected with HIV might be apical; however, apical cavitary disease is less common among such patients. More common chest radiograph findings for HIV-infected persons are infiltrates in any lung zone, mediastinal or hilar adenopathy, or, occasionally, a normal chest radiograph. Typical and cavitary lesions are usually observed in patients with higher CD4 counts, and more atypical patterns are observed in patients with lower CD4 counts (31,49,94,142,349–354). In patients with symptoms and signs of TB, a negative chest radiograph result does not exclude TB. Such patients might be candidates for airborne precautions during medical evaluation.

Evaluation of Sputum Samples

Sputum examination is a critical diagnostic procedure for pulmonary TB disease (30) and is indicated for the following persons:

- anyone suspected of having pulmonary or laryngeal TB disease;
- persons with chest radiograph findings consistent with TB disease (current, previous, or healed TB);
- persons with symptoms of infection in the lung, pleura, or airways, including larynx;
- HIV-infected persons with any respiratory symptoms or signs, regardless of chest radiograph findings; and
- persons suspected of having pulmonary TB disease for whom bronchoscopy is planned.

Sputum Specimen Collection

Persons requiring sputum collection for smear and culture should have at least three consecutive sputum specimens obtained, each collected in 8–24-hours intervals (124), with at least one being an early morning specimen (355). Specimens should be collected in a sputum induction booth or in an AII room. In resource-limited settings without environmental containment or when an AII room is not available, sputum collection can be performed safely outside of a building, away from other persons, windows, and ventilation intakes. Patients should be instructed on how to produce an adequate sputum specimen (containing little saliva) and should be supervised and observed by an HCW during the collection of sputum, if possible (30). If the patient's specimen is determined to be inadequate, it should still be sent for bacteriologic testing, although the inadequate nature of the specimen should be recorded. The HCW should wear an N95 disposable respirator during sputum collection.

Sputum Induction

For patients who are unable to produce an adequate sputum specimen, expectoration can be induced by inhalation of an aerosol of warm, hypertonic saline. Because sputum induction is a cough-inducing procedure, pre-treatment with a bronchodilator should be considered in patients with a history of asthma or other chronic obstructive airway diseases. Medical assistance and bronchodilator medication should be available during any sputum induction in the event of induced bronchospasm (109,356,357).

The patient should be seated in a small, well-ventilated sputum induction booth or in an AII room (see Environmental Controls; and Supplement, Environmental Controls). For best results, an ultrasonic nebulizer that generates an aerosol of approximately 5 mL/minute should be used. A 3% hypertonic saline is commercially available, and its safety has been demonstrated. At least 30 mL of 3% saline should be administered; administration of smaller volumes will have a lower yield. Higher concentrations can be used with an adjustment in the dose and closer monitoring for adverse effects.

Patients should be instructed to breathe deeply and cough intermittently. Sputum induction should be continued for up to 15 minutes or until an adequate specimen (containing little saliva) is produced. Induced sputum will often be clear and watery. Any expectorated material produced should be labeled as expectorated sputum and sent to the laboratory.

Laboratory Examination

Detection of AFB in stained smears by microscopy can provide the first bacteriologic indication of TB disease. Laboratories should report any positive smear results within 24 hours of receipt of the specimen (30). A positive result for AFB in a sputum smear is predictive of increased infectiousness. Smears allow presumptive detection of mycobacteria, but definitive identification, strain typing, and drug-susceptibility testing of *M. tuberculosis* require that a culture be performed (30). Negative AFB sputum smear results do not exclude a diagnosis of TB disease, especially if clinical suspicion of disease is high. In the United States, approximately 63% of patients with reported positive sputum culture results have positive AFB sputum smear results (26).

A culture of sputum or other clinical specimen that contains *M. tuberculosis* provides a definitive diagnosis of TB disease. In the majority of cases, identification of *M. tuberculosis* and drug-susceptibility results are available within 28 days (or 4–6 weeks) when recommended rapid methods such as liquid culture and DNA probes are used. Negative culture results are obtained in approximately 14% of patients with confirmed pulmonary TB disease (4,5). Testing sputum with rapid techniques (e.g., NAA) facilitates the rapid detection and identification of *M. tuberculosis* but should not replace culture and drug-susceptibility testing in patients with suspected TB disease (30,125,358). Mixed mycobacterial infection can obscure the identification of *M. tuberculosis* during the laboratory evaluation (e.g., because of cross-contamination or dual infections) and can be distinguished by the use of mycobacterial species-specific DNA probes (359). Examination of colony morphology on solid culture media can also be useful.

Drug-susceptibility tests should be performed on initial isolates from all patients to assist in identifying an effective antituberculosis treatment regimen. Drug-susceptibility tests should be repeated if sputum specimens continue to be culture-positive after 3 months of antituberculosis treatment or if culture results become positive for *M. tuberculosis* after a period of negative culture results (30,31).

Bronchoscopy

If possible, bronchoscopy should be avoided in patients with a clinical syndrome consistent with pulmonary or laryngeal TB disease because bronchoscopy substantially increases the risk for transmission either through an airborne route (63,80,81,162,360) or a contaminated bronchoscope (80,82,163–169), including in persons with negative AFB sputum smear results. Microscopic examination of three consecutive sputum specimens obtained in 8–24-hour intervals, with at least one obtained in the early morning, is recommended instead of bronchoscopy, if possible. In a patient who is intubated and mechanically ventilated, closed circuitry can reduce the risk for exposure.

If the suspicion for pulmonary TB disease is high or if the patient is seriously ill with a disorder, either pulmonary or extrapulmonary, that is believed to be TB disease, multidrug antituberculosis treatment using one of the recommended regimens should be initiated promptly, frequently before AFB smear results are known (31). Obtaining three sputum samples is safer than performing bronchoscopy. For AFB smear and culture results, three sputum samples have an increased yield compared with a single specimen (110,357), and induced specimens have better yield than specimens obtained without induction. Sputum induction is well-tolerated (90,109,132,133,357,361,362), even in children (134,356), and sputum specimens (either spontaneous or induced) should be obtained in all cases before a bronchoscopy (109,356,363,364).

In circumstances where a person who is suspected of having TB disease is not on a standard antituberculosis treatment regimen and the sputum smear results (possibly including induced specimens) are negative and a reasonably high suspicion for TB disease remains, additional consideration to initiate treatment for TB disease should be given. If the underlying cause of a

radiographic abnormality remains unknown, additional evaluation with bronchoscopy might be indicated; however, in cases where TB disease remains a diagnostic possibility, initiation of a standard antituberculosis treatment regimen for a period before bronchoscopy might reduce the risk for transmission. Bronchoscopy might be valuable in establishing the diagnosis; in addition, a positive culture result can be both of clinical and public health importance to obtain drug-susceptibility results. Bronchoscopy in patients with suspected or confirmed TB disease should not be undertaken until after consideration of the risks for transmission of *M. tuberculosis* (30,63,81,162,360). If bronchoscopy is performed, because it is a cough-inducing procedure, additional sputum samples for AFB smear and culture should be collected after the procedure to increase the diagnostic yield.

Treatment Procedures for LTBI and TB Disease

Treatment for LTBI

Treatment for LTBI is essential to control and eliminate TB disease in the United States because it substantially reduces the risk that infection with *M. tuberculosis* will progress to TB disease (10,28). Certain groups of persons are at substantially high risk for developing TB disease after being infected, and every effort should be made to begin treatment for LTBI and to ensure that those persons complete the entire course of treatment ([Table 3](#)).

Before beginning treatment of LTBI, a diagnosis of TB disease should be excluded by history, medical examination, chest radiography, and, when indicated, bacteriologic studies. In addition, before offering treatment of LTBI, ensure that the patient has not experienced adverse reactions with previous isoniazid (INH) treatment (215).

Candidates for Treatment of LTBI

Persons in the following groups at high risk should be administered treatment for LTBI if their TST result is ≥ 5 mm or if their BAMT result is positive, regardless of age (31,39):

- persons infected with HIV,
- recent contacts with a person with TB disease,
- persons with fibrotic changes on chest radiograph consistent with previous TB disease,
- organ transplant recipients, and
- other immunosuppressed persons (e.g., persons receiving ≥ 15 mg/day of prednisone for ≥ 1 month).

Persons in the following groups at high risk should be considered for treatment of LTBI if their TST result is ≥ 10 mm, or if the BAMT result is positive:

- persons with TST or BAMT conversions;
- persons born or who have lived in developing countries or countries with a high-incidence of TB disease;
- persons who inject illicit drugs;
- residents and employees in congregate settings that are at high risk (i.e., correctional facilities and LTCFs [e.g., hospices and skilled nursing facilities]), hospitals and other health-care facilities, residential settings for persons with HIV/AIDS or other immunocompromising conditions, and homeless shelters;
- personnel from mycobacteriology laboratories;
- persons with any of the following clinical conditions or other immunocompromising conditions that place them at high risk for TB disease:
 - silicosis,
 - diabetes mellitus,
 - chronic renal failure,
 - certain hematologic disorders (e.g., leukemias and lymphomas),
 - other specific malignancies (e.g., carcinoma of the head, neck, or lung),
 - unexplained weight loss of $\geq 10\%$ of ideal body weight,
 - gastrectomy, or
 - jejunioileal bypass;
- persons living in areas with high incidence of TB disease;

- children aged <4 years; and
- infants, children, and adolescents exposed to adults at high risk for developing TB disease.

Persons who use tobacco or alcohol (40,41), illegal drugs, including injection drugs and crack cocaine (43–48), might also be at increased risk for infection and disease, but because of the multiple other potential risk factors that commonly occur among such persons, use of these substances has been difficult to identify as separate risk factors.

Persons with no known risk factors for TB disease can be considered for treatment of LTBI if their TST result is ≥ 15 mm. However, programs to screen HCWs for infection with *M. tuberculosis* should only be conducted among groups at high risk. All testing activities should be accompanied by a plan for follow-up care for persons with LTBI or, if it is found, TB disease. A decision to test for infection with *M. tuberculosis* should be based on a commitment to treat LTBI after a medical examination (39).

Persons who might not be good candidates for treatment of LTBI include those with a previous history of liver injury or a history of excessive alcohol consumption. Active hepatitis and end-stage liver disease (ESLD) are relative contraindications to the use of INH for treatment of LTBI (39,240). If the decision is made to treat such patients, baseline and follow-up monitoring of serum aminotransaminases should be considered.

For persons who have previous positive TST or BAMT results and who completed treatment for LTBI previously, treating them again is not necessary. Documentation of completed therapy for LTBI is critical. Instead of participating in serial skin testing, the HCW should receive a medical evaluation and a symptom screen annually. A symptom screen is a procedure used during a clinical evaluation in which patients are asked if they have experienced any departure from normal in function, appearance, or sensation related to TB disease (e.g., cough).

Screening HCWs for infection with *M. tuberculosis* is an essential administrative measure for the control of transmission of *M. tuberculosis* in health-care settings. By conducting TB screening, ongoing transmission of *M. tuberculosis* can be detected, and future transmission can be prevented by identifying lapses in infection control and identifying persons infected with *M. tuberculosis* and TB disease. The majority of individual HCWs, however, do not have the risk factors for progression to disease that serve as the basis for the current recommendations for targeted testing and treatment of LTBI. The majority of HCWs in the United States do not provide care in areas in which the prevalence of TB is high. Therefore, HCWs should be tested, as determined by risk classification for the health-care setting, and can be categorized as having a positive test result or conversion for *M. tuberculosis* infection. HCWs can be categorized as part of the TB infection-control program for the purpose of surveillance and referral, but they might not necessarily be candidates for treatment of LTBI.

HCWs should receive serial screening for infection with *M. tuberculosis* (either TST or BAMT), as determined by the health-care setting's risk classification ([Appendix B](#)). For infection-control purposes, the results of the testing should be recorded and interpreted as part of the TB infection-control program as either a 1) negative TST result, 2) previously documented positive TST or BAMT result, or 3) TST or BAMT conversion. All recordings of TST results should also document the size of the induration in millimeters, not simply as negative or positive. BAMT results should be recorded in detail. The details should include date of blood draw, result in specific units, and the laboratory interpretation (positive, negative, or indeterminate) and the concentration of cytokine measured (e.g., IFN- γ).

To determine whether treatment for LTBI should be indicated, HCWs should be referred for medical and diagnostic evaluation according to the TST result criteria ([Box 5](#)). In conjunction with a medical and diagnostic evaluation, HCWs with positive test results for *M. tuberculosis* should be considered for treatment of LTBI ([Box 5](#)) after TB disease has been excluded by further medical evaluation. HCWs cannot be compelled to take treatment for LTBI, but they should be encouraged to do so if they are eligible for treatment.

HCWs' TST or BAMT results might be considered positive as part of the TB infection-control program for the purposes of surveillance and referral (i.e., meet the criterion for a conversion), and this occurrence is important to note. However, not all of these HCWs may be considered candidates for treatment of LTBI, according to the individual medical and diagnostic evaluation. After an HCW has been classified as having a positive result or conversion for *M. tuberculosis* infection, additional testing for *M. tuberculosis* infection is not necessary.

Treatment Regimens for LTBI

For persons suspected of having LTBI, treatment of LTBI should not begin until TB disease has been excluded. Persons highly suspected of having TB disease should receive the standard multidrug antituberculosis treatment regimen for TB disease until the diagnosis is excluded. Standard drug regimens for the treatment of LTBI have been presented (Table 3); however, modifications to those regimens should be considered under certain circumstances, including HIV infection, suspected drug resistance, and pregnancy (47,365).

Reports of severe liver injury and death associated with the combination of rifampin and pyrazinamide (RZ) for treatment of LTBI (366–368) prompted the American Thoracic Society and CDC to revise previous recommendations (39,53) to indicate that RZ generally should not be offered for the treatment of LTBI (240). If the potential benefits substantially outweigh the demonstrated risk for severe liver injury and death associated with this regimen and the patient has no contraindications, a physician with experience treating LTBI and TB disease should be consulted before using this regimen (246). Clinicians should continue the appropriate use of rifampin and pyrazinamide in standard multidrug antituberculosis treatment regimens for the treatment of TB disease (31). Collaborate with the local or state health department on decisions regarding DOT arrangements.

For all regimens for treatment of LTBI, nonadherence to intermittent dosing (i.e., once or twice weekly) results in a larger proportion of total doses missed than daily dosing. DOT should be used for all doses during the course of treatment of LTBI whenever feasible (31). Collaborate with the local or state health department on decisions regarding DOT arrangements.

Contacts of patients with drug-susceptible TB disease. Persons with a previously negative TST or BAMT result who are contacts of patients with drug-susceptible TB disease and who subsequently have a positive TST result (≥ 5 mm) or positive BAMT result should be evaluated for treatment of LTBI, regardless of age. The majority of persons who are infected with *M. tuberculosis* will have a positive TST result within 6 weeks of exposure (74,228,369–371). Therefore, contacts of patients with drug-susceptible TB disease with negative TST (or BAMT) results should be retested 8–10 weeks after the end of exposure to a patient with suspected or confirmed TB disease. Persons infected with *M. tuberculosis* should be advised that they possibly can be reinfected with *M. tuberculosis* if re-exposed (246,372–375). Persons infected with HIV, persons receiving immunosuppressive therapy, regardless of TST result, and persons with a previous positive TST or BAMT result who are close contacts of a person with suspected or confirmed TB disease should be considered for treatment of LTBI.

The interpretation of TST results is more complicated in a contact investigation among HCWs who have negative baseline TST results from two-step testing but where the induration was >0 mm on the baseline TST or subsequent serial testing. Differences in the TST results between the contact investigation and previous baseline and serial TST could be a result of 1) inter-test variability in reaction size; 2) intervening exposure to NTM, BCG, or *M. tuberculosis*; and 3) reversion. In practice, for TST, only inter-test variability and exposure to or infection with NTM or *M. tuberculosis* are likely.

Treatment of LTBI should not be started until a diagnosis of TB disease has been excluded. If uncertainty exists concerning the presence of TB disease because of an ambiguous chest radiograph, a standard multidrug antituberculosis treatment regimen can be started and adjusted as necessary based on the results of sputum cultures and the patient's clinical response (31). If cultures are

obtained without initiating therapy, treatment for LTBI should not be initiated until culture results are reported as negative.

Contacts of patients with drug-resistant TB disease. Treatment for LTBI caused by drug-resistant or MDR TB disease is complex and should be conducted in consultation with the local or state health department's infection-control program and experts in the medical management of drug-resistant TB. In certain instances, medical decision making for the person with LTBI will benefit from the results of drug susceptibility testing of the isolate of the index TB case. Treatment should be guided by susceptibility test results from the isolate to which the patient was exposed and presumed to be infected (31,376,377).

Pretreatment Evaluation and Monitoring of Treatment

The pretreatment evaluation of persons who are targeted for treatment of LTBI provides an opportunity for health-care providers to 1) establish rapport with patients; 2) discuss details of the patient's risk for progression from LTBI to TB disease; 3) explain the benefits of treatment and the importance of adhering to the drug regimen; 4) review possible adverse effects of the regimen, including interactions with other medications; and 5) establish an optimal follow-up plan.

Monitoring for adverse effects of antituberculosis medications must be individualized. Persons receiving treatment for LTBI should be specifically instructed to look for symptoms associated with the most common reactions to the medications they are taking (39). Laboratory testing should be performed to evaluate possible adverse effects (31,39). Routine laboratory monitoring during treatment of LTBI is indicated for patients with abnormal baseline test results and for persons with a risk for hepatic disease. Baseline laboratory testing is indicated for persons infected with HIV, pregnant women, women in the immediate postpartum period (usually within 3 months of delivery), persons with a history of liver disease, persons who use alcohol regularly, and those who have or are at risk for chronic liver disease.

All patients being treated for LTBI should be clinically monitored at least monthly, including a brief clinical assessment conducted in the person's primary language for signs of hepatitis (e.g., nausea, vomiting, abdominal pain, jaundice, and yellow or brown urine). Patients receiving treatment for LTBI should be advised about the adverse effects of the drugs and the need for prompt cessation of treatment and clinical evaluation if adverse effects occur.

Because of the risk for serious hepatic toxicity and death, the use of the combination of RZ for the treatment of LTBI generally should not be offered. If RZ is used, a physician with experience treating LTBI and TB disease should be consulted before the use of this regimen. In addition, more extensive biochemical and clinical monitoring is recommended (240).

Treatment for TB Disease

Suspected or confirmed TB cases must be reported to the local or state health department in accordance with laws and regulations. Case management for TB disease should be coordinated with officials of the local or state health department. Regimens for treatment of TB disease must contain multiple drugs to which the organisms are susceptible. For persons with TB disease, treatment with a single drug can lead to the development of mycobacterial resistance to that drug. Similarly, adding a single drug to a failing antituberculosis treatment regimen can lead to resistance to the added drug (31).

For the majority of patients, the preferred regimen for treating TB disease consists of an initiation 2-month phase of four drugs (INH, rifampin, pyrazinamide, and ethambutol) and at least a 4-month continuation phase of INH and rifampin (for a minimum total treatment of 6 months). Ethambutol may be discontinued if supporting drug susceptibility results are available. Completion of therapy is based on the number of doses taken within a maximal period and not simply 6 months (31). Persons with cavitary pulmonary TB disease and positive culture results of sputum specimens at the completion of 2 months of therapy should receive a longer (7-month continuation) phase because of the significantly higher rate of relapse (31).

TB treatment regimens might need to be altered for persons infected with HIV who are on ART (49). Whenever feasible, the care of persons with both TB disease and HIV infection should be provided by or in consultation with experts in the management of both TB and HIV-related disease (31). To prevent the emergence of rifampin-resistant organisms, persons with TB disease, HIV infection, and CD4 cell counts of <100 cells/mm³ should not be treated with highly intermittent (i.e., once or twice weekly) regimens. These patients should receive daily treatment during the intensive phase by DOT (if feasible) and daily or three times weekly by DOT during the continuation phase (378). Detailed information on TB treatment for persons infected with HIV has been published and is available (http://www.dhfs.state.wi.us/AIDS-HIV/Resources/Overviews/AIDS_HIV.htm , <http://www.hiv-druginteractions.org> , and http://www.cdc.gov/nchstp/tb/TB_HIV_Drugs/TOC.htm) and published (31,53).

Drug-susceptibility testing should be performed on all initial isolates from patients with TB disease. When results from drug-susceptibility tests become available, the antituberculosis treatment regimen should be reassessed, and the drugs used in combination should be adjusted accordingly (376,377,379–381). If drug resistance is present, clinicians who are not experts in the management of patients with drug-resistant TB disease should seek expert consultation (31) and collaborate with the local or state health department for treatment decisions.

The major determinant of the outcome of treatment is adherence to the drug regimen. Therefore, careful attention should be paid to measures designed to enable and foster adherence (31,319,382). DOT is an adherence-enhancing strategy in which a trained HCW or other specially trained person watches a patient swallow each dose of medication and records the dates that the DOT was observed. DOT is the standard of care for all patients with TB disease and should be used for all doses during the course of therapy for TB disease and for LTBI, whenever feasible. Plans for DOT should be coordinated with the local or state health department (31).

Reporting Serious Adverse Events

HCWs should report serious adverse events associated with the administration of tuberculin antigen or treatment of LTBI or TB disease to the FDA MedWatch, Adverse Event Reporting System (AERS), telephone: 800-FDA-1088, fax: 800-FDA-0178, <http://www.fda.gov/medwatch> . Report Form 3500, Physicians' Desk Reference. Specific instructions for the types of adverse events that should be reported are included in MedWatch report forms.

Surveillance and Detection of *M. tuberculosis* Infections in Health-Care Settings

TB disease should be considered for any patient who has symptoms or signs of disease, including coughing for ≥ 3 weeks, loss of appetite, unexplained weight loss, night sweats, bloody sputum or hemoptysis, hoarseness, fever, fatigue, or chest pain. The index of suspicion for TB disease will vary by individual risk factors, geographic area, and prevalence of TB disease in the population served by the health-care setting. Persons exposed to patients with infectious TB disease might acquire LTBI, depending on host immunity and the degree and duration of exposure. Diagnostic tests for TB disease include chest radiography and laboratory tests of sputum (examination for AFB and culture). The treatment of persons with TB disease involves vital aspects of TB control by stopping transmission of *M. tuberculosis* and preventing persons with LTBI from developing infectious TB disease (36).

In the majority of the U.S. population, targeted testing for LTBI and TB disease is performed to identify persons with LTBI and TB disease who would benefit from treatment. Therefore, all testing activities should be accompanied by a plan for follow-up care of persons with LTBI or TB disease. A decision to test for infection with *M. tuberculosis* should be based on a commitment to treat LTBI after a medical examination (39). Health-care agencies or other settings should consult with the local or state health department before starting a program to test HCWs for *M. tuberculosis* infection. This step ensures that adequate provisions are in place for the evaluation and treatment of persons whose test results are positive, including the medical supervision of the course of treatment for those who are treated for LTBI or TB disease.

Groups that are not at high risk for LTBI or TB disease should not be tested routinely because testing in populations at low risk diverts resources from other priority activities. In addition, testing persons at low risk for *M. tuberculosis* infection is discouraged because a substantial proportion of persons from populations at low risk who have positive TST results might actually have false-positive TST results and might not represent true infection with *M. tuberculosis* (39,316). Testing for infection with *M. tuberculosis* should be performed for well-defined groups at high risk. These groups can be divided into two categories: 1) persons at higher risk for exposure to and infection with *M. tuberculosis* and 2) persons at higher risk for progression from LTBI to TB disease (see TB Infection-Control Program for Settings in Which Patients with Suspected or Confirmed TB Disease Are Expected To Be Encountered; and TB Infection-Control Program for Settings in Which Patients with Suspected or Confirmed TB Disease Are Not Expected To Be Encountered).

Flexibility is needed in defining high-priority groups for TB screening. The changing epidemiology of TB indicates that the risk for TB among groups currently considered as high priority might decrease over time, and groups currently not identified originally as being at high risk might be considered as high priority.

Baseline Testing with BAMT

For the purposes of establishing a baseline, a single negative BAMT result is sufficient evidence that the HCW is probably not infected with *M. tuberculosis* ([Box 2](#)). However, cautions regarding making medical care decisions for persons whose conditions are at increased risk for progressing to TB disease from *M. tuberculosis* infection have been presented ([Box 4](#)).

If BAMT is used for baseline testing of HCWs, including those in settings that are low risk, one negative BAMT result is sufficient to demonstrate that the HCW is not infected with *M. tuberculosis* ([Box 2](#)). Perform and document the baseline BAMT result preferably within 10 days of starting employment. HCWs with positive baseline results should be referred for a medical and diagnostic evaluation to exclude TB disease and then treatment for LTBI should be considered in accordance with CDC guidelines. Persons with a positive BAMT result do not need to be tested again for surveillance. For HCWs who have indeterminate test results, providers should consult the responsible laboratorian for advice on interpreting the result and making additional decisions (383).

Serial Testing with BAMT for Infection-Control Surveillance

When using BAMT for serial testing, a conversion for administrative purposes is a change from a negative to a positive result ([Box 3](#)). For HCWs who have indeterminate test results, providers should consult the responsible laboratorian for advice on interpreting the result and making additional decisions (383). Persons with indeterminate results should not be counted for administrative calculations of conversion rates.

Exposure of HCWs and Patients to *M. tuberculosis*

Known and Presumed Exposure

For HCWs with known and presumed exposure to *M. tuberculosis*, administer a symptom screen and obtain the BAMT result. A BAMT conversion probably indicates recent *M. tuberculosis* infection; therefore, TB disease must be excluded. Experience with BAMT in contact investigations is limited. Specific attention is needed in the management of certain populations (e.g., infants and children aged <4 years and immunocompromised persons, including those who are HIV-infected) ([Box 4](#)).

If the symptom screen or the BAMT result is positive, the exposed person should be evaluated for TB disease promptly, which includes a chest radiograph. If TB disease is excluded, additional medical and diagnostic evaluation for LTBI is needed, which includes a judgment regarding the extent of exposure.

Performing QFT-G

The QFT-G should be performed as described in the product insert provided with the BAMT kit. This insert is also available from the manufacturer's website (<http://www.cellestis.com> [↗](#)).

Interpretation of BAMT Results and Referral for Evaluation

HCWs who meet the criteria for referral should have a medical and diagnostic evaluation (see Supplements, Estimating the Infectiousness of a TB Patient; Diagnostic Procedures for LTBI and TB Disease; and Treatment Procedures for LTBI and TB Disease). The factors affecting treatment decisions during medical and diagnostic evaluation by risk for infection with *M. tuberculosis* have been presented ([Box 5](#)). In addition, because BAMT and other indirect tests for *M. tuberculosis* infection are diagnostic aids, the test results must be interpreted in the context of epidemiologic, historical, physical, and diagnostic findings. A higher likelihood of infection, as estimated from historical or epidemiologic details (e.g., exposure to *M. tuberculosis*) or because of the presence of an illness consistent with TB disease, increases the predictive value of a positive result. Setting-based risk factors (e.g., the prevalence of TB disease in the setting) should be considered when making decisions regarding the diagnosis and treatment of LTBI.

Medical conditions that impair or alter immune function ([Box 4](#)) decrease the predictive value of a negative result, and additional diagnostic methods (e.g., bacteriology, radiography, and histology) are required as evidence before excluding *M. tuberculosis* infection when the BAMT result is negative. Medical evaluations can occur in different settings, including an occupational health clinic, local or state health department, hospital, or private medical clinic.

Indeterminate QFT-G results are reported for either of two test conditions.

- The IFN- γ responses to all antigens (ESAT-6, CFP-10, and mitogen) are below a cut-off threshold. The weak response to mitogen could be caused by nonstandard storage or transportation of the blood sample, by laboratory errors, or by lymphocytic insensitivity caused by immune dysfunction.

OR,

- The IFN- γ response to the Nil exceeds a specified threshold, and the responses to both ESAT-6 and CFP-10 do not exceed the response to Nil by at least 50%. This response could be caused by nonstandard storage or transportation, laboratory errors, or circulating IFN- γ , which can be increased in ill HCWs or patients. For HCWs who have indeterminate test results, providers should consult the responsible laboratorian for advice on interpreting the result and making further decisions (383).

Interpreting the BAMT Result for Infection Control and Surveillance

BAMT conversion rates should be determined routinely. The precision of the BAMT conversion rate will depend, in part, on the number of HCWs tested, which should be considered when establishing a regular interval for evaluation and monitoring of HCWs with BAMT. Health-care settings with a substantial number of HCWs might have testing schedules that can accurately determine the BAMT conversion rate each month (i.e., from annual results of an HCW cohort tested within the given month), if testing is staggered throughout the year. BAMT conversion rates are more difficult to calculate in settings with fewer test results.

QC Program for the BAMT

Multiple processes are necessary to assure quality BAMT results: specimen collection, transport and handling, and conducting the test in the laboratory. BAMT must meet performance parameters for a valid test result to be achieved. QC is an ongoing laboratory issue. The infection-control team should assist the laboratory in assuring that all requisite conditions are present. The laboratory performing the BAMT will be required to validate its performance of the test before processing clinical samples. State and federal laboratory requirements regulate laboratory-testing procedures.

Additional Considerations

An indeterminate QFT-G result does not mean that the test has failed; it indicates that the specimen has inadequate responsiveness for the test to be performed. This result might reflect the condition of the HCW or patient, who, for example, might be immunosuppressed. Alternatively, the specimen

might have been handled incorrectly. For HCWs who have indeterminate test results, providers should consult the responsible laboratorian for advice on interpreting the result and making further decisions (383). Skin testing for cutaneous anergy is not useful in screening for asymptomatic LTBI or for diagnosing TB disease (339).

QFT-G use with HIV-infected persons taking ART. The effect of HIV infection and of ART on the performance of the QFT-G have not been fully evaluated.

Persons aged <17 years or pregnant women. The use of the QFT-G has not been evaluated in persons aged <17 years or pregnant women (35).

Booster phenomenon and BAMT. BAMT does not involve the injection of any substance into the persons being tested and is not affected by the booster phenomenon.

BCG vaccination. In the United States, vaccination with BCG is not routinely recommended (227). However, BCG is the most commonly used vaccine in the world. Foreign-born persons are commonly employed in the United States as HCWs. Previous BCG vaccination is not a contraindication to having a BAMT performed. BCG does not influence BAMT results with the version of the test approved in 2005 (i.e., QFT-G). HCWs who have received BCG vaccination should receive a baseline BAMT in the same manner as those without BCG vaccination, and the test result should be interpreted without reference to BCG.

Environmental Controls

Overview

Environmental controls include the following technologies to remove or inactivate *M. tuberculosis*: local exhaust ventilation, general ventilation, HEPA filtration, and UVGI. These controls help to prevent the spread and reduce the concentration of airborne infectious droplet nuclei. Environmental controls are the second line of defense in the TB infection-control program, and they work in harmony with administrative controls.

The reduction of exposures to *M. tuberculosis* can be facilitated through the effective use of environmental controls at the source of exposure (e.g., coughing patient or laboratory specimen) or in the general workplace environment. Source control is amenable to situations where the source has been identified and the generation of the contaminant is localized. Source-control techniques can prevent or reduce the spread of infectious droplet nuclei into the air by collecting infectious particles as they are released. These techniques are especially critical during procedures that will probably generate infectious aerosols (e.g., bronchoscopy, sputum induction, endotracheal intubation, suctioning, irrigating TB abscesses, aerosol treatments, autopsies on cadavers with untreated TB disease, and certain laboratory specimen manipulations) and when patients with infectious TB disease are coughing or sneezing.

Unsuspected and undiagnosed cases of infectious TB disease are believed to represent a substantial proportion of the current risk to HCWs (10,85). In such situations, source control is not a feasible option. Instead, general ventilation and air cleaning must be relied upon for control. General ventilation can be used to dilute the air and remove air contaminants and to control airflow patterns in rooms or in a health-care setting. Air-cleaning technologies include HEPA filtration to reduce the concentration of *M. tuberculosis* droplet nuclei and UVGI to kill or inactivate the microorganisms so that they no longer pose a risk for infection.

Ventilation systems for health-care settings should be designed, and modified when necessary, by ventilation engineers in collaboration with infection-control practitioners and occupational health staff. Recommendations for designing and operating ventilation systems have been published (117,118,178). The multiple types and conditions for use of ventilation systems in health-care settings and the needs of persons in these settings preclude the provision of extensive guidance in this document.

The information in this section is conceptual and intended to educate HCWs regarding environmental controls and how these controls can be used in the TB infection-control program. This information should not be used in place of consultation with experts who can give advice on ventilation system design, selection, installation, and maintenance. Because environmental controls will fail if they are not properly operated and maintained, routine training and education of staff are key components to a successful TB infection-control program. These guidelines do not specifically address mechanical ventilators in detail (see Intensive Care Units [ICUs]).

Local Exhaust Ventilation

Local exhaust ventilation captures airborne contaminants at or near their source and removes the contaminants without exposing persons in the area to infectious agents. This method is considered the most efficient way to remove airborne contaminants because it captures them before they can disperse. In local exhaust devices, hoods are typically used. Two types of hoods are 1) enclosing devices, in which the hood either partially or fully encloses the infectious source; and 2) exterior devices, in which the infectious source is near but outside the hood. Fully enclosed hoods, booths, or tents are always preferable to exterior devices because of their superior ability to prevent contaminants from escaping into the HCW's breathing space. Descriptions of both enclosing and exterior devices have been published (178).

Enclosing Devices

Enclosing devices for local exhaust ventilation include 1) booths for sputum induction or administration of aerosolized medications ([Figure 2](#)), 2) tents or hoods for enclosing and isolating a patient, and 3) BSCs (165). These devices are available in various configurations. The simplest device is a tent placed over the patient; the tent has an exhaust connection to the room-discharge exhaust system. The most complex device is an enclosure with a self-contained airflow and recirculation system ([Figure 2](#)).

Tents and booths should have sufficient airflow to remove at least 99% of airborne particles during the interval between the departure of one patient and the arrival of the next ([Table 1](#)). The time required to remove 99% or 99.9% of airborne particles from an enclosed space depends on 1) the number of ACH, which is a function of the volume (number of cubic feet of air) in the room or booth and the rate at which air is exiting the room or booth at the intake source; 2) the location of the ventilation inlet and outlet; and 3) the configuration of the room or booth. The surfaces of tents and booths should be periodically cleaned in accordance with recommendations and guidance from the manufacturers (see Supplement, Cleaning, Disinfecting, and Sterilizing Patient-Care Equipment and Rooms).

Exterior Devices

Exterior devices for local exhaust ventilation are usually hoods that are near to but not enclosing an infectious patient. The airflow produced by these devices should be sufficient to prevent cross-currents of air near the patient's face from allowing droplet nuclei to escape. Whenever possible, the patient should face directly into the opening of the hood to direct any coughing or sneezing into the hood. The device should maintain an air velocity of 200 feet per minute (fpm) at the patient's breathing zone to ensure the capture of droplet nuclei. Smoke tubes should be used to verify that the control velocity at the typical location of the patient's breathing zone is adequate to provide capture for the condition of highest expected cross-drafts and then the patient's breathing zone should be maintained at this location for the duration of the treatment.

Discharge of Exhaust from Booths, Tents, and Hoods

Air from booths, tents, and hoods is either discharged into the room in which the device is located or to the outside. If the exhaust air is discharged into the room, a HEPA filter should be incorporated at the discharge duct or vent of the device. The exhaust fan should be located on the discharge side of the HEPA filter to ensure that the air pressure in the filter housing and booth is negative compared with adjacent areas. Uncontaminated air from the room will flow into the booth through all openings, preventing infectious droplet nuclei in the booth from escaping into the room. Additional information

on the installation, maintenance, and monitoring of HEPA filters is included in this report ([Appendix A](#)).

The majority of commercially available booths, tents, and hoods are fitted with HEPA filters; additional HEPA filtration is not needed with these devices. If a device does not incorporate a HEPA filter, the air from the device should be exhausted directly to the outside and away from air-intake vents, persons, and animals, in accordance with applicable federal, state, and local regulations on environmental discharges.

General Ventilation

General ventilation is used to 1) dilute and remove contaminated air, 2) control the direction of airflow in a health-care setting, and 3) control airflow patterns in rooms.

Dilution and Removal of Contaminated Air

General ventilation maintains air quality by both air dilution and removal of airborne contaminants. Uncontaminated supply air mixes with contaminated room air (dilution), and air is subsequently removed from the room by the exhaust system (removal). These processes reduce the concentration of droplet nuclei in the room air.

Ventilation systems for air dilution and removal. Two types of general ventilation systems are used to dilute and remove contaminated air: single-pass air systems and recirculating air systems.

In a single-pass air system, the supply air is either outside air that has been heated or cooled or air that is uncontaminated from a central system that supplies multiple areas. After air passes through the room or area, 100% of the air is exhausted to the outside. A single-pass system is the preferred choice for an AII room because the system prevents contaminated air from being recirculated to other areas of the health-care setting. In a recirculating air system, a limited portion of the exhaust air is discharged directly to the outside and replaced with fresh outside air, which mixes with the portion of exhaust air that was not discharged. If the resulting air mixture is not treated, it can contain a substantial proportion of contaminated air when it is recirculated to areas serviced by the system. This air mixture can be recirculated into the general ventilation, and infectious particles can be carried from contaminated areas to uncontaminated areas. Alternatively, the air mixture could be recirculated in a specific room or area so that other areas are not affected. The use of air-cleaning technologies for removing or inactivating infectious particles in recirculated air systems has been discussed ([Appendix A](#)).

Delivery of general ventilation. General ventilation is delivered by either constant air volume (CAV) systems or VAV systems. In general, CAV systems are best for AII rooms and other negative-pressure rooms because the negative-pressure differential is easier to maintain. VAV systems are acceptable if provisions are made to maintain the minimum mechanical and outside ACH and a negative pressure ≥ 0.01 inch of water gauge compared with adjacent areas at all times.

Ventilation rates. Recommended ventilation rates (air change rates) for health-care settings are usually expressed in numbers of ACH, which is the ratio of the volume of air entering the room per hour to the room volume. ACH equals the exhaust airflow (Q cubic feet per minute [cfm]) divided by the room volume (V cubic feet) multiplied by 60.

$$\text{ACH} = (Q \div V) \times 60$$

Ventilation recommendations for selected areas in new or renovated health-care settings have been presented ([Table 2](#)). These recommendations have been adapted from those published by AIA (118). The feasibility of achieving a specific ventilation rate depends on the construction and operational requirements of the ventilation system and might differ for retrofitted and newly constructed facilities. The expense and effort of achieving a high ventilation rate might be reasonable for new construction but less reasonable when retrofitting an existing setting.

In existing settings, air-cleaning technologies (e.g., fixed or portable room-air recirculation units [also called portable air cleaners] or UVGI) can be used to increase the equivalent ACH. This equivalent

ventilation concept has been used to compare microbial inactivation by UVGI with particle-removal by mechanical ventilation (384,385) and to compare particle removal by HEPA filtration of recirculated air with particle removal by mechanical ventilation. The equivalent ventilation approach does not, however, negate the requirement to provide sufficient fresh outside air for occupant comfort ([Table 2](#)).

To dilute the concentration of normal room-air contaminants and minimize odors, a portion of the supply air should come from the outdoors ([Table 2](#)). Health-care settings should consult the American Society of Heating, Refrigerating, and Air-Conditioning Engineers, Inc. (ASHRAE), Standard 62.1, Ventilation for Acceptable Indoor Air Quality, for outside air recommendations in areas not listed in this report (386).

Control of Airflow Direction in a Health-Care Setting

Airflow direction is controlled in health-care settings to contain contaminated air and prevent its spread to uncontaminated areas.

Directional airflow. The general ventilation system should be designed and balanced so that air flows from less contaminated (more clean) to more contaminated (less clean) areas (118,117). For example, air should flow from corridors (cleaner areas) into AII rooms (less clean areas) to prevent the spread of contaminants. In certain rooms in which surgical and invasive procedures are performed and in protective environment (PE) rooms, the direction of airflow should be from the room to the hallway. Environmental control recommendations for situations involving the care and treatment of patients with TB disease in ORs and PE rooms have been presented (see Other Selected Settings). Cough-inducing or aerosol-generating procedures should not be performed on patients with suspected or confirmed TB disease in rooms where air flows from the room to the hallway.

Negative pressure for achieving directional airflow. The direction of airflow is controlled by creating a lower (negative) pressure in the area into which the flow of air is desired. Negative pressure is the approximate air-pressure difference between two areas in a health-care setting. For air to flow from one area to another, the air pressure in the two areas must be different. Air will flow from a higher pressure area to a lower pressure area. A room that is under negative pressure has a lower pressure than adjacent areas, which keeps air flowing from the adjacent rooms or areas into the room. Negative pressure is achieved by exhausting air at a higher volumetric rate than the rate that the air is being supplied.

Control of Airflow Patterns in Rooms

General ventilation systems should be designed to provide controlled patterns of airflow in rooms and to prevent air stagnation or short-circuiting of air from the supply to the exhaust (i.e., passage of air directly from the air supply to the exhaust). To provide controlled airflow patterns, the air supply and exhaust should be located so that clean air flows first to parts of the room where HCWs probably work and then across the infectious source and into the exhaust. Therefore, HCWs are not positioned between the infectious source and the exhaust. This configuration is not always possible but should be used whenever feasible.

One way to achieve a controlled airflow pattern is to supply air at the side of the room opposite the patient and exhaust it from the side where the patient is located ([Figure 3](#)). Another method, which is most effective when the supply air is cooler than the room air, is to supply air near the ceiling and exhaust it near the floor ([Figure 3](#)). Care must be taken to ensure that furniture or moveable equipment does not block the low exhausts. Airflow patterns are affected by air temperature differentials, location of the supply diffusers and exhaust grilles, location of furniture, movement of HCWs and patients, and the configuration of the space.

If the room ventilation is not designed for a plug-flow type of airflow pattern ([Figure 3](#)), then adequate mixing must be maintained to minimize air stagnation. The majority of rooms with properly installed supply diffusers and exhaust grilles will have adequate mixing. A qualitative measure of mixing is the visualization of air movement with smoke tubes at multiple locations in the room.

Smoke movement in all areas of the room indicates good mixing. Additional sophisticated studies can be conducted by using a tracer gas to quantify air-mixing and air-exchange rates.

If areas of air stagnation are present, air mixing can be improved by adding a circulating fan or repositioning the supply and exhaust vents. Room-air recirculation units positioned in the room or installed above the ceiling can also improve air mixing. If supply or exhaust vents, circulating fans, or room-air recirculation units are placed incorrectly, HCWs might not be adequately protected.

Achieving Negative Pressure in Rooms

Negative pressure is needed to control the direction of airflow between selected rooms in a health-care setting and their adjacent spaces to prevent contaminated air from escaping from the room into other areas (118) (Figure 4). Control of a room's differential airflow and total leakage area is critical to achieving and maintaining negative pressure. Differential airflow, differential pressure, and leakage area are interrelated. This relation is illustrated (Figure 4) and is expressed in an empirical equation (387).

$$A_E = 0.01138 * (\Delta Q^{1.170} / \Delta P^{0.602})$$

In the equation, AE is the leakage area in square inches; ΔQ is the differential airflow rate in cfm; and ΔP is the differential pressure drop in inches of water gauge. This empirical equation was used (Figure 4), which indicates that changing one parameter will influence one or both of the other parameters. For example, the control of differential pressure can frequently be improved by increasing the air tightness or seal of a room, maintaining the HVAC system, and ensuring continuous monitoring. In a room that is already substantially tight (e.g., with 10 square inches of leakage), however, a small change in differential pressure will have a substantial effect on differential airflow. Similarly, a room with a more substantial leakage area (e.g., 300 square inches of leakage) requires a higher differential airflow rate to achieve a pressure differential of 0.01 inch of water gauge. Reducing the leakage in a room with 300 square inches of leakage can help achieve a pressure differential of 0.01 inch of water gauge (Figure 4). If the leakage area is reduced to approximately 40 square inches, a pressure differential of 0.01 inch of water gauge can be achieved by exhausting approximately 100 cubic feet per minute (cfm) more air from the room than is supplied to the room.

Room leakage can occur through cracks or spaces near doors, windows, ceiling, and utility connections. Steps should be taken to minimize these leaks. Changes in the performance of the HVAC system will affect the pressure differential in a room and can potentially cause a negative-pressure room to become positive-pressure. Therefore, each of these parameters requires close monitoring to ensure that minor changes in the performance of the HVAC system do not adversely affect the entire system (388,389).

Pressure differential. To achieve negative pressure in a room that has a normally functioning ventilation system, first measure and balance the supply and exhaust airflows to achieve an exhaust flow higher than the supply flow. Next, measure the pressure differential across the closed door. Although the minimum pressure difference needed for airflow into a room is substantially small (approximately 0.001 inch of water gauge), a pressure differential of ≥ 0.01 inch of water gauge (≥ 2.5 Pascals [Pa]) is recommended. This higher pressure differential is easier to measure and offers a margin of safety for maintaining negative pressure as the pressure in surrounding areas changes because of the opening and closing of doors, operation of elevators, stack effect (rising of warm air, similar to a chimney), ventilation system fluctuations, and other factors. The higher pressurization value is consistent with the most recent AIA recommendations for airborne precautions in health-care settings (118) and is the generally accepted level of negative pressurization for microbiology and biomedical laboratories (390).

Opening doors and windows can substantially affect the negative pressure in an AII room. Infection-control criteria requires AII room windows and doors to remain closed, except when doors must be opened for persons to enter or leave the room. Keeping certain doors in the corridor outside the AII rooms closed might be necessary to maintain the negative-pressure differential between an AII room and the corridor. Pressurization cannot be maintained in rooms or spaces that are not enclosed.

If ≥ 0.01 inch of water gauge is not achieved and cannot be achieved by increasing the flow differential (within the limits of the ventilation system), the room should be inspected for leakage. The total room leakage is based on the previously measured pressure, and air flow differentials can be estimated (Figure 4). If the room leakage is too substantial (e.g., 300 square inches), maintaining a negative-pressure differential as high as 0.01 inch of water gauge might be difficult. A lower value is acceptable if air-pressure monitoring indicates that negative pressure is always maintained (or airflow indicators consistently demonstrate that air is flowing in the desired direction). If negative pressure cannot be maintained, the leakage area might need to be reduced by sealing cracks around windows or replacing porous suspended ceiling panels with gasketed or sealed solid panels.

Because negative pressure in an AII room can be affected by even minimal changes in the operation of the ventilation system, negative pressure can be difficult to maintain with a VAV ventilation system. To maintain negative pressure, a VAV supply system should be coupled with a compensating exhaust system that increases when the supply flow rate increases. Alternatively, the exhaust can be set at a fixed rate that ensures negative pressure throughout the VAV supply cycle. The VAV minimum flow rate must also be adequate to maintain the recommended minimum mechanical and outdoor ACH (Table 2).

Alternate methods for achieving negative pressure. An anteroom is not a substitute for negative pressure in an AII room. However, an anteroom can reduce the escape of droplet nuclei during the opening and closing of the door to an AII room and can buffer an AII room from pressure fluctuations in the corridor. To function properly, an anteroom must have more air exhausted from the room than supplied to remove *M. tuberculosis* that can enter from the AII room. An anteroom can also have its own supply diffuser, if needed, to balance the pressure with the corridor. If an anteroom is unventilated or not properly ventilated, it will function only as a lesser contaminated vestibule between the AII room and the corridor and might not prevent the escape of droplet nuclei into the corridor. To adjust airflow and pressure differentials, health-care settings should consult a ventilation engineer who is knowledgeable regarding all applicable regulations, including building fire codes.

If the desired negative pressure cannot be achieved because a room does not have a separate ventilation system or a system that can provide the proper airflow, steps should be taken to provide a method to discharge air from an AII room. One method to achieve negative pressure in a room is to add a supplemental exhaust unit. If an AII room has a window or an outside wall, a small exhaust fan can be used. An engineer should be consulted to evaluate the potential for negative effects on surrounding areas (e.g., disruption of exhaust airflow in adjoining bathrooms) and to ensure the provision of the recommended amounts of outdoor air. The exhaust must not be discharged where it can immediately re-enter the building or pose a hazard to persons outside.

Fixed room-air recirculation systems (i.e., systems that recirculate the air in an entire AII room) can be designed to achieve negative pressure by discharging a portion of the air to the outside. Some portable room-air recirculation units are also designed to discharge air to the outside to achieve negative pressure. These air cleaners must be designed specifically for this purpose.

Monitoring negative pressure. Negative pressure must be monitored to ensure that air is always flowing from the corridor (or surrounding area) into the AII room. Negative pressure can be monitored either continuously or periodically. Monitoring methods include chemical aerosols (e.g., smoke tube), differential pressure-sensing devices (e.g., manometer), and physical indicators (e.g., flutter strips).

A chemical aerosol resembling smoke can be used to observe airflow between a room and the surrounding area, or within a room. Devices called smoke tubes generate the chemical aerosol resembling smoke, which follows the local air currents wherever it is released. To check the negative pressure in a room, hold a smoke tube approximately 2 inches in front of the base of the closed door of the AII room or in front of the air transfer grille, if the door has such a feature. Hold the smoke tube parallel to the door. A small amount of smoke should be generated slowly to ensure that the velocity of smoke emanating from the tube does not overpower the air velocity (Figure 5). If the room is under negative pressure, the smoke will travel into the room (from higher to lower pressure). If the

room is not under negative pressure, the smoke will be blown outward or stay in front of the door. Room air cleaners in the room should be operating. Persons using smoke tubes should avoid inhaling the smoke, because direct inhalation of high concentrations of the smoke can be irritating (391) (Figure 5).

Manometers are used to monitor negative pressure. They provide either periodic (noncontinuous) pressure measurements or continuous pressure monitoring. A continuous monitoring indicator can simply be a visible or audible warning signal indicating that air pressure is positive. Both periodic and continuous pressure detectors generate a digital or analog signal that can be recorded for later verification or used to automatically adjust the room's ventilation control system.

Physical indicators (e.g., flutter strips) are occasionally used to provide a continuous visual sign that a room is under negative pressure. These simple and inexpensive devices are placed directly in the door and can be useful in identifying a pressure differential problem.

Pressure-measuring devices should sense the pressure just inside the airflow path into the AII room (e.g., at the base of the door). Unusual airflow patterns can cause pressure variations. For example, the air can be under negative pressure at the middle of a door and under positive pressure at the base of the same door. The ideal location of a pressure-measuring device has been illustrated (Figure 6). If the pressure-sensing ports of the device cannot be located directly across the airflow path, validating that the negative pressure at the sensing point is and remains the same as the negative pressure across the flow path might be necessary.

Pressure-sensing devices should incorporate an audible warning with a time delay to indicate an open door. When a door is open, the negative pressure cannot be maintained, but this situation should not generate an alarm unless the door is left open. Therefore, the time delay should allow adequate time for persons to enter or leave an AII room without activating the alarm.

The pressure differentials used to achieve low negative pressure (<0.005 inch) require the use of substantially sensitive mechanical devices, electronic devices, or pressure gauges to ensure accurate measurements. Pressure-measuring and monitoring devices can give false readings if the calibration has drifted. For example, a sensor might indicate that the room pressure is slightly negative compared with the corridor, but, because air current momentum effects or "drift" of the electrical signal, air might actually be flowing out of the AII room through the opening at the base of the door. In one study of 38 AII rooms with electrical or mechanical devices to continuously monitor air pressurization, one half had airflow at the door in the opposite direction of that indicated by the continuous monitors (392). The investigators attributed this problem to instrument limitations and device malfunction. A negative pressure differential of ≥ 0.01 inch of water gauge (compared with the previously recommended 0.001 inch of water gauge) might help to minimize this problem.

Periodic checks are required to maintain the desired negative pressure and the optimal operation of monitoring devices.

- AII rooms should be checked for negative pressure before occupancy.
- When occupied by a patient, an AII room should be checked daily with smoke tubes or other visual checks for negative pressure.
- If pressure-sensing devices are used in AII rooms occupied by patients with suspected or confirmed TB disease, negative pressure should be checked daily by using smoke tubes or other visual checks.
- If the AII rooms are not being used for patients who have suspected or confirmed TB disease but potentially could be used for such patients, the negative pressure should be checked monthly.
- Laboratories should be checked daily for negative pressure.

AII Rooms and Other Negative-Pressure Rooms

AII rooms are used to 1) separate patients who probably have infectious TB from other persons, 2) provide an environment in which environmental factors are controlled to reduce the concentration of droplet nuclei, and 3) prevent the escape of droplet nuclei from such rooms into adjacent areas using

directional airflow. Other negative-pressure rooms include bronchoscopy suites, sputum induction rooms, selected examination and treatment rooms, autopsy suites, and clinical laboratories.

Preventing the escape of droplet nuclei. AII rooms used for TB isolation should be single-patient rooms with negative pressure, compared with the corridor or other areas connected to the room. Opening doors and windows can substantially affect the negative pressure in an AII room. Infection-control criteria require AII room windows and doors to remain closed, except when doors must be opened for persons to enter or leave the room. It might also be necessary to keep certain doors in the corridor outside the AII rooms closed to maintain the negative-pressure differential between an AII room and the corridor. The use of self-closing doors is recommended. The openings in the room (e.g., windows, and electrical and plumbing entries) should be sealed as much as possible, with the exception of a small gap (1/8–1/2 inch) at the base of the door to provide a controlled airflow path. Proper use of negative pressure will prevent contaminated air from escaping the room (393,394).

Reducing the concentration of droplet nuclei. AII rooms in existing health-care settings should have an air change rate of ≥ 6 mechanical ACH. Whenever feasible, this airflow rate should be increased to ≥ 12 mechanical ACH by adjusting or modifying the ventilation system or should be increased to ≥ 12 equivalent ACH by supplementing with air-cleaning technologies (e.g., fixed or portable room-air recirculation systems or UVGI systems). New construction or renovation of existing health-care settings should be designed so that AII rooms achieve a total air change rate of ≥ 12 mechanical ACH. These recommendations are consistent with guidelines by ASHRAE and AIA that recommend ≥ 12 mechanical ACH for AII rooms (117,118). Ventilation recommendations for other negative-pressure rooms in new or renovated health-care settings have been presented (see Risk Classification Examples).

To dilute the concentration of normal room air contaminants and minimize odors, a portion of the supply air should come from the outdoors. A minimum of 2 ACH of outdoor air should be provided to AII rooms and other negative-pressure rooms (117,118).

Exhaust from AII rooms and other negative-pressure rooms. Air from AII rooms and other negative-pressure rooms for patients with suspected or confirmed TB disease should be exhausted directly to the outside and away from air-intake vents, persons, and animals, in accordance with applicable federal, state, and local regulations on environmental discharges. Exhaust ducts should be located away from sidewalks or windows that can be opened. Ventilation system exhaust discharges and inlets should be designed to prevent the re-entry of exhausted air. Wind blowing over a building creates a substantially turbulent recirculation zone that can cause exhausted air to re-enter the building. Exhaust flow should be discharged above this zone. Design guidelines for proper placement of exhaust ducts have been published (395). If recirculation of air from such rooms into the general ventilation system is unavoidable, the air should be passed through a HEPA filter before recirculation.

Alternatives to negative-pressure rooms. AII can also be achieved by the use of negative-pressure enclosures (e.g., tents or booths). These enclosures can provide patient isolation in EDs and medical testing and treatment areas and can supplement AII in designated negative-pressure rooms.

Other Selected Settings

Operating rooms, autopsy suites, sputum-induction rooms, and aerosolized treatment rooms pose potential hazards from infectious aerosols generated during procedures on patients with TB disease (72,90,396–398). Recommended administrative, environmental, and respiratory-protection controls for these and other selected settings have been summarized ([Appendix A](#)). Additional or specialized TB infection controls that are applicable to special circumstances and types of health-care delivery settings have also been described (see Managing Patients Who Have Suspected or Confirmed TB Disease: Considerations for Special Circumstances and Settings). Ventilation recommendations for these settings in new or renovated health-care facilities have been included in this report ([Table 2](#)). Existing facilities might need to augment the current ventilation system or use the air-cleaning methods to increase the number of equivalent ACH.

Patients with TB disease who also require a PE room (e.g., severely immunocompromised patients) are special cases. These patients require protection from common airborne infectious microorganisms and must be placed in a room that has HEPA-filtered supply air and is under positive pressure compared with its surroundings (118). If an anteroom is not available, the use of other air-cleaning methods should be considered to increase the equivalent ACH. The air-cleaning systems can be placed in the room and in surrounding areas to minimize contamination of the surroundings. Similar controls can be used in ORs that are used for patients with TB disease because these rooms must be maintained under positive pressure, compared with their surroundings to maintain a sterile field.

Air-Cleaning Methods

HEPA Filtration

HEPA filtration can be used to supplement other recommended ventilation measures by providing a minimum removal efficiency of 99.97% of particles equal to 0.3 μm in diameter. This air-cleaning method is considered an adjunct to other ventilation measures. Used alone, this method neither provides outside air for occupant comfort nor satisfies other recommended ventilation measures (e.g., using source control whenever possible and minimizing the spread of contaminants in a setting through control of airflow patterns and pressure differentials).

HEPA filters have been demonstrated to reduce the concentration of *Aspergillus* spores (range in size: 5–6 μm) to below measurable levels (399–401). Because infective droplet nuclei generated by TB patients are believed to range from 1–5 μm in diameter (300) (comparable in size to *Aspergillus* spores) (402), HEPA filters will remove *M. tuberculosis*–containing infectious droplet nuclei from contaminated air. HEPA filters can be used to clean air before it is 1) exhausted to the outside, 2) recirculated to other areas of a health-care setting, or 3) recirculated in an AII room. Because electrostatic filters can degrade over time with exposure to humid environments and ambient aerosols (403), their use in systems that recirculate air back into the general ventilation system from AII rooms and treatment rooms should be avoided. If used, the filter manufacturer should be consulted regarding the performance of the filter to ensure that it maintains the desired filtration efficiency over time and with loading.

Use of HEPA filtration when exhausting air to the outside. HEPA filters can be used as an added safety measure to clean air from AII rooms and local exhaust devices (e.g., booths, tents, and hoods) before exhausting it to the outside. This added measure is not necessary, however, if the exhaust air cannot re-enter the ventilation system supply and does not pose a risk to persons and animals where it is exhausted.

Exhaust air frequently is not discharged directly to the outside; instead, the air is directed through heat-recovery devices (e.g., heat wheels or radiator-like devices). Heat wheels are frequently used to reduce the costs of operating ventilation systems (404). As the wheel rotates, energy is transferred into or removed from the supply inlet air stream. If a heat wheel is used with a system, a HEPA filter should also be used. The HEPA filter should be placed upstream from the heat wheel because of the potential for leakage across the seals separating the inlet and exhaust chambers and the theoretical possibility that droplet nuclei might be impacted on the wheel by the exhaust air and subsequently stripped off into the supply air.

Recirculation of HEPA-filtered air. Air from AII rooms and other negative-pressure rooms should be exhausted directly to the outside. In certain instances, however, recirculation of air into the general ventilation system from such rooms is unavoidable (e.g., settings in which the ventilation system or building configuration causes venting the exhaust to the outside impossible). In such cases, HEPA filters should be installed in the exhaust duct exiting the room to remove infectious organisms from the air before it is returned to the general ventilation system.

Individual room-air recirculation can be used in areas in which no general ventilation system exists, where an existing system is incapable of providing sufficient ACH, or where air-cleaning (particulate removal) is desired without affecting the fresh air supply or negative-pressure system. Recirculation

of HEPA-filtered air in a room can be achieved by 1) exhausting air from the room into a duct, passing it through a HEPA filter installed in the duct, and returning it to the room ([Figure 7](#)); 2) filtering air through HEPA recirculation systems installed on the wall or ceiling of the room ([Figure 8](#)); or 3) filtering air through portable HEPA recirculation systems. In this report, the first two approaches are referred to as fixed room-air recirculation systems because the recirculation systems are not easily movable.

Fixed room-air recirculation systems. The preferred method of recirculating HEPA-filtered air is by using a built-in system in which air is exhausted from the room into a duct, filtered through a HEPA filter, and returned to the room ([Figure 7](#)). This technique can add equivalent ACH in areas in which the recommended minimum ACH is difficult to meet with general ventilation. This equivalent ventilation concept compares particle removal by HEPA filtration of the recirculated air with particle clearance from exhaust ventilation. Because the air does not have to be conditioned, airflow rates that are higher than those produced by the general ventilation system can usually be achieved. An alternative is to install HEPA filtration units on the wall or ceiling ([Figure 8](#)).

Fixed recirculation systems are preferred to portable (free-standing) units because they can be installed with a higher degree of reliability. In addition, certain fixed systems have a higher airflow capacity than portable systems, and the potential for short-circuiting of air is reduced as the distance between the air intake and exhaust is increased.

Portable room-air recirculation systems. Portable room-air recirculation units with HEPA filters (also called portable air cleaners) can be considered when 1) a room has no general ventilation system, 2) the system cannot provide adequate ACH, or 3) increased effectiveness in airflow is needed. Effectiveness depends on the ability of the portable room-air recirculation unit to circulate as much of the air in the room as possible through the HEPA filter. Effectiveness can vary depending on the room's configuration, the furniture and persons in the room, the placement of the HEPA filtration unit compared with the supply diffusers and exhaust grilles, and the degree of mixing of air within the room.

Portable room-air recirculation units have been demonstrated to be effective in removing bioaerosols and aerosolized particles from room air (405–410). Findings indicate that various commercially available units are useful in reducing the concentration of airborne particles and are therefore helpful in reducing airborne disease transmission. The performance of 14 units was evaluated for volumetric airflow, airborne particle reduction, noise level, and other parameters (406). The range of volumetric airflow rates was 110 cfm–1,152 cfm, and the equivalent ACH range was an average of 8–22 in a standard-sized, substantially well-mixed, single-patient room. Recommendations were provided to make subsequent models safer, more effective, quieter, and easier to use and service. Purchasers should be aware that the majority of manufacturer specifications indicated flow rates of free-wheeling fans and not the fan under the load of a filter.

Portable HEPA filtration units should be designed to 1) achieve ≥ 12 equivalent ACH, 2) ensure adequate air mixing in all areas of the rooms, and 3) be compatible with the ventilation system. An estimate of the ability of the unit to circulate the air in a room can be made by visualizing airflow patterns (estimating room air mixing [see Supplements, Environmental Controls; and General Ventilation]). If the air movement is adequate in all areas of the room, the unit should be effective.

If portable devices are used, units with high volumetric airflow rates that provide maximum flow through the HEPA filter are preferred. Placement should be selected to optimize the recirculation of AII room air through the HEPA filter. Careful consideration must be given to obstacles (e.g., furnishings, medical equipment, and walls) that could disrupt airflow and to system specifications (e.g., physical dimensions, airflow capacity, locations of air inlet and exhaust, and noise) to maximize performance of the units, minimize short-circuiting of air, and reduce the probability that the units will be switched off by room occupants.

Installing, maintaining, and monitoring HEPA filters. The performance of HEPA filters depends on proper installation, testing, and meticulous maintenance (411), especially if the system

recirculates air to other parts of the health-care setting. Improper design, installation, or maintenance could allow infectious particles to circumvent filtration and escape into the general ventilation system (117). These failures also could impede proper ventilation performance.

HEPA filters should be installed to prevent leakage between filter segments and between the filter bed and its frame. A regularly scheduled maintenance program is required to monitor filters for possible leakage and filter loading. A quantitative filter performance test (e.g., the dioctyl phthalate penetration test [412,413]) should be performed at the initial installation and each time the filter is changed. Records should be maintained for all filter changes and testing. A leakage test using a particle counter or photometer should be performed every 6–12 months for filters in general-use areas and in areas with systems that will probably be contaminated with *M. tuberculosis* (e.g., AII rooms).

A manometer or other pressure-sensing device should be installed in the filter system to provide an accurate and objective means of determining the need for filter replacement. Pressure-drop characteristics of the filter are supplied by the manufacturer. Installation of the filter should allow for maintenance that will not contaminate the delivery system or the area served. For general infection-control purposes, special care should be taken to avoid jarring or dropping the filter element during or after removal.

The scheduled maintenance program should include procedures for installation, removal, and disposal of filter elements. HEPA filter maintenance should be performed only by adequately trained personnel and only while the ventilation system or room-air recirculation unit is not being operated.

Laboratory studies indicate that re-aerosolization of viable mycobacteria from filter material (HEPA filters and N95 disposable respirator filter media) is not probable under normal conditions (414–416). Although these studies indicate that *M. tuberculosis* becoming an airborne hazard is not probable after it is removed by a HEPA filter (or other high efficiency filter material), the risks associated with handling loaded HEPA filters in ventilation systems under field-use conditions have not been evaluated. Therefore, persons performing maintenance and replacing filters on any ventilation system that is probably contaminated with *M. tuberculosis* should wear a respirator (see Respiratory Protection) in addition to eye protection and gloves. When feasible, HEPA filters can be disinfected in 10% bleach solution or other appropriate mycobacteriacide before removal (417). In addition, filter housing and ducts leading to the housing should be labeled clearly with the words "TB-Contaminated Air" or other similar warnings. Disposal of filters and other potentially contaminated materials should be in accordance with applicable local or state regulations.

One or more lower-efficiency disposable pre-filters installed upstream can extend the life of a HEPA filter by at least 25%. If the disposable filter is replaced by a 90% extended surface filter, the life of the HEPA filter can be extended by approximately 900% (178). Pre-filters should be handled and disposed of in the same manner as the HEPA filter.

UVGI

Ultraviolet germicidal irradiation (UVGI) is a form of electromagnetic radiation with wavelengths between the blue region of the visible spectrum and the radiograph region. UV-C radiation (short wavelengths; range: 100–280 nm) (418) can be produced by various artificial sources (e.g., arc lamps and metal halide lamps). The majority of commercially available UV lamps used for germicidal purposes are low-pressure mercury vapor lamps that emit radiant energy in the UV-C range, predominantly at a wavelength of 253.7 nm (418).

Research has demonstrated that UVGI is effective in killing or inactivating *M. tuberculosis* under experimental conditions (292,385,419–423) and in reducing transmission of other infectious agents in hospitals (424), military housing (425), and classrooms (426–428). Because of the results of multiple studies (384,429–432) and the experiences of clinicians and mycobacteriologists during the preceding decades, UVGI has been recommended as a supplement or adjunct to other TB infection-control and ventilation measures in settings in which the need to kill or inactivate *M. tuberculosis* is

essential (6,7,196,433,434). UVGI alone does not provide outside air or circulate interior air, both of which are essential in achieving acceptable air quality in occupied spaces.

Applications of UVGI. UVGI is considered a method of air cleaning because it can kill or inactivate microorganisms so that they are no longer able to replicate and form colonies. UVGI is not a substitute for HEPA filtration before exhausting the air from AII rooms back into the general circulation. UVGI lamps can be placed in ducts, fixed or portable room air-recirculation units, or upper-air irradiation systems. The use of this air-cleaning technique has increased, particularly in substantial open areas in which unsuspected or undiagnosed patients with TB disease might be present (e.g., ED waiting rooms, shelters, and correctional facilities), and the costs of conditioning substantial volumes of outdoor air are prohibitive.

For each UVGI system, guidelines should be followed to maximize effectiveness. Effectiveness can be expressed in terms of an equivalent air change rate (427,435–437), comparing the ability of UVGI to inactivate organisms with removal through general ventilation. Initially, understanding and characterizing the application for which UVGI will be used is vital. Because the effectiveness of UVGI systems will vary, the use of UVGI must be carefully evaluated and the level of efficacy clearly defined and monitored.

The effective use of UVGI is associated with exposure of *M. tuberculosis*, as contained in an infectious droplet, to a sufficient dose of UV-C radiation at 253.7 nm to ensure inactivation. Because dose is a function of irradiance and time, the effectiveness of any application is determined by its ability to deliver sufficient irradiance for enough time to result in inactivation of the organism within the infectious droplet. Achieving a sufficient dose can be difficult with airborne inactivation because the exposure time can be substantially limited; therefore, attaining sufficient irradiance is essential.

The number of persons who are properly trained in the design and installation of UVGI systems is limited. One critical recommendation is that health-care facility managers consult a UVGI system designer to address safety and efficacy considerations before such a system is procured and installed. Experts who can be consulted include industrial hygienists, engineers, and health physicists.

Duct irradiation. Duct irradiation is designed to kill or inactivate *M. tuberculosis* without exposing persons to UVGI. In duct irradiation systems, UVGI lamps are placed inside ducts to disinfect the exhaust air from AII rooms or other areas in which *M. tuberculosis* might be present before it is recirculated to the same room (desirable) or to other areas served by the system (less desirable). When UVGI duct systems are not properly designed, installed, and maintained, high levels of UVGI can be produced in the duct that can potentially cause high UVGI exposures during maintenance operations.

Duct-irradiation systems depend on the circulation of as much of the room air as possible through the duct. Velocity profiles and mixing are important factors in determining the UVGI dose received by airborne particles. Design velocity for a typical UVGI unit is approximately 400 fpm (438). The particle residence time must be sufficient for inactivation of the microorganisms.

Duct irradiation can be used in three ways.

- Ventilation systems serving AII rooms to recirculate air from the room, through a duct containing UV lamps, and back into the same room. UVGI duct systems should not be used either in place of HEPA filters, if air from AII rooms must be recirculated to other areas of a setting, or as a substitute for HEPA filtration of air from booths, tents, or hoods used for cough-inducing or aerosol-generating procedures.
- Return air ducts serving patient rooms, waiting rooms, EDs, and general-use areas in which patients with undiagnosed TB disease could potentially contaminate the recirculated air.
- Recirculating ventilation systems serving rooms or areas in which ceiling heights are too low for the safe and effective use of upper-air UVGI.

Upper-air irradiation. In upper-air irradiation, UVGI lamp fixtures are suspended from the ceiling and installed on walls. The base of the lamps are shielded to direct the radiation upward and outward to create an intense zone of UVGI in the upper air while minimizing the levels of UVGI in the

lower part of the room where the occupants are located. The system depends on air mixing to move the air from the lower part of the room to the upper part where microbial-contaminated air can be irradiated.

A major consideration is the placement of UVGI fixtures to achieve sufficient irradiance of the upper-air space. The ceiling should be high enough (≥ 8 feet) for a substantial volume of upper air to be irradiated without overexposing occupants in the lower part of the room to UVGI. System designers must consider the mechanical ventilation system, room geometry, and emission characteristics of the entire fixture.

Upper-air UVGI can be used in various settings.

- All rooms and rooms in which aerosol-generating or aerosol-producing procedures (e.g., bronchoscopy, sputum induction, and administration of aerosolized medications) are performed.
- Patient rooms, waiting rooms, EDs, corridors, central areas, and other substantial areas in which patients with undiagnosed TB disease could potentially contaminate the air.
- Operating rooms and adjacent corridors where procedures are performed on patients with TB disease.
- Medical settings in correctional facilities.

Portable room air recirculation systems. In portable room air-recirculation units containing UVGI, a fan moves a volume of room air across UVGI lamps to disinfect the air before it is recirculated back to the room. Some portable units contain both a HEPA filter (or other high efficiency filter) and UVGI lamps.

In addition to the guidelines described for the use of portable room air-recirculation systems containing HEPA filtration, consideration must be given to the volume of room air that passes through the unit, the UVGI levels, particle residence time, and filtration efficiency (for devices with a filter). One study in which a bioaerosol chamber was used demonstrated that portable room air cleaners with UVGI lamps as the primary air-cleaning mechanism are effective ($>99\%$) in inactivating or killing airborne vegetative bacteria (439). Additional studies need to be performed in rooms with portable air cleaners that rely only on UVGI for air cleaning.

Portable room air cleaners with UVGI can be used in 1) All rooms as an adjunct method of air cleaning and 2) waiting rooms, EDs, corridors, central areas, or other substantial areas in which patients with undiagnosed TB disease could potentially contaminate the air.

Effectiveness of UVGI. Air mixing, air velocity, relative humidity, UVGI intensity, and lamp configuration affect the efficacy of all UVGI applications. For example, with upper-air systems, airborne microorganisms in the lower, occupied areas of the room must move to the upper part of the room to be killed or inactivated by upper-air UVGI. Air mixing can occur through convection caused by temperature differences, fans, location of supply and exhaust ducts, or movement of persons.

Air-mixing. UVGI has been demonstrated to be effective in killing bacteria in the upper-air applications under conditions in which air mixing was accomplished primarily by convection. In a 1976 study on aerosolization of *M. bovis* BCG (a surrogate for *M. tuberculosis*) in a room without mechanical ventilation that relied primarily on convection and infiltration resulted in 10–25 equivalent ACH, depending on the number of UVGI fixtures used (384). Other early studies examined the effect of air-mixing on UVGI efficacy (440,441). These studies indicated that the efficacy of UVGI was substantially increased if cold supply air relative to the lower portion of the room entered through diffusers in the ceiling. The findings indicated that substantial temperature gradients between the upper and lower portions of the room favored (cold air in the upper portion of the room) or inhibited (hot air in the upper portion of the room) vertical mixing of air between the two zones.

When large-bladed ceiling fans were used to promote mixing in the experimental room, the ability of UVGI to inactivate *Serratia marcescens*, an organism known to be highly sensitive to UVGI, was doubled (442,443). Similar effects were reported in studies conducted during 2000–2002 in which louvered UVGI fixtures were used. One study documented an increase in UVGI effectiveness of 16% at

2 ACH and 33% at 6 ACH when a mixing fan was used (444). Another study conducted in a simulated health-care room determined that 1) at 0 ACH, a high degree of efficacy of upper-air UVGI was achieved in the absence or presence of mixing fans when no temperature gradient was created; and 2) at 6 ACH, bringing in warm air at the ceiling resulted in a temperature gradient with cooler room air near the floor and a UVGI efficacy of only 9% (422). Turning on box fans under these winter conditions increased UVGI efficacy nearly 10-fold (to 89%) (445).

To reduce variability in upper-air UVGI efficacy caused by temperature gradients in the room, a fan should be routinely used to continually mix the air, unless the room has been determined to be well mixed under various conditions of operation. Use of a fan would also reduce or remove the variable winter versus summer ACH requirements for optimal upper-air UVGI efficacy (446).

Relative humidity. In studies conducted in bioaerosol chambers, the ability of UVGI to kill or inactivate microorganisms declined substantially when the relative humidity exceeded 60% (447–450). In room studies, declines in the ability of upper-air UVGI to kill or inactivate microorganisms at high relative humidity (65%, 75%, and 100%) (384,422) have also been reported. The exact mechanism responsible for the reduced effectiveness of UVGI at these higher levels of relative humidity is unknown but does not appear to be related to changes in UV irradiance levels. Relative humidity changes from 55%–90% resulted in no corresponding changes in measured UVGI levels (437). In another study, an increase in relative humidity from 25%–67% did not reduce UVGI levels (422). Bacteria have been demonstrated to absorb substantial amounts of water from the air as the relative humidity increases. At high humidity, the UV irradiance levels required to inactivate bacteria might approach the higher levels that are needed for liquid suspensions of bacteria (448). The ability of bacteria to repair UVGI damage to their DNA through photoreactivation has also been reported to increase as relative humidity increases (422,448).

For optimal efficacy of upper-air UVGI, relative humidity should be maintained at $\leq 60\%$, a level that is consistent with recommendations for providing acceptable indoor air quality and minimizing environmental microbial contamination in indoor environments (386,451).

Ventilation rates. The relation between ventilation and UVGI has also been evaluated. Certain predicted inactivation rates have been calculated and published for varying flow rates, UV intensity, and distances from the lamp, based on radiative heat transfer theory (438). In room studies with substantially well-mixed air, ventilation rates (0 ACH, 3 ACH, and 6 ACH) were combined with various irradiation levels of upper-air UVGI. All experiments were conducted at 50% relative humidity and 70° F (21.2° C). When *M. parafortuitum* was used as a surrogate for *M. tuberculosis*, ventilation rates usually had no adverse effect on the efficiency of upper-air UVGI. The combined effect of both environmental controls was primarily additive in this artificial environment, with possibly a small loss of upper-air UVGI efficiency at 6 ACH (422). Therefore, ventilation rates of up to 6 ACH in a substantially well-mixed room might achieve ≥ 12 ACH (mechanical ACH plus equivalent ACH) by combining these rates with the appropriate level of upper-air irradiation (422). Higher ventilation rates (>6 ACH) might, however, decrease the time the air is irradiated and, therefore, decrease the killing of bacteria (429,452).

Ventilation rates up to six mechanical ACH do not appear to adversely affect the performance of upper-air UVGI in a substantially well-mixed room. Additional studies are needed to examine the combined effects of mechanical ventilation and UVGI at higher room-air exchange rates.

UVGI intensity. UVGI intensity field plays a primary role in the performance of upper-air UVGI systems. The UVGI dose received by microorganisms is a function of UVGI times duration of exposure. Intensity is influenced by the lamp wattage, distance from the lamp, surface area, and presence of reflective surfaces. The number of lamps, location, and UVGI level needed in a room depends on the room's geometry, area, and volume, and the location of supply air diffusers (422,436). UVGI fixtures should be spaced to reduce overlap while maintaining an even irradiance zone in the upper air.

The emission profile of a fixture is a vital determinant of UVGI effectiveness. Information regarding total UVGI output for a given fixture (lamp plus housing and louvers) should be requested from the manufacturer and used for comparison when selecting UVGI systems. Information concerning only the UVGI output of the lamp is inadequate; the lamp output will be higher than the output for the fixture because of losses from reflectors and nonreflecting surfaces and the presence of louvers and other obstructions (436,437). In addition, information provided by the manufacturer reflects ideal laboratory conditions; damage to fixtures or improper installation will affect UV radiation output. Because old or dust-covered UVGI lamps are less effective, routine maintenance and cleaning of UVGI lamps and fixtures is essential. UVGI system designers should consider room geometry, fixture output, room ventilation, and the desired level of equivalent ACH in determining the types, numbers, and placement of UVGI fixtures in a room to achieve target irradiance levels in the upper air.

Health and safety issues. Short-term overexposure to UV radiation can cause erythema (i.e., abnormal redness of the skin), photokeratitis (inflammation of the cornea), and conjunctivitis (i.e., inflammation of the conjunctiva) (453). Symptoms of photokeratitis and conjunctivitis include a feeling of sand in the eyes, tearing, and sensitivity to light. Photokeratitis and conjunctivitis are reversible conditions, but they can be debilitating while they run their course. Because the health effects of UVGI are usually not evident until after exposure has ended (typically 6–12 hours later), HCWs might not recognize them as occupational injuries.

In 1992, UV-C (100–280 nm) radiation was classified by the International Agency for Research on Cancer as "probably carcinogenic to humans (Group 2A)" (454). This classification was based on studies indicating that UV-C radiation can induce skin cancers in animals and create DNA damage, chromosomal aberrations, and sister chromatid exchange and transformation in human cells in vitro. In addition, DNA damage in mammalian skin cells in vivo can be caused. In the animal studies, a contribution of UV-C radiation to the tumor effects could not be excluded, but the effects were higher than expected for UV-B radiation alone (454). Certain studies have demonstrated that UV radiation can activate HIV gene promoters (i.e., genes in HIV that prompt replication of the virus) in laboratory samples of human cells (455–460). The potential for UV-C radiation to cause cancer and promote HIV in humans is unknown, but skin penetration might be an important factor. According to certain reports, only 20% of incident 250 nm UV penetrates the stratum corneum, compared with approximately 30–60% of 300 nm UV (UV-B) radiation (461).

In upper-air UVGI systems, fixtures must be designed and installed to ensure that UVGI exposures to occupants are below current safe exposure levels. Health-hazard evaluations have identified potential problems at some settings using UVGI systems. These problems include overexposure of HCWs to UVGI and inadequate maintenance, training, labeling, and use of personal protective equipment (PPE) (398,462,463).

An improperly maintained (unshielded) germicidal lamp was believed to be the cause of dermatosis or photokeratitis in five HCWs in an ED (464) and three HCWs who were inadvertently exposed to an unshielded UVGI lamp in a room that had been converted from a sputum induction room to an office (465). These case reports highlight the importance of posting warning signs to identify the presence of UVGI (see Supplement, Labeling and Posting) and are reminders that shielding should be used to minimize UVGI exposures to occupants in the lower room. In the majority of applications, properly designed, installed, and maintained UVGI fixtures provide protection from the majority of, if not all, the direct UVGI in the lower room. However, radiation reflected from glass, polished metal, and high-gloss ceramic paints can be harmful to persons in the room, particularly if more than one UVGI fixture is in use. Surfaces in irradiated rooms that can reflect UVGI into occupied areas of the room should be covered with non-UV-reflecting material.

Although more studies need to be conducted, lightweight clothing made of tightly woven fabric and UV-absorbing sunscreens with solar-protection factors (SPFs) of ≥ 15 might help protect photosensitive persons. Plastic eyewear containing a UV inhibitor that prevents the transmission of $\geq 95\%$ of UV radiation in the 210–405 nm range is commercially available. HCWs should be advised

that any eye or skin irritation that develops after UVGI exposure should be evaluated by an occupational health professional.

Exposure criteria. In 1972, CDC published a recommended exposure limit (REL) for occupational exposure to UV radiation (453). REL is intended to protect HCWs from the acute effects of UV light exposure. Photosensitive persons and those exposed concomitantly to photoactive chemicals might not be protected by the recommended standard.

The CDC/NIOSH REL for UV radiation is wavelength dependent because different wavelengths have different adverse effects on the skin and eyes (453). At 254 nm, the predominant wavelength for germicidal UV lamps, the CDC/NIOSH REL is 0.006 joules per square centimeter (J/cm²) for a daily 8-hour work shift. ACGIH has a Threshold Limit Value(r) for UV radiation that is identical to the REL for this spectral region (466). HCWs frequently do not stay in one place in the setting during the course of their work and, therefore, are not exposed to UV irradiance levels for 8 hours. Permissible exposure times (PET) for HCWs with unprotected eyes and skin can be calculated for various irradiance levels as follows:

$$\text{PET (seconds)} = \frac{0.006 \text{ J/cm}^2 \text{ (CDC/NIOSH REL at 254 nm)}}{\text{Measured irradiance level (at 254 nm) in W/cm}^2}$$

Exposures exceeding the CDC/NIOSH REL require the use of PPE to protect the skin and eyes.

Labeling, Maintenance, and Monitoring

Labeling and posting. Health-care settings should post warning signs on UV lamps and wherever high-intensity (i.e., UVGI exposure greater than the REL) UVGI irradiation is present to alert maintenance staff, HCWs, and the general public of the hazard. The warning signs should be written in the languages of the affected persons ([Box 6](#)).

Maintenance. Because the UVGI output of the lamps declines with age, a schedule for replacing the lamps should be developed in accordance with manufacturer recommendations. The schedule can be determined from a time-use log, a system based on cumulative time, or routinely (e.g., at least annually). UVGI lamps should be checked monthly for dust build-up, which lessens radiation output. A dirty UVGI lamp should be allowed to cool and then should be cleaned in accordance with the manufacturer recommendations so that no residue remains.

UVGI lamps should be replaced if they stop glowing, if they flicker, or if the measured irradiance (see Supplement, Environmental Controls) drops below the performance criteria or minimum design criterion set forth by the design engineers. Maintenance personnel must switch off all UVGI lamps before entering the upper part of the room or before accessing ducts for any purpose. Only limited seconds of direct exposure to the intense UVGI in the upper-air space or in ducts can cause dermatosis or photokeratitis. Protective clothing and equipment (e.g., gloves, goggles, face shield, and sunscreen) should be worn if exposure greater than the recommended levels is possible or if UVGI radiation levels are unknown.

Banks of UVGI lamps can be installed in ventilation system ducts. Safety devices and lock-out or tag-out protocols should be used on access doors to eliminate exposures of maintenance personnel. For duct irradiation systems, the access door for servicing the lamps should have an inspection window through which the lamps are checked periodically for dust build-up and to ensure that they are functioning properly. The access door should have a warning sign written in appropriate languages to alert maintenance personnel to the health hazard of looking directly at bare UV lamps. The lock for this door should have an automatic electric switch or other device that turns off the lamps when the door is opened.

Types of fixtures used in upper-air irradiation include wall-mounted, corner-mounted, and ceiling-mounted fixtures that have louvers or baffles to block downward radiation and ceiling-mounted fixtures that have baffles to block radiation below the horizontal plane of the fixtures. If possible, light switches that can be locked should be used to prevent injury to persons who might unintentionally turn the lamps on during maintenance procedures. Because lamps must be discarded after use,

consideration should be given to selecting germicidal lamps that are manufactured with relatively low amounts (i.e., ≤ 5 mg) of mercury. UVGI products should be listed with the Underwriters Laboratories (UL) or Electrical Testing Laboratories (ETL) for their specific application and installed in accordance with the National Electric Code.

Monitoring. UVGI intensity should be measured by an industrial hygienist or other person knowledgeable in the use of UV radiometers with a detector designed to be most sensitive at 254 nm. Equipment used to measure UVGI should be maintained and calibrated on a regular schedule, as recommended by the manufacturer.

UVGI should be measured in the lower room to ensure that exposures to occupants are below levels that could result in acute skin and eye effects. The monitoring should consider typical duties and locations of the HCWs and should be done at eye level. At a minimum, UVGI levels should be measured at the time of initial installation and whenever fixtures are moved or other changes are made to the system that could affect UVGI. Changes to the room include those that might result in higher exposures to occupants (e.g., addition of UV-reflecting materials or painting of walls and ceiling). UVGI monitoring information, lamp maintenance, meter calibration, and lamp and fixture change-outs should be recorded.

UVGI measurements should also be made in the upper air to define the area that is being irradiated and determine if target irradiance levels are met (467). Measurements can be made using UVGI radiometers or other techniques (e.g., spherical actinometry), which measures the UVGI in an omnidirectional manner to estimate the energy to which microorganisms would be exposed (468). Because high levels of UVGI can be measured in the upper air, persons making the measurements should use adequate skin and eye protection. UVGI radiation levels close to the fixture source can have permissible exposure times on the order of seconds or minutes for HCWs with unprotected eyes and skin. Therefore, overexposures can occur with brief UVGI exposures in the upper air (or in ventilation system ducts where banks of unshielded UV lamps are placed) in HCWs who are not adequately protected.

Upper-air UVGI systems and portable room-air recirculation units. A study in 2002 examined the relation between three portable room-air recirculation units with different capture or inactivation mechanisms and an upper-air UVGI system in a simulated health-care room (409). The study determined that the equivalent ACH produced by the recirculation units and produced by the upper-air UVGI system were approximately additive. For example, one test using aerosolized *M. parafortuitum* provided an equivalent ACH for UVGI of 17 and an equivalent ACH for the recirculation unit of 11; the total experimentally measured equivalent ACH for the two systems was 27. Therefore, the use of portable room-air recirculation units in conjunction with upper-air UVGI systems might increase the overall removal of *M. tuberculosis* droplet nuclei from room air.

Environmental Controls: Program Concerns

To be most effective, environmental controls must be installed, operated, and maintained correctly. Ongoing maintenance is a critical part of infection control that should be addressed in the written TB infection-control plan. The plan should outline the responsibility and authority for maintenance and address staff training needs. At one hospital, improperly functioning ventilation controls were believed to be an important factor in the transmission of MDR TB disease to three patients and a correctional officer, three of whom died (469). In three other multihospital studies evaluating the performance of AII rooms, failure to routinely monitor air-pressure differentials or a failure of the continuous monitoring devices installed in the AII rooms resulted in a substantial percentage of the rooms being under positive pressure (57,392,470,471).

Routine preventive maintenance should be scheduled and should include all components of the ventilation systems (e.g., fans, filters, ducts, supply diffusers, and exhaust grilles) and any air-cleaning devices in use. Performance monitoring should be conducted to verify that environmental controls are operating as designed. Performance monitoring can include 1) directional airflow assessments using smoke tubes and use of pressure monitoring devices that are sensitive to pressures

as low as approximately 0.005 inch of water gauge and 2) measurement of supply and exhaust airflows to compare with recommended air change rates for the respective areas of the setting. Records should be kept to document all preventive maintenance and repairs.

Standard procedures should be established to ensure that maintenance staff notifies infection-control personnel before performing maintenance on ventilation systems servicing patient-care areas. Similarly, infection-control staff should request assistance from maintenance personnel in checking the operational status of AII rooms and local exhaust devices (e.g., booths, hoods, and tents) before use. A protocol that is well-written and followed will help to prevent unnecessary exposures of HCWs and patients to infectious aerosols. Proper labeling of ventilation system components (e.g., ducts, fans, and filters) will help identify air-flow paths. Clearly labeling which fan services a given area will help to prevent accidental shutdowns (472).

In addition, provisions should be made for emergency power to avoid interruptions in the performance of essential environmental controls during a power failure.

Respiratory Protection

Considerations for Selection of Respirators

The overall effectiveness of respiratory protection is affected by 1) the level of respiratory protection selected (e.g., the assigned protection factor), 2) the fit characteristics of the respirator model, 3) the care in donning the respirator, and 4) the adequacy of the fit-testing program. Although data on the effectiveness of respiratory protection from various hazardous airborne materials have been collected, the precise level of effectiveness in protecting HCWs from *M. tuberculosis* transmission in health-care settings has not been determined.

Information on the transmission parameters of *M. tuberculosis* is also incomplete. Neither the smallest infectious dose of *M. tuberculosis* nor the highest level of exposure to *M. tuberculosis* at which transmission will not occur has been defined conclusively (159,473,474). In addition, the size distribution of droplet nuclei and the number of particles containing viable *M. tuberculosis* organisms that are expelled by patients with infectious TB disease have not been adequately defined, and accurate methods of measuring the concentration of infectious droplet nuclei in a room have not been developed. Nonetheless, in certain settings (e.g., AII rooms and ambulances during the transport of persons with suspected or confirmed infectious TB disease), administrative and environmental controls alone might not adequately protect HCWs from infectious airborne droplet nuclei.

On October 17, 1997, OSHA published a proposed standard for occupational exposure to *M. tuberculosis* (267). On December 31, 2003, OSHA announced the termination of rulemaking for a TB standard (268). Previous OSHA policy permitted the use of any Part 84 particulate filter respirator for protection against infection with *M. tuberculosis* (269). Respirator usage for TB had been regulated by OSHA under CFR Title 29, Part 1910.139 (29 CFR 1910.139) (270) and compliance policy directive (CPL) 2.106 (Enforcement Procedures and Scheduling for Occupational Exposure to Tuberculosis). Respirator usage for TB is now regulated under the general industry standard for respiratory protection (29 CFR 1910.134) (271). General information on respiratory protection for aerosols, including *M. tuberculosis*, has been published (272–274).

Performance Criteria for Respirators

Performance criteria for respirators are derived from data on 1) effectiveness of respiratory protection against noninfectious hazardous materials in workplaces other than health-care settings and an interpretation of how these data can be applied to respiratory protection against *M. tuberculosis*, 2) efficiency of respirator filters in filtering biologic aerosols, 3) face-seal leakage, and 4) characteristics of respirators used in conjunction with administrative and environmental controls in outbreak settings to stop transmission of *M. tuberculosis* to HCWs and patients.

Particulate filter respirators certified by CDC/NIOSH, either nonpowered respirators with N95, N99, N100, R95, R99, R100, P95, P99, and P100 filters (including disposable respirators), or PAPRs with high efficiency filters can be used for protection against airborne *M. tuberculosis*.

The most essential attribute of a respirator is the ability to fit the different facial sizes and characteristics of HCWs. Studies have demonstrated that fitting characteristics vary substantially among respirator models. The fit of filtering facepiece respirators varies because of different facial types and respirator characteristics (10,280–289). Selection of respirators can be done through consultation with respirator fit-testing experts, CDC, occupational health and infection-control professional organizations, peer-reviewed research, respirator manufacturers, and from advanced respirator training courses. Data have determined that fit characteristics cannot be determined solely by physical appearance of the respirator (282).

Types of Respiratory Protection for TB

Respirators encompass a range of devices that vary in complexity from flexible masks covering only the nose and mouth, to units that cover the user's head (e.g., loose-fitting or hooded PAPRs), and to those that have independent air supplies (e.g., airline respirators). Respirators must be selected from those approved by CDC/NIOSH under the provisions of 42 CFR, Part 84 (475).

Nonpowered air-purifying respirators. Nine classes of nonpowered, air-purifying, particulate-filter respirators are certified under 42 CFR 84. These include N-, R-, and P-series respirators of 95%, 99%, and 100% (99.7%) filtration efficiency when challenged with 0.3 μm particles (filters are generally least efficient at this size) (Table 4). The N, R, and P classifications are based on the capacity of the filter to withstand exposure to oil. All of these respirators meet or exceed CDC's filtration efficiency performance criteria during the service life of the filter (1,272,273).

Nonpowered air-purifying respirators work by drawing ambient air through the filter during inhalation. Inhalation causes negative pressure to develop in the tight-fitting facepiece and allows air to enter while the particles are captured on the filter. Air leaves the facepiece during exhalation because positive pressure develops in the facepiece and forces air out of the mask through the filter (disposable) or through an exhalation valve (replaceable and certain ones are disposable).

The classes of certified nonpowered air-purifying respirators include both filtering facepiece (disposable) respirators and elastomeric (rubber-like) respirators with filter cartridges. The certification test for filtering facepieces and filter cartridges consists only of a filter performance test. It does not address respirator fit. Although all N-, R-, and P-series respirators are recommended for protection against *M. tuberculosis* infection in health-care settings and other workplaces that are usually free of oil aerosols that could degrade filter efficiency, well-fitting N-series respirators are usually less expensive than R- and P-series respirators (272,273). All respirators should be replaced as needed, based on hygiene considerations, increased breathing resistance, time-use limitations specified in the CDC/NIOSH approval guidelines, respirator damage, and in accordance with manufacturer user's instructions.

PAPRs. PAPRs use a blower that draws air through the filters into the facepiece. PAPRs can be equipped with a tight-fitting or loose-fitting facepiece, a helmet, or a hood. PAPR filters are classified as high efficiency and are different from those presented in this report (Table 4). A PAPR high efficiency filter meets the N100, R100, and P100 criteria at the beginning of their service life. No loading tests using 0.3 μm particles are conducted as part of certification. PAPRs can be useful for persons with facial hair or other conditions that prevent an adequate face to facepiece seal (476).

Atmosphere-supplying respirators. Positive-pressure airline (supplied-air) respirators are provided with air from a stationary source (compressor) or an air tank.

Effectiveness of Respiratory-Protection Devices

Data on the effectiveness of respiratory protection against hazardous airborne materials are based on experience in the industrial setting; data on protection against transmission of *M. tuberculosis* in health-care settings are not available. The parameters used to determine the effectiveness of a respiratory protective device are face-seal efficacy and filter efficiency.

Face-seal leakage. Face-seal leakage is the weak link that limits a respirator's protective ability. Excessive face-seal leakage compromises the ability of particulate respirators to protect HCWs from

airborne materials (477). A proper seal between the respirator's sealing surface and the face of the person wearing the respirator is essential for the effective and reliable performance of any tight-fitting, negative-pressure respirator.

For tight-fitting, negative-pressure respirators (e.g., N95 disposable respirators), the amount of face-seal leakage is determined by 1) the fit characteristics of the respirator, 2) the care in donning the respirator, and 3) the adequacy of the fit-testing program. Studies indicate that a well-fitting respirator and a fit test produces better results than a well-fitting respirator without a fit test or a poor-fitting respirator with a fit test. Increased face-seal leakage can result from additional factors, including incorrect facepiece size, failure to follow the manufacturer's instructions at each use, beard growth, perspiration or facial oils that can cause facepiece slippage, improper maintenance, physiological changes of the HCW, and respirator damage.

Face-seal leakage is inherent in tight-fitting negative-pressure respirators. Each time a person wearing a nonpowered particulate respirator inhales, negative pressure (relative to the workplace air) is created inside the facepiece. Because of this negative pressure, air containing contaminants can leak into the respirator through openings at the face-seal interface and avoid the higher-resistance filter material. A half-facepiece respirator, including an N95 disposable respirator, should have <10% leakage. Full facepiece, nonpowered respirators have the same leakage (<2%) as PAPRs with tight-fitting full-facepieces.

The more complex PAPRs and positive-pressure airline respirators reduce or eliminate this negative facepiece pressure and, therefore, reduce leakage into the respirator and enhance protection. A PAPR is equipped with a blower that forcibly draws ambient air through high efficiency filters and then delivers the filtered air to the facepiece. This air is blown into the facepiece at flow rates that generally exceed the expected inhalation flow rates. The pressure inside the facepiece reduces face-seal leakage to low levels, particularly during the relatively low inhalation rates expected in health-care settings. PAPRs with a tight-fitting facepiece have <2% face-seal leakage under routine conditions (278). PAPRs with loose-fitting facepieces, hoods, or helmets have <4% inward leakage under routine conditions (278). Therefore, a PAPR might offer lower levels of face-seal leakage than nonpowered, half-mask respirators.

Filter penetration. Aerosol penetration through respirator filters depends on at least five independent variables: 1) filtration characteristics for each type of filter, 2) size distribution of the droplets in the aerosol, 3) linear velocity through the filtering material, 4) filter loading (i.e., amount of contaminant deposited on the filter), and 5) electrostatic charges on the filter and on the droplets in the aerosol (284).

When N95 disposable respirators are used, filter penetration might approach 5% (50% of the allowable leakage of 10% for an N95 disposable respirator). When high efficiency filters are used in PAPRs or for half-facepiece respirators, filter efficiency is high (effectively 100%), and filter penetration is less of a consideration. Therefore, for high efficiency or 100-series filter respirators, the majority of inward leakage of droplet nuclei occurs at the respirator's face seal or exhalation valve.

Implementing a Respiratory-Protection Program

If respirators are used in a health-care setting, OSHA requires the development, implementation, administration, and periodic reevaluation of a respiratory-protection program (271,277,278). The most critical elements of a respiratory-protection program include 1) assigning of responsibility, 2) training, and 3) fit testing (1). All HCWs who use respirators for protection against infection with *M. tuberculosis* should be included in the respiratory-protection program.

Visitors to AII rooms and other areas with patients who have suspected or confirmed infectious TB disease may be offered respirators (e.g., N95 disposable respirators) and should be instructed by an HCW on the use of the respirator before entering an AII room (see Respiratory Protection section for User-Seal Check FAQs). The health-care setting should develop a policy on use of respirators by visitors.

The number of HCWs included in the respiratory-protection program will vary depending on the 1) number of persons who have suspected or confirmed TB disease examined in a setting, 2) number of rooms or areas in which patients with suspected or confirmed infectious TB disease stay or are encountered, and 3) number of HCWs needed to staff these rooms or areas. In settings in which respiratory-protection programs are required, enough HCWs should be included to provide adequate care for patients with suspected or confirmed TB disease. However, administrative measures should be used to limit the number of HCWs exposed to *M. tuberculosis* (see Prompt Triage).

Information on the development and management of a respiratory-protection program is available in technical training courses that cover the basics of respiratory protection. Such courses are offered by OSHA, the American Industrial Hygiene Association, universities, manufacturers, and private contractors. To be effective and reliable, respiratory-protection programs must include at least the following elements (274,277,278).

Assignment of Responsibility

One person (the program administrator) must be in charge of the respiratory-protection program and be given the authority and responsibility to manage all aspects of the program. The administrator must have sufficient knowledge (obtained by training or experience) to develop and implement a respiratory-protection program. Preferably, the administrator should have a background in industrial hygiene, safety, health care, or engineering. The administrator should report to the highest official possible (e.g., manager of the safety department, supervisor of nurses, HCWs' health manager, or infection-control manager) and should be allocated sufficient time to administer the respiratory-protection program in addition to other assigned duties.

Standard Operating Procedures

The effectiveness of a respiratory-protection program requires the development of written standard procedures. These procedures should include information and guidance for the proper selection, use, and care of respirators (274).

Screening

HCWs should not be assigned a task requiring use of respirators unless they are physically able to perform job duties while wearing the respirator. HCWs who might need to use a respirator should be screened by a physician or other licensed health-care professional for pertinent medical conditions at the time they are hired and then re-screened periodically (274). The screening process should begin with a screening questionnaire for pertinent medical conditions, the results of which should be used to identify HCWs who need further evaluation ([Appendix G](#)). Unless prescribed by the screening physician, serial physical examination or testing with chest radiographs or spirometry is neither necessary nor required (287).

Training

HCWs should be provided annual training on multiple topics.

- Nature, extent, and hazards of TB disease in the health-care setting. This training can be conducted in conjunction with other related training on infectious disease associated with airborne transmission (e.g., severe acute respiratory syndrome [SARS]-coronavirus [CoV] and measles) and with serial TB screening.
- The risk assessment process and its relation to the respirator program.
- Signs and symbols used to demonstrate that respirators are required in an area.
- Reasons for using respirators.
- Environmental controls used to prevent the spread and reduce the concentration of infectious droplet nuclei.
- Reasons for selecting a particular respirator for a given hazard (see Selection of Respirators; and Respirator Options: Special Circumstances).
- Operation, capabilities, and limitations of respirators.
- Respirator care.
- Cautions regarding facial hair and respirator use.

- Applicable federal, state, and local regulations regarding respirators, including assessment of employees' knowledge.

Trainees should be provided resources as an adjunct to the respiratory-protection program.

- Opportunities to handle and wear a respirator until they are proficient (see Supplement, Fit Testing).
- Educational material for use as references.
- Instructions to refer all respirator problems immediately to the respirator program administrator.

Selection

Filtering facepiece respirators used for protection against *M. tuberculosis* must be selected from those approved by CDC/NIOSH under the provisions of 42 CFR 84 (<http://www.cdc.gov/niosh/celintro.html>). A listing of CDC/NIOSH-approved disposable particulate respirators (filtering facepieces) is available at http://www.cdc.gov/niosh/npptl/topics/respirators/disp_part. If a health-care setting uses respirators for protection against other regulated hazards (e.g., formaldehyde and ethylene oxide), then these potential exposures should be specifically addressed in the program. Combination product surgical mask/N95 disposable respirators (respirator portion certified by CDC/NIOSH and surgical mask portion listed by FDA) are available that provide both respiratory protection and bloodborne pathogen protection. Selection of respirators can be chosen through consultation with respirator fit-testing experts, CDC, occupational health and infection-control professional organizations, peer-reviewed research, respirator manufacturers, and advanced respirator training courses (10,280–289).

Fit Testing

A fit test is used to determine which respirator fits the user adequately and to ensure that the user knows when the respirator fits properly. After a risk assessment is conducted to validate the need for respiratory protection, perform fit testing during the initial respiratory-protection program training and periodically thereafter, in accordance with federal, state, and local regulations.

Fit testing provides a method to determine which respirator model and size fits the wearer best and to confirm that the wearer can properly fit the respirator. Periodic fit testing for respirators used in environments where a risk for *M. tuberculosis* transmission exists can serve as an effective training tool in conjunction with the content included in employee training and retraining. The frequency of periodic fit testing should be determined by the occurrence of 1) a risk for transmission of *M. tuberculosis*, 2) a change in facial features of the wearer, 3) a medical condition that would affect respiratory function, 4) physical characteristics of respirator (despite the same model number), or 5) a change in the model or size of the assigned respirator (281).

Inspection and Maintenance

Respirator maintenance should be an integral part of an overall respirator program. Maintenance applies both to respirators with replaceable filters and to respirators that are classified as disposable but are reused. Manufacturer instructions for inspecting, cleaning, maintaining, and using (or reuse) respirators should be followed to ensure that the respirator continues to function properly (278).

When respirators are used for protection against noninfectious aerosols (e.g., wood dust) that might be present in the air in heavy concentrations, the filter can become obstructed with airborne material. This obstruction in the filter material can result in increased resistance, causing breathing to be uncomfortable. In health-care settings in which respirators are used for protection against biologic aerosols, the concentration of infectious particles in the air is probably low. Thus, the filter in a respirator is unlikely to become obstructed with airborne material. In addition, no evidence exists to indicate that particles that affect the filter material in a respirator are reaerosolized easily. Therefore, the filter material used in respirators in health-care settings might remain functional for weeks. Because electrostatic filter media can degrade, the manufacturer should be contacted for the product's established service life to confirm filter performance.

Respirators with replaceable filters are reusable, and a respirator classified as disposable can be reused by the same HCW as long as it remains functional and is used in accordance with local infection-control procedures. Respirators with replaceable filters and filtering facepiece respirators can be reused by HCWs as long as they have been inspected before each use and are within the specified service life of the manufacturer. If the filter material is physically damaged or soiled or if the manufacturer's service life criterion has been exceeded, the filter (in respirators with replaceable filters) should be changed or the disposable respirator should be discarded according to local regulations. Infection-control personnel should develop standard procedures for storing, reusing, and disposing of respirators that have been designated for disposal.

Evaluation

The respirator program must be evaluated periodically to ensure its continued effectiveness.

Cleaning, Disinfecting, and Sterilizing Patient-Care Equipment and Rooms

General

Medical instruments and equipment, including medical waste, used on patients who have TB disease are usually not involved in the transmission of *M. tuberculosis* (478–480). However, transmission of *M. tuberculosis* and pseudo-outbreaks (e.g., contamination of clinical specimens) have been linked to inadequately disinfected bronchoscopes contaminated with *M. tuberculosis* (80,81,160,163,164,166). Guidelines for cleaning, disinfecting, and sterilizing flexible endoscopic instruments have been published (481–485).

The rationale for cleaning, disinfecting, or sterilizing patient-care instruments and equipment can be understood more readily if medical devices, equipment, and surgical materials are divided into three general categories (486). The categories are critical, semicritical, and noncritical and are based on the potential risk for infection if an item remains contaminated at the time of use.

Critical Medical Instruments

Instruments that are introduced directly into the bloodstream or other normally sterile areas of the body (e.g., needles, surgical instruments, cardiac catheters, and implants) are critical medical instruments. These items should be sterile at the time of use.

Semicritical Medical Instruments

Instruments that might come into contact with mucous membranes but do not ordinarily penetrate body surfaces (e.g., noninvasive flexible and rigid fiberoptic endoscopes or bronchoscopes, endotracheal tubes, and anesthesia breathing circuits) are semicritical medical instruments. Although sterilization is preferred for these instruments, high-level disinfection that destroys vegetative microorganisms, the majority of fungal spores, mycobacteria (including tubercle bacilli), and small nonlipid viruses can be used. Meticulous cleaning of such items before sterilization or high-level disinfection is essential (481). When an automated washer is used to clean endoscopes and bronchoscopes, the washer must be compatible with the instruments to be cleaned (481,487). High-level disinfection can be accomplished with either manual procedures alone or use of an automated endoscope reprocessor with manual cleaning (80,481). In all cases, manual cleaning is an essential first-step in the process to remove debris from the instrument.

Noncritical Medical Instruments or Devices

Instruments or devices that either do not ordinarily touch the patient or touch only the patient's intact skin (e.g., crutches, bed boards, and blood pressure cuffs) are noncritical medical instruments. These items are not associated with transmission of *M. tuberculosis*. When noncritical instruments or equipment are contaminated with blood or body substances, they should be cleaned and then disinfected with a hospital-grade, Environmental Protection Agency (EPA)-registered germicide disinfectant with a label claim for tuberculocidal activity (i.e., an intermediate-level disinfectant). Tuberculocidal activity is not necessary for cleaning agents or low-level disinfectants that are used to clean or disinfect minimally soiled noncritical items and environmental surfaces (e.g., floors, walls, tabletops, and surfaces with minimal hand contact).

Disinfection

The rationale for use of a disinfectant with tuberculocidal activity is to ensure that other potential pathogens with less intrinsic resistance than that of mycobacteria are killed. A common misconception in the use of surface disinfectants in health care relates to the underlying purpose of products labeled as tuberculocidal germicides. Such products will not interrupt and prevent transmission of *M. tuberculosis* in health-care settings, because TB is not acquired from environmental surfaces. The tuberculocidal claim is used as a benchmark by which to measure germicidal potency. Because mycobacteria have the highest intrinsic level of resistance among the vegetative bacteria, viruses, and fungi, any germicide with a tuberculocidal claim on the label (i.e., an intermediate-level disinfectant) is considered capable of inactivating many pathogens, including much less resistant organisms such as the bloodborne pathogens (e.g., hepatitis B virus, hepatitis C virus, and HIV). Rather than the product's specific potency against mycobacteria, a germicide that can inactivate many pathogens is the basis for protocols and regulations indicating the appropriateness of tuberculocidal chemicals for surface disinfection.

Policies of health-care settings should specify whether cleaning, disinfecting, or sterilizing an item is necessary to decrease the risk for infection. Decisions regarding decontamination processes should be based on the intended use of the item, not on the diagnosis of the condition of the patient for whom the item is used. Selection of chemical disinfectants depends on the intended use, the level of disinfection required, and the structure and material of the item to be disinfected.

The same cleaning procedures used in other rooms in the health-care setting should be used to clean AII rooms. However, personnel should follow airborne precautions while cleaning these rooms when they are still in use. Personal protective equipment is not necessary during the final cleaning of an AII room after a patient has been discharged if the room has been ventilated for the appropriate amount of time ([Table 1](#)).

Frequently Asked Questions (FAQs)

The following are FAQs regarding TST, QFT-G, BAMT, treatment for LTBI, risk assessment, environmental controls, respiratory protection, and cough-inducing and aerosol-generating procedures.

TST and QFT-G

- **Does having more than one TST placed in 1 year pose any risk?** No risk exists for having TSTs placed multiple times per year.
- **Can repeated TSTs, by themselves, cause the TST result to convert from negative to positive?** No, the TST itself does not cause false-positive results. Exposure to other mycobacteria or BCG vaccination can cause false-positive TST results.
- **What defines a negative TST result?** A TST result of 0 mm or a measurement below the defined cut point for each criteria category is considered a negative TST result ([Box 3](#)).
- **What defines a positive TST result?** A TST result of any millimeter reading above or at the defined cut point for each criteria category is considered a positive TST result ([Box 3](#)). The cut point (5 mm, 10 mm, and 15 mm) varies according to the purpose of the test (e.g., infection-control surveillance or medical and diagnostic evaluation, or contact investigation versus baseline testing).
- **What defines a false-negative result?** A false-negative TST or QFT-G result is one that is interpreted as negative for a particular purpose (i.e., infection-control surveillance versus medical and diagnostic evaluation) in a person who is actually infected with *M. tuberculosis*. False-negative TST results might be caused by incorrect TST placement (too deeply or too shallow), incorrect reading of the TST result, use of an incorrect antigen, or if the person being tested is anergic (i.e., unable to respond to the TST because of an immunocompromising condition) or sick with TB disease.
- **What defines a false-positive result?** A false-positive TST or QFT-G result is one that is interpreted as positive for a particular purpose (i.e., infection-control surveillance versus medical and diagnostic evaluation) in a person who is actually not infected with *M. tuberculosis*. False-positive TST results are more likely to occur in persons who have been vaccinated with BCG or who are infected with NTM, also known as mycobacteria other than TB (MOTT). A false-positive

TST result might also be caused by incorrect reading of the TST result (reading erythema rather than induration) or use of incorrect antigen (e.g., tetanus toxoid).

- **Is placing a TST on a nursing mother safe?** Yes, placing a TST on a nursing mother is safe.
- **A pregnant HCW in a setting is reluctant to get a TST. Should she be encouraged to have the test administered?** Yes, placing a TST on a pregnant woman is safe. The HCW should be encouraged to have a TST or offered BAMT. The HCW should receive education that 1) pregnancy is not a contraindication to having a TST administered and 2) skin testing does not affect the fetus or the mother. Tens of thousands of pregnant women have received TST since the test was developed, and no documented episodes of TST-related fetal harm have been reported. Guidelines issued by ACOG emphasize that postponement of the application of a TST as indicated and postponement of the diagnosis of infection with *M. tuberculosis* during pregnancy is unacceptable.
- **A pregnant HCW in a setting has a positive TST result and is reluctant to get a chest radiograph. Should she be encouraged to have the chest radiograph performed?** Pregnant women with positive TST results or who are suspected of having TB disease should not be exempted from recommended medical evaluations and radiography. Shielding consistent with safety guidelines should be used even during the first trimester of pregnancy.
- **Are periodic chest radiographs recommended for HCWs (or staff or residents of LTCFs) who have positive TST or BAMT results?** No, persons with positive TST or BAMT results should receive one baseline chest radiograph to exclude a diagnosis of TB disease. Further chest radiographs are not needed unless the patient has symptoms or signs of TB disease or unless ordered by a physician for a specific diagnostic examination. Instead of participating in serial skin testing, HCWs with positive TST results should receive a medical evaluation and a symptom screen. The frequency of this medical evaluation should be determined by the risk assessment for the setting. HCWs who have a previously positive TST result and who change jobs should carry documentation of the TST result and the results of the baseline chest radiograph (and documentation of treatment history for LTBI or TB disease, if applicable) to their new employers.
- **What is boosting?** Boosting is a phenomenon in which a person has a negative TST (i.e., false-negative) result years after infection with *M. tuberculosis* and then a positive subsequent TST result. The positive TST result is caused by a boosted immune response of previous sensitivity rather than by a new infection (false-positive TST conversion). Two-step testing reduces the likelihood of mistaking a boosted reaction for a new infection.
- **What procedure should be followed for a newly hired HCW who had a documented negative TST result 3 months ago at their previous job?** This person should receive one baseline TST upon hire (ideally before the HCW begins assigned duties). The negative TST result from the 3 months preceding new employment (or a documented negative TST result anytime within the previous 12 months) should be considered the first step of the baseline two-step TST. If the HCW does not have documentation of any TST result, the HCW should be tested with baseline two-step TST (one TST upon hire and one TST placed 1–3 weeks after the first TST result was read).
- **Why are two-step TSTs important for the baseline (the beginning of an HCW's employment)?** If TST is used for TB screening (rather than BAMT), performing two-step TST at baseline minimizes the possibility that boosting will lead to suspicion of transmission of *M. tuberculosis* in the setting during a later contact investigation or during serial testing (false-positive TST conversions). HCWs who do not have documentation of a positive TST result or who have not been previously treated for LTBI or TB disease should receive baseline two-step TST.
- **If a person does not return for a TST reading within 48–72 hours, when can a TST be placed on them again?** A TST can be administered again as soon as possible. If the second step of a two-step TST is not read within 48–72 hours, administer a third test as soon as possible (even if several months have elapsed), and ensure that the result is read within 48–72 hours.
- **Should a TST reading of ≥ 10 mm be accepted 7 days after the TST was placed?** If the TST was not read between 48–72 hours, another TST should be placed as soon as possible and read within 48–72 hours. However, certain studies indicate that positive TST reactions might still be measurable 4–7 days after the TST was placed. If the TST reaction is read as ≥ 15 mm 7 days after placement, the millimeter result can be recorded and considered to be a positive result.
- **Do health-care settings or areas in the United States exist for which baseline two-step TST for newly hired HCWs is not needed?** Ideally, all newly hired HCWs who might share air space with patients should receive baseline two-step TST (or one-step BAMT) before starting duties. In certain settings, a choice might be offered not to perform baseline TST on HCWs who will never be in contact with or share air space with patients who have TB disease, or who will never be in contact with clinical specimens (e.g., telephone operators in a separate building from patients).

- **In our setting, workers are hired to provide health care in homes, and they are not medically trained. Two-step skin testing is difficult because of the requirement to return for testing and reading multiple times. Can the two-step TST be omitted?** No, ideally, all HCWs who do not have a previously documented positive TST result or treated LTBI or TB disease should receive two-step baseline skin testing in settings that have elected to use TST for screening. BAMT is a single test procedure. Baseline testing for *M. tuberculosis* infection will ensure that TB disease or LTBI is detected before employment begins and treatment for LTBI or TB disease is offered, if indicated.
- **When performing two-step skin testing, what should be done if the second-step TST is not placed in 1–3 weeks?** Perform the second-step TST as soon as possible, even if several months have passed.
- **Should gloves be worn when placing TST?** Specific CDC recommendations do not exist regarding this topic. If your local area indicates that universal precautions should be practiced with skin testing, the local areas should determine what precautions should be followed in their setting.
- **Is TST QC important?** Yes, performing QC for HCWs during training and retraining of placing and reading TST is important to avoid false-negative and false-positive TST results, and to ensure appropriate treatment decisions.
- **If the longitudinal reading of the induration of the TST result is 12 mm and the horizontal reading is 8 mm, what should be recorded?** The correct TST reading should be recorded as 8 mm (not 12 mm or 8 x 12 mm). For purposes of standardization, only record the millimeters of induration, which should be measured transversely (i.e., perpendicular), to the long axis of the forearm. Erythema (redness) around the TST site should not be read as part of the TST result. Consideration should be given to retesting if the selected area for placement was on or near a muscle margin, scar, heavy hair, veins, or tattoos, which could be barriers to reading the TST result, or consider offering a BAMT. BAMT results should be recorded in detail. The details should include date of blood draw, result in specific units, and the laboratory interpretation (positive, negative, or indeterminate—and the concentration of cytokine measured, e.g., IFN- γ).
- **Should HCWs who report upon hire that they have had a positive TST result or have been previously treated for LTBI or TB disease receive baseline two-step TST when beginning work at a new health-care setting?** Unless the HCW has documentation of a positive TST result or previously treated LTBI or TB disease, they should usually receive baseline two-step testing before starting duties. If documentation is available of a positive TST result, that result can be considered as the baseline TST result for the HCW at the new setting, and additional testing is not needed. Recommendations for testing HCWs who transfer from one setting to another where the risk assessment might be different are presented (see Use of Risk Classification to Determine Need for TB Screening and Frequency of Screening HCWs).
- **If an HCW has a baseline first-step TST result between 0–9 mm, does a second-step TST need to be placed?** Yes, if the baseline first-step TST result is <10 mm, a second-step TST should be applied 1–3 weeks after the first TST result was read. HCWs who are immunocompromised are still subject to the 10 mm cutoff for baseline two-step testing for surveillance purposes but would be referred for medical evaluation for LTBI using the 5 mm cutoff.
- **An HCW in a medium-risk setting who had a two-step baseline TST result of 8 mm is retested 1 year later for serial TB screening and had a TST result of 16 mm. No known exposure to *M. tuberculosis* had occurred. Although the TST is now >10 mm, a ≥ 10 mm increase did not occur in the TST result to meet the criteria for a TST conversion. How should this reading be interpreted?** The TST result needs to be interpreted from two perspectives: 1) administrative and 2) individual medical interpretation. Because an increase by ≥ 10 mm did not occur, the result would not be classified as a TST conversion for administrative purposes. However, this HCW should be referred for a medical evaluation. The following criteria are used to determine whether a TST result is positive or negative, considering individual clinical grounds: 1) absolute measured induration (i.e., ≥ 5 , ≥ 10 , or ≥ 15 mm induration, depending on the level of risk and purpose of testing); 2) the change in the size of the TST result; 3) time frame of the change; 4) risk for exposure, if any; and 5) occurrence of other documented TST conversions in the setting. For HCWs at low risk for LTBI, TST results of 10–14 mm can be considered negative from a clinical standpoint, and these HCWs should not have repeat TST, because an additional increase in induration of ≥ 10 mm will not be useful in determining the likelihood of LTBI.
- **Are baseline two-step TSTs needed for HCWs who begin jobs that involve limited contact with patients (e.g., medical records staff)?** Yes, all HCWs who might share air space with patients should receive baseline two-step TST (or one-time BAMT) before starting duties. However, in certain settings, a choice might be offered not to perform baseline TST on

HCWs who will never be in contact with or share air space with patients who have TB disease, or who will never be in contact with clinical specimens (e.g., telephone operators in a separate building from patients).

- **A setting conducts skin testing annually on the anniversary of each HCW's employment. Last year, multiple TST conversions occurred in April; therefore, all HCWs received a TST during that month. In the future, do all HCWs need to be tested annually in April?** No, after a contact investigation is performed, the best and preferred schedule for annual TB screening is on the anniversary of the HCW's employment date or on their birthday (rather than testing all HCWs at the same time each year), because it increases the opportunity for early recognition of infection-control problems that can lead to TST conversions.
- **An HCW who has been vaccinated with BCG is being hired. She states that BCG will make her TST result positive and that she should not have a TST. Should this HCW be exempted from baseline two-step TST?** Unless she has documentation of a positive TST result or previously treated LTBI or TB disease, she should receive baseline two-step TST or one BAMT. Some persons who received BCG never have a positive TST result. For others, the positive reaction wanes after 5 years. U.S. guidelines state that a positive TST result in a person who received BCG should be interpreted as indicating LTBI.
- **Does BCG affect TST results and interpretations?** BCG is the most commonly used vaccine in the world. BCG might cause a positive TST (i.e., false-positive) result initially; however, tuberculin reactivity caused by BCG vaccination typically wanes after 5 years but can be boosted by subsequent TST. No reliable skin test method has been developed to distinguish tuberculin reactions caused by vaccination with BCG from reactions caused by natural mycobacterial infections, although TST reactions of ≥ 20 mm of induration are not usually caused by BCG.
- **What steps should be taken when an HCW has had a recent BCG vaccination?** When should the TST be placed? A TST may be placed anytime after a BCG vaccination, but a positive TST result after a recent BCG vaccination can be a false-positive result. QFT-G should be used, because the assay test avoids cross reactivity with BCG.
- **A hospital HCW has not had a TST in 18 months because she was on maternity leave and missed her annual TST. She has been employed at the hospital for the previous 5 years. Is two-step testing necessary on her next skin test date?** No, two-step TSTs are needed only to establish a baseline for a specific setting for newly hired HCWs and others who will receive serial TST (e.g., residents or staff of correctional facilities or LTCFs). The HCW should have a single TST or BAMT upon returning to work and should then resume a routine testing schedule on the next normal TST anniversary date.
- **Should two-step testing be performed in a contact investigation for HCWs who have not had a TST within the preceding 12 months?** No, two-step testing should only be used for baseline TST screening and has no role in a contact investigation. In a contact investigation, a follow-up TST should be placed 8–10 weeks after an initial negative TST result is read.
- **What length of time should a person who has had contact with someone with TB disease be included in a contact investigation?** This decision can best be made in consultation with the local TB program, which frequently has experience responding to similar situations. A minimum exposure time has not been established, but the minimum length of contact time with a person who has TB disease necessary for transmission will depend on multiple factors. Begin by estimating the duration of the infectious period (see Supplement, Contact Investigations). The highest priority for evaluation should be given to 1) persons with a medical risk factor for TB disease (e.g., HIV infection or immunosuppressive therapy); 2) infants and children <4 years; 3) household or congregate setting contacts; and 4) persons present during medical procedures (e.g., bronchoscopies, sputum induction, or autopsies). In addition, offer TB screening to all persons named by the patient as work or social contacts during the infectious period. Determining whether to broaden the investigation will depend on whether evidence of transmission to any of the above contacts exists (positive TST or BAMT results or conversions), the duration of the potential exposure, and the intensity of the exposure (e.g., in a poorly ventilated environment versus outdoors). If the exposure was to pulmonary TB that was cavitary on chest radiograph or if the patient had positive AFB sputum smear results, usually the minimum exposure duration for a person to be considered a contact would be shorter. Nonetheless, infection with *M. tuberculosis* requires some degree of prolonged or regular exposure (i.e., days to weeks, not just a few hours).
- **If an HCW in a setting has a latex allergy, should this person receive a TST?** A person with a latex allergy can receive a TST when latex-free products are used. Latex allergy can be a contraindication to skin testing if the allergy is severe and the products used to perform the test (e.g., syringe plungers, PPD antigen bottle stopper, and gloves) contain latex. Latex-free products are, however, usually available. If a person with a latex allergy does have a TST performed using

products or equipment that contain latex, interpretation of the TST results can be difficult, because the TST reaction might be the result of the latex allergy, reaction to PPD, or a combination of both. Consider repeating the TST using latex-free products or use BAMT.

- **Should the TST site be covered with an adhesive bandage?** No, avoid covering the TST site with anything that might interfere with reading the TST result (e.g., adhesive bandages, cream, ointment, lotion, liquids, and medication).
- **When can a TST be placed if other vaccines are also being administered (e.g., measles, varicella, yellow fever, and smallpox)?** A TST should be administered either on the same day as vaccination with live virus or 4–6 weeks later. Vaccines that might cause a false-negative TST result are measles, varicella, yellow fever, smallpox, BCG, mumps, rubella, oral polio, oral typhoid, and live-attenuated influenza.
- **How frequently should persons in the general public receive TST?** Testing for LTBI in the general public is not necessary unless the person is at risk for exposure to *M. tuberculosis* (e.g., someone who had contact with a person with TB disease) or at increased risk for progression to TB disease (e.g., someone infected with HIV).
- **Should we use a multiple puncture (Tine®) skin test to perform a TST?** No, in the United States, the Mantoux method of skin testing is the preferred method because it is more accurate than Tine(r) skin tests. BAMT (currently QFT-G) is also now recommended as a test for *M. tuberculosis* infection.
- **What steps should be taken if an HCW has a baseline TST result of 16 mm and 1 year later the TST result was read as 0 mm?** If documentation existed for the 16 mm result, administering another TST to the HCW subsequently was not necessary. One or both of these TST results could be false results. The first result might have been documented as 16 mm, but perhaps 16 mm of erythema was measured and no induration was present. The second result of 0 mm might have been caused by incorrect administration of the TST (i.e., too deeply or too shallow), or was read and recorded incorrectly (if it was actually positive). In this instance, another TST should be placed, or a BAMT should be offered, or if TB disease is suspected, a chest radiograph should be performed.
- **What steps should be taken if the TST is administered intramuscularly instead of intradermally?** QC for administering TST is critical. If the TST is administered intramuscularly (too deeply), repeat the skin test immediately, or offer BAMT.
- **How are annual TST conversion rates for HCWs calculated?** A TST conversion is a change in the result of a test for *M. tuberculosis* infection wherein the condition is interpreted as having progressed from uninfected to infected. Annual TST conversion rates are calculated for a given year by dividing the number of test conversions among HCWs in the setting that year (numerator) by the total number of HCWs who received tests in the setting that year (denominator) multiplied by 100. By calculating annual TST conversion rates, year-to-year comparisons can be used to identify transmission of *M. tuberculosis* that was not previously detected.
- **Where can PPD be obtained?** Local and state health departments can provide PPD antigen for TST without charge to selected targeted testing and treatment programs. Purchase of the antigen and supplies is regulated by local and state laws related to professional licensure.
- **Where can millimeter rulers be obtained to measure TST results?** A TST training kit, which includes a TST training video, guide for facilitators, and a TST millimeter ruler is available free of charge from CDC (https://www2.cdc.gov/nchstp_od/PIWeb/TBorderform.asp). In addition, check with your local or state health department and TST antigen manufacturers.
- **Where can materials be obtained for educating HCWs regarding TB?** A list of TB websites and resources is available ([Appendix E](#)). Local or state health departments should have additional materials and access to resources and might be able to help develop a setting-specific TB education program.
- **Where can self-reading TST cards be obtained that allow HCWs to report their own results?** HCWs and patients should not be allowed to read and report their own TST results; therefore, self-reading cards for reporting TST results are not recommended. All TST results should be read and recorded by a trained TST reader other than the person on whom the TST was placed.

Treatment for LTBI

- **Who should be treated for LTBI?** Persons with LTBI who are at increased risk for developing TB disease should be offered treatment for LTBI regardless of age, if they have no contraindication to the medicine.
- **What are contraindications to treatment of LTBI?** Active hepatitis and ESLD are contraindications to the use of INH for treatment of LTBI. Persons who have these conditions

might be eligible for rifampin for 4 months for treatment of LTBI. Because of the substantial and complex drug-drug interactions between rifamycins and HIV protease inhibitors (PI) and nonnucleoside reverse transcriptase inhibitors (NNRTI), clinicians are encouraged to seek expert advice if the concurrent use of these drugs is being considered in persons infected with HIV. Information regarding use of these drugs is available at http://www.cdc.gov/nchstp/tb/tb_hiv_drugs/toc.htm.

- **Do persons need to be in a specific age range to be eligible for treatment of LTBI?** No age restriction for eligibility of treatment for LTBI currently exists. Targeted TST programs should be conducted for persons at high risk, and these programs are discouraged for persons or settings considered to be low risk. However, for infection-control programs that conduct TB screening that includes HCWs who are frequently at low risk, proper medical evaluation needs to be conducted when an HCW with a positive TST result is identified. In this context, age might be a factor in the decision to administer treatment, because older persons are at increased risk for hepatic toxicity caused by INH.
- **What is the preferred regimen for treatment of LTBI?** Nine months of daily INH is the preferred treatment regimen for patients who have LTBI. The 6-month regimen of INH or the 4-month regimen of rifampin are also acceptable alternatives.
- **Why is the 2-month regimen of RZ generally not offered for treatment of LTBI?** Although the 2-month regimen of RZ was previously recommended as an option for the treatment of LTBI, reports of severe liver injury and death prompted the American Thoracic Society and CDC to revise recommendations to indicate that this regimen should generally not be offered for treatment of LTBI.
- **Can sputum specimens collected over a 2-day period that are reported as negative for AFB be used to exclude a diagnosis of TB disease?** Yes, airborne precautions can be discontinued when infectious TB disease is considered unlikely and either 1) another diagnosis is made that explains the clinical syndrome or 2) the patient has three negative AFB sputum smear results (109–112). Each of the three consecutive sputum specimens should be collected 8–24 hours apart (124), and at least one specimen should be an early morning specimen, because respiratory secretions pool overnight. Generally, this method will allow patients with negative sputum smear results to be released from airborne precautions in 2 days.
- **When does an infectious TB patient become noninfectious?** Historically, health-care professionals have believed that the effect of antituberculosis treatment to reduce infectiousness was virtually immediate; older texts state that patients on antituberculosis treatment are not infectious. Surrogates that are used for noninfectiousness include conversion of positive sputum AFB results to negative AFB results and clinical response to antituberculosis treatment (i.e., improvement of symptoms and chest radiograph result).

Risk Assessment

- **In certain health-care settings (e.g., outpatient clinics or emergency medical settings) where patients are evaluated before a hospitalization during which TB disease is diagnosed, determining the number of TB patients who were encountered can be difficult. How should the risk classification be assigned?** These situations underscore the importance of obtaining an accurate patient history, completing contact investigations for all persons with suspected or confirmed TB disease, and ensuring effective communication to all settings in which persons with TB disease are encountered before diagnosis. Collaboration between infection-control personnel at the setting and the TB-control program staff at the local health department can help with this estimation.
- **At a pediatric hospital, the parents are normally with the child at the time of the TB diagnosis, and the parents can be diagnosed with TB disease at the same time as the child. To determine the number of patients diagnosed at the health-care setting, should the parents with TB disease who are visiting also be included in the total TB patient count?** Only patients with TB disease who were evaluated or treated in the health-care setting count, not visitors who have TB (unless they were diagnosed at the same setting).
- **In a 160-bed hospital, three HCWs have had TST conversions during a 2-month period, which is usually the number of TST conversions detected in the hospital in 1 year. Should the setting be classified as potential ongoing transmission?** If the HCWs with TST conversions can be linked together in some way, either through a job type, location of work, or DNA fingerprinting, then the classification of potential ongoing transmission might apply to one group of HCWs or one part of the setting. Evidence of ongoing transmission in this setting appears to exist, and a problem evaluation should be conducted to ascertain the reason for the TST conversions (see Problem Evaluation). Reasons could range from an undiagnosed case of TB in the setting to incorrect placement or reading of TST. Early consultation with the

local health department and an expert in TB infection control might be helpful in identifying and resolving the problem.

- **If a health-care setting has a risk classification of potential ongoing transmission, how long should that classification be applied?** The classification of potential ongoing transmission should be assigned only on a temporary basis and always warrants a problem evaluation (see Problem Evaluation). After resolution of problems, settings with a classification of potential ongoing transmission should be reclassified as a medium-risk classification for at least 1 year.

Environmental Controls

- **What is the difference between environmental controls and engineering controls ?** "Environmental controls" is a more inclusive term than "engineering controls". Examples of environmental controls are UVGI, HEPA filters and AII rooms. Examples of engineering controls are local exhaust ventilation (e.g., booths, hoods, and tents) and general ventilation (including directional airflow and negative pressure).
- **Is an AII room the same as a negative-pressure isolation room?** "AII room" is an accepted term and is used in the AIA guidelines that describe the purpose for and details of ventilation of AII rooms. An AII room is a special negative-pressure room for the specific purpose of isolating persons who might have suspected or confirmed infectious TB disease from other parts of the setting. Not all negative-pressure rooms are AII rooms, because they might not have the required air flow or differential pressure of an AII room.
- **Our TB clinic only treats persons with LTBI. Do we need an AII room and a respiratory-protection program?** Ideally, yes, because persons with LTBI are at risk for developing TB disease. TB clinics usually should have at least one AII room and a respiratory-protection program. An AII room and a respiratory-protection program might not be needed if 1) each person treated in the clinic will be adequately screened before admission and are determined to not have TB disease, 2) a system exists to promptly detect and triage persons who have symptoms or signs of TB disease, and 3) no cough-inducing procedures will ever be performed in the clinic.
- **Can airborne precautions be discontinued for a patient with suspected TB disease who has positive AFB sputum smear results but has a negative NAA for *M. tuberculosis*?** Yes, if the NAA test result is negative and dual infection with *M. tuberculosis* and another mycobacterial species is not clinically suspected, the patient may be released from airborne precautions. An NAA test is highly sensitive and specific for the identification of *M. tuberculosis* when performed properly on a patient who has a positive AFB sputum smear result.
- **During the winter months at a hospital, inadequate numbers of AII rooms are available for all patients with suspected or confirmed infectious TB disease. Can only two negative sputum smear results be obtained for AFB before releasing patients from airborne precautions?** In general, the criterion for the release of a patient with suspected infectious TB disease from airborne precautions is that infectious TB disease is considered unlikely and either 1) another diagnosis is made that explains the clinical syndrome or 2) the patient has three negative AFB sputum smear results (109–112). Each of the three consecutive sputum specimens should be collected 8–24 hours apart (124), and at least one specimen should be an early morning specimen. Generally, this method will allow patients with negative sputum smear results to be released from airborne precautions in 2 days. If the number of AII rooms in the setting is inadequate, consider adding one or more AII rooms. Before undertaking this expense, however, ensure that the criteria for placing patients in AII rooms are correct and that the available rooms are not being used for patients in whom infectious TB disease is not suspected. In addition, the following intervals should be reviewed to identify any delays that could be corrected and decrease time for patients in AII rooms: 1) time between admission and ordering of sputum specimens for AFB examination, 2) time between ordering and collecting specimens, and 3) time between collection of specimens and receipt of results from the laboratory.
- **How many AII rooms are required in a 120-bed hospital?** For a hospital with 120 beds, a minimum of one AII room is needed. Although no available data exist to quantify the number of rooms needed for a given number of cases of suspected or confirmed TB disease, a reasonable choice is one additional AII room for every 200 patient-days of cases of suspected or confirmed TB disease. The setting's risk assessment will help determine the number of AII rooms needed.
- **Who is responsible for ensuring that negative pressure is achieved in AII rooms?** Ensuring that negative pressure is achieved in AII rooms is a function of the infection-control program at each health-care setting. This responsibility may be delegated to engineering, maintenance, or other appropriate staff to perform the actual negative pressure tests. AII rooms should be checked for negative pressure before occupation by a patient with suspected or

confirmed infectious TB disease, and when in use by a person with TB disease, negative pressure should be checked daily with smoke tubes or other visual checks.

- **What is the difference between VAV and CAV?** How do I determine which settings need them? VAV is variable air volume, and CAV is constant air volume. These terms refer to how the ventilation system is designed to deliver air to and maintain temperature and relative humidity control within a room. CAV systems usually are best for AII rooms and other negative-pressure rooms, because the negative-pressure differential is easier to maintain. VAV systems are acceptable if provisions are made to maintain the minimum total and outside ACH and a negative pressure ≥ 0.01 inch of water gauge relative to adjacent areas at all times.
- **Why was the differential pressure requirement for an AII room increased from 0.001 inch of water gauge to ≥ 0.01 inch of water gauge?** In an ideal, controlled environment, 0.001 inches of water gauge has been demonstrated to ensure negative pressure in AII rooms. However, AIA and other organizations have demonstrated that a minimum of 0.01 inches of water gauge is needed in certain installations to ensure that negative pressure is consistently achieved.
- **How can a portable HEPA filter unit help control TB?** Portable HEPA filtration units recirculate room air, and the HEPA filters effectively remove all particles from the air in the size range of droplet nuclei, resulting in a dilution of the concentration of infectious particles in the room.

Respiratory Protection

- **What is the difference between a CDC/NIOSH-certified respirator and a surgical or procedure mask?** Respirators are designed to help reduce the wearer's (i.e., HCW's) exposure to airborne particles. The primary purpose of a surgical or procedure mask is to help prevent biologic particles from being expelled into the air by the wearer (i.e., patient).
- **How important is the fit of the respirator?** This step is critical. The fit of a respirator is substantially important. If a respirator does not fit tightly on the face, airborne hazards can penetrate or enter underneath the facepiece seal and into the breathing zone. Before each use, the wearer of a respirator should perform a user-seal check on themselves to minimize contaminant leakage into the facepiece (<http://www.cdc.gov/niosh/topics/respirators>).
- **How do I perform a respirator user-seal check?** Performing a user-seal check (formerly called "fit check") after redonning the respirator each time is critical to ensure adequate respiratory protection. The seal checks for respirators are described in the respirator user instructions and should be consulted before the respirator is used. The two types of user-seal checks usually are positive-pressure and negative-pressure checks.
To check positive pressure seal after donning the respirator, the wearer should cover the surface of the respirator with their hands or with a piece of household plastic film and exhale gently. If air is felt escaping around the facepiece, the respirator should be repositioned, and the user-seal check should be performed again. If the wearer does not feel air escaping around the facepiece, the positive pressure user-seal check was successful.
To check the negative pressure seal after donning the respirator, the wearer should cover the surface of the respirator and gently inhale, which should create a vacuum, causing the respirator to be drawn in toward the face. If the respirator is not drawn in toward the face or if the wearer feels air leaking around the face seal, the respirator should be removed and examined for any defects (e.g., a small hole or poor molding of the respirator to the face [especially around the nose area]). If no holes are found, the respirator should be repositioned and readjusted, and a second attempt at negative pressure user-seal check should be made. If the check is not successful, try a new respirator.
- **Is performing a user-seal check (formerly called "fit check") on a respirator before each use always necessary?** Yes, performing a user-seal check on respirators before each use is essential to minimize contaminant leakage into the facepiece. Each respirator manufacturer has a recommended user-seal check procedure that should be followed by the user each time the respirator is worn.
- **What is a respirator fit test and who does fit testing?** A fit test is used to determine which respirator does or does not fit the user adequately and to ensure that the user knows when the respirator fits properly. Fit testing must be performed by a qualified health professional. Fit testing should be performed during the initial respiratory-protection program training and periodically thereafter, based on the risk assessment for the setting and in accordance with applicable federal, state, or local regulations.
Periodic fit testing for respirators used in TB environments can serve as an effective training tool in conjunction with the content included in employee training and retraining. The frequency of fit testing should be determined by a change in the 1) risk for transmission of *M. tuberculosis*, 2) facial features of the wearer, 3) medical condition that would affect respiratory function, 4)

physical characteristics of the respirator (despite the same model number), or 5) model or size of the assigned respirator.

- **What kind of respiratory protection should HCWs use when providing care to persons with suspected or confirmed infectious TB disease in the home?** The recommended respiratory protection for HCWs who provide care in the homes of patients with suspected or confirmed infectious TB disease is at least an N95 respirator.
- **What kind of respiratory protection should HCWs use when transporting patients with suspected or confirmed infectious TB disease?** The risk assessment for the setting should consider the potential for shared air. Drivers, HCWs and other staff who are transporting patients with suspected or confirmed infectious TB disease in an enclosed vehicle should consider wearing an N95 disposable respirator. If the patient has symptoms or signs of infectious TB disease (e.g., productive cough or positive AFB sputum smear result), the patient should wear a surgical or procedure mask, if possible, during transport, in waiting areas, or when other persons are present. Patients who cannot tolerate masks because of medical conditions should observe strict respiratory hygiene and cough etiquette procedures.
- **What type of respiratory protection should be used in the operating room (OR) by HCWs with facial hair or other factors that preclude proper fitting of an N95 respirator?** Will wearing a surgical or procedure mask underneath a PAPR solve this problem? HCWs with facial hair should not wear negative pressure respirators (e.g., N95 disposable respirators that require a tight faceseal). In the OR, HCWs with facial hair who are caring for a person with suspected or confirmed infectious TB disease should consult their infection-control committee and respirator manufacturers regarding optimal respiratory protection and adequate infection-control measures. The HCW in this case might wear a surgical or procedure mask to protect the surgical field underneath a loose-fitting PAPR. However, the user cannot be assured of proper operation unless the PAPR's manufacturer tested the PAPR over a surgical or procedure mask or N95 respirator. All respiratory-protection equipment should be used in accordance with the manufacturer's instructions.
- **Should bacterial filters be used routinely on the breathing circuits of all ventilators and anesthesia equipment on patients with suspected or confirmed infectious TB disease?** Yes, bacterial filters should be used routinely on the exhalation breathing circuits of patients with suspected or confirmed infectious TB disease to prevent exhaled air containing infectious droplet nuclei from contaminating the room air. Filters should be used on mechanical ventilators and also on hand-held ventilating bags (i.e., manual resuscitators [e.g., ambu-bags®]). The bacterial filter should be specified by the manufacturer to filter particles 0.3 µm in both the unloaded and the loaded states, with a filter efficiency of ≥95% (i.e., filter penetration of <5%) at the maximum design flow rates of the ventilator.
- **Who should not wear an N95 respirator?** Any HCW who is restricted from using a respirator because of medical reasons should not wear one nor should persons who cannot pass a fit test because of the presence of facial hair or other condition that interferes with the seal of the respirator to the face.
- **How long can I use my respirator for TB exposures before I discard it?** Disposable respirators can be functional for weeks to months and reused by the same HCW. Reuse is limited by hygiene, damage, and breathing resistance, and manufacturer instructions should be considered.
- **Should persons who perform maintenance on and replace filters on any ventilation system that is likely to be contaminated with *M. tuberculosis* wear a respirator?** Laboratory studies indicate that re-aerosolization of viable mycobacteria from HEPA filters and N95 disposable respirator filter media is unlikely under normal conditions; however, the risks associated with handling loaded HEPA filters in ventilation systems under field-use conditions have not been evaluated. Therefore, persons performing maintenance and replacing filters on any ventilation system that is likely to be contaminated with *M. tuberculosis* should wear a respirator (see Respiratory Protection) and adhere to local recommendations for eye protection and gloves.

Cough-Inducing and Aerosol-Generating Procedures

- **Should a bronchoscopic procedure be performed on a patient with TB disease?** If possible, bronchoscopic procedures should be avoided for patients with 1) a clinical syndrome consistent with infectious pulmonary or laryngeal TB disease and 2) in persons with positive AFB sputum smear results, because bronchoscopic procedures substantially increase the risk for transmission either through an airborne route or a contaminated bronchoscope. If the diagnosis of TB is suspected, consideration should be given to empiric antituberculosis treatment, but a bronchoscopic procedure might have the advantage of confirmation of the diagnosis with histologic specimens; collection of additional specimens, including post bronchoscopy sputum,

can increase the diagnostic yield and increase the opportunity to confirm an alternate diagnosis. Microscopic examination of three consecutive sputum specimens obtained at least 8 hours apart is recommended instead of bronchoscopy.

- **For ORs without an AII room, postoperative recovery is usually in the OR suite. Is this location acceptable?** If the OR has an anteroom, this location is acceptable. Reversible flow rooms (OR or isolation) are not recommended by CDC, AIA, or ASHRAE.

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References

1. CDC. Guidelines for preventing the transmission of *Mycobacterium tuberculosis* in health-care facilities, 1994. MMWR 1994;43(No. RR-13).
2. Bennett CL, Schwartz DN, Parada JP, et al. Delays in tuberculosis isolation and suspicion among persons hospitalized with HIV-related pneumonia. *Chest* 2000;117:110–6.
3. Greenaway C, Menzies D, Fanning A, et al. Delay in diagnosis among hospitalized patients with active tuberculosis—predictors and outcomes. *Am J Respir Crit Care Med* 2002;165:927–33.
4. CDC. Trends in tuberculosis—United States, 1998–2003. MMWR 2004;53:209–14.
5. CDC. Trends in tuberculosis morbidity—United States, 1992–2002. MMWR 2003;52:217–22.
6. CDC. Guidelines for preventing the transmission of tuberculosis in health-care settings, with special focus on HIV-related issues. MMWR 1990;39(No. RR-17).
7. CDC. Guidelines for prevention of TB transmission in hospitals. Atlanta, GA: US Department of Health and Human Services, Public Health Service, CDC; 1982.
8. Fridkin SK, Manangan L, Bolyard E, Jarvis WR. Society for Healthcare Epidemiology of America. SHEA-CDC TB survey, part I: status of TB infection control programs at member hospitals, 1989–1992. *Infect Control Hosp Epidemiol* 1995;16:129–34.
9. Fridkin SK, Manangan L, Bolyard E, Jarvis WR. Society for Healthcare Epidemiology of America. SHEA-CDC TB survey, part II: efficacy of TB infection control programs at member hospitals, 1992. Society for Healthcare Epidemiology of America. *Infect Control Hosp Epidemiol* 1995;16:135–40.
10. Institute of Medicine. Tuberculosis in the workplace. Washington, DC: National Academy Press; 2001.
11. Kellerman SE, Simonds D, Banerjee S, Towsley J, Stover BH, Jarvis W. APIC and CDC survey of *Mycobacterium tuberculosis* isolation and control practices in hospitals caring for children. Part 1: patient and family isolation policies and procedures. *Am J Infect Control* 1998;26:478–82.
12. Kellerman SE, Simonds D, Banerjee S, Towsley J, Stover BH, Jarvis W. APIC and CDC survey of *Mycobacterium tuberculosis* isolation and control practices in hospitals caring for children. Part 2: environmental and administrative controls. *Am J Infect Control* 1998;26:483–7.
13. Manangan LP, Simonds DN, Pugliese G, et al. Are US hospitals making progress in implementing guidelines for prevention of *Mycobacterium tuberculosis* transmission? *Arch Intern Med* 1998;158:1440–4.
14. Manangan LP, Collazo ER, Tokars J, Paul S, Jarvis WR. Trends in compliance with the guidelines for preventing the transmission of *Mycobacterium tuberculosis* among New Jersey hospitals, 1989 to 1996. *Infect Control Hosp Epidemiol* 1999;20:337–40.
15. Manangan LP, Bennett CL, Tablan N, et al. Nosocomial tuberculosis prevention measures among two groups of US hospitals, 1992 to 1996. *Chest* 2000;117:380–4.
16. Fella P, Rivera P, Hale M, Squires K, Sepkowitz K. Dramatic decrease in tuberculin skin test conversion rate among employees at a hospital in New York City. *Am J Infect Control* 1995;23:352–6.
17. Louthier J, Rivera P, Feldman J, Villa N, DeHovitz J, Sepkowitz KA. Risk of tuberculin conversion according to occupation among health care workers at a New York City hospital. *Am J Respir Crit Care Med* 1997;156:201–5.
18. Maloney SA, Pearson ML, Gordon MT, Del Castillo R, Boyle JF, Jarvis WR. Efficacy of control measures in preventing nosocomial transmission of multidrug-resistant tuberculosis to patients and health care workers. *Ann Intern Med* 1995;122:90–5.
19. Stroud LA, Tokars JI, Grieco MH, et al. Evaluation of infection control measures in preventing the nosocomial transmission of multidrug-resistant *Mycobacterium tuberculosis* in a New York

- City hospital. *Infect Control Hosp Epidemiol* 1995;16:141–7.
20. Wenger PN, Otten J, Breeden A, Orfas D, Beck-Sague CM, Jarvis WR. Control of nosocomial transmission of multidrug-resistant *Mycobacterium tuberculosis* among healthcare workers and HIV-infected patients. *Lancet* 1995;345:235–40.
 21. Cook S, Maw KL, Munsiff SS, Fujiwara PI, Frieden TR. Prevalence of tuberculin skin test positivity and conversions among healthcare workers in New York City during 1994 to 2001. *Infect Control Hosp Epidemiol* 2003;24:807–13.
 22. McCray E, Weinbaum CM, Braden CR, Onorato IM. The epidemiology of tuberculosis in the United States. *Clin Chest Med* 1997;18:99–113.
 23. Blumberg HM, Watkins DL, Berschling JD, et al. Preventing the nosocomial transmission of tuberculosis. *Ann Intern Med* 1995;122:658–63.
 24. CDC. Trends in tuberculosis morbidity—United States, 2004. *MMWR* 2005;54:245–9.
 25. Tokars JI, McKinley GF, Otten J, et al. Use and efficacy of tuberculosis infection control practices at hospitals with previous outbreaks of multidrug-resistant tuberculosis. *Infect Control Hosp Epidemiol* 2001;22:449–55.
 26. CDC. Reported tuberculosis in the United States, 2004. Atlanta, GA: US Department of Health and Human Services, Public Health Service, CDC; 2005.
 27. Horsburgh CR, Moore M, Castro KG. Epidemiology of tuberculosis in the United States. In: Rom WN, Garay SM, eds. *Tuberculosis*. 2 ed. Philadelphia, PA: Lippincott, Williams & Wilkins; 2004:31–45.
 28. Institute of Medicine. Ending neglect: the elimination of tuberculosis in the United States. Washington, DC: National Academy Press; 2000.
 29. Culver DA, Gordon SM, Mehta AC. Infection control in the bronchoscopy suite: a review of outbreaks and guidelines for prevention. *Am J Respir Crit Care Med* 2003;167:1050–6.
 30. American Thoracic Society, CDC, Infectious Disease Society of America. Diagnostic standards and classification of tuberculosis in adults and children. *Am J Respir Crit Care Med* 2000;161:1376–95.
 31. American Thoracic Society, CDC, and Infectious Disease Society of America. Treatment of tuberculosis. *MMWR* 2003;52(No. RR-11).
 32. Wells WF. Aerodynamics of droplet nuclei [Chapter 3]. In: *Airborne contagion and air hygiene*. Cambridge, MA: Harvard University Press; 1955:13–9.
 33. Canetti G. The Tubercle bacillus in the pulmonary lesion of man: Histobacteriology and its bearing on the therapy of pulmonary tuberculosis. New York, NY: Springer Publishing Company, Inc.; 1955.
 34. CDC. Guidelines for the investigation of contacts of persons with infectious tuberculosis. Recommendations from the National Tuberculosis Controllers Association and CDC. *MMWR* 2005;54(No. RR-15):1–47.
 35. CDC. Guidelines for using the QuantiFERON(r)-TB Gold test for detecting *Mycobacterium tuberculosis* infection—United States. *MMWR* 2005;54(No. RR-15):49–55.
 36. Ferebee SH. Controlled chemoprophylaxis trials in tuberculosis. A general review. *Adv Tuberc Res* 1970;17:28–106.
 37. Sutherland I, Bleiker MA, Meijer J, Styblo K. The risk of tuberculous infection in The Netherlands from 1967 to 1979. *Tubercle* 1983;64:241–53.
 38. Comstock GW, Livesay VT, Woolpert SF. The prognosis of a positive tuberculin reaction in childhood and adolescence. *Am J Epidemiol* 1974;99:131–8.
 39. American Thoracic Society, CDC. Targeted tuberculin testing and treatment of latent tuberculosis infection. *MMWR* 2000;49(No. RR-6).
 40. US Department of Health and Human Services. The health consequences of smoking: a report of the Surgeon General. Atlanta, GA: US Department of Health and Human Services, CDC, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health; 2004.
 41. Buskin SE, Gale JL, Weiss NS, Nolan CM. *tuberculosis* risk factors in adults in King County, Washington, 1988 through 1990. *Am J Public Health* 1994;84:1750–6.
 42. CDC. Core curriculum on tuberculosis: what every clinician should know. 4 ed. Atlanta, GA: US Department of Health and Human Services, Public Health Service, CDC; 2000.
 43. Leonhardt KK, Gentile F, Gilbert BP, Aiken M. A cluster of tuberculosis among crack house contacts in San Mateo County, California. *Am J Public Health* 1994;84:1834–6.
 44. McElroy PD, Southwick KL, Fortenberry ER, et al. Outbreak of tuberculosis among homeless persons coinfecting with human immunodeficiency virus. *Clin Infect Dis* 2003;36:1305–12.
 45. McElroy PD, Rothenberg RB, Varghese R, et al. A network-informed approach to investigating a tuberculosis outbreak: implications for enhancing contact investigations. *Int J Tuberc Lung Dis* 2003;7:S486–S493.

46. Reyes JC, Robles RR, Colon HM, Marrero CA, Castillo X, Melendez M. Mycobacterium tuberculosis infection among crack and injection drug users in San Juan, Puerto Rico. *PR Health Sci J* 1996;15:233–6.
47. Taubes T, Galanter M, Dermatis H, Westreich L. Crack cocaine and schizophrenia as risk factors for PPD reactivity in the dually diagnosed. *Journal of Addictive Diseases* 1998;17:63–74.
48. Howard TP, Solomon DA. Reading the tuberculin skin test: who, when, and how? *Arch Intern Med* 1988;148:2457–9.
49. CDC. Treating opportunistic infections among HIV-infected adults and adolescents. Recommendations from CDC, the National Institutes of Health, and the HIV Medicine Association/Infectious Diseases Society of America. MMWR 2004;53(No. RR-15).
50. CDC. Voluntary HIV testing as part of routine medical care—Massachusetts, 2002. MMWR 2004;53:523–6.
51. CDC. Advancing HIV prevention: new strategies for a changing epidemic—United States, 2003. MMWR 2003;52:329–32.
52. CDC. Essential components of a tuberculosis prevention and control program. Recommendations of the Advisory Council for the Elimination of Tuberculosis. MMWR 1995;44(No. RR-11):1–16.
53. CDC. Prevention and treatment of tuberculosis among patients infected with human immunodeficiency virus: principles of therapy and revised recommendations. MMWR 1998;47(No. RR-20).
54. Daley CL, Small PM, Schechter GF, et al. An outbreak of tuberculosis with accelerated progression among persons infected with the human immunodeficiency virus. An analysis using restriction-fragment-length polymorphisms. *N Engl J Med* 1992;326:231–5.
55. Dooley SW, Villarino ME, Lawrence M, et al. Nosocomial transmission of tuberculosis in a hospital unit for HIV-infected patients. *JAMA* 1992;267:2632–4.
56. Edlin BR, Tokars JI, Grieco MH, et al. An outbreak of multidrug-resistant tuberculosis among hospitalized patients with the acquired immunodeficiency syndrome. *N Engl J Med* 1992;326:1514–21.
57. Kenyon TA, Ridzon R, Luskin-Hawk R, et al. A nosocomial outbreak of multidrug-resistant tuberculosis. *Ann Intern Med* 1997;127:32–6.
58. CDC, US Public Health Service, Infectious Disease Society of America. Guidelines for preventing opportunistic infections among HIV-infected persons—2002. Recommendations of the U.S. Public Health Service and the Infectious Diseases Society of America. MMWR 2002;51(No. RR-8).
59. Colditz GA, Brewer TF, Berkey CS, et al. Efficacy of BCG vaccine in the prevention of tuberculosis: meta-analysis of the published literature. *JAMA* 1994;271:698–702.
60. Rodrigues LC, Diwan VK, Wheeler JG. Protective effect of BCG against tuberculous meningitis and miliary tuberculosis: a meta-analysis. *Int J Epidemiol* 1993;22:1154–8.
61. Barrett-Connor E. The epidemiology of tuberculosis in physicians. *JAMA* 1979;241:33–8.
62. Styblo K. Epidemiology of tuberculosis. The Hague, Netherlands: Royal Netherlands Tuberculosis Association (KNCV); 1991.
63. Catanzaro A. Nosocomial tuberculosis. *Am Rev Respir Dis* 1982;125:559–62.
64. Di Perri G, Cruciani M, Danzi MC, et al. Nosocomial epidemic of active tuberculosis among HIV-infected patients. *Lancet* 1989;2:1502–4.
65. Koppaka VR, Ridzon R. Prevention and control of the nosocomial transmission of Mycobacterium tuberculosis. In: Wenzel RP, ed. Prevention and control of nosocomial infections. 4 ed. Philadelphia, PA: Lippincott Williams & Wilkins; 2003:229–52.
66. Ehrenkranz NJ, Kicklighter JL. Tuberculosis outbreak in a general hospital: evidence for airborne spread of infection. *Ann Intern Med* 1972;77:377–82.
67. Goldman KP. Tuberculosis in hospital doctors. *Tubercle* 1988;69:237–40.
68. Haley CE, McDonald RC, Rossi L, Jones WD Jr, Haley RW, Luby JP. Tuberculosis epidemic among hospital personnel. *Infect Control Hosp Epidemiol* 1989;10:204–10.
69. Hutton MD, Stead WW, Cauthen GM, Bloch AB, Ewing WM. Nosocomial transmission of tuberculosis associated with a draining abscess. *J Infect Dis* 1990;161:286–95.
70. Jereb JA, Kleven RM, Privett TD, et al. Tuberculosis in health care workers at a hospital with an outbreak of multidrug-resistant Mycobacterium tuberculosis. *Arch Intern Med* 1995;155:854–9.
71. Kantor HS, Poblete R, Pusateri SL. Nosocomial transmission of tuberculosis from unsuspected disease. *Am J Med* 1988;84:833–8.
72. Lundgren R, Norrman E, Asberg I. Tuberculosis infection transmitted at autopsy. *Tubercle* 1987;68:147–50.

73. McGowan JE Jr. Nosocomial tuberculosis: new progress in control and prevention. *Clin Infect Dis* 1995;21:489–505.
74. Menzies D, Fanning A, Yuan L, Fitzgerald M. *tuberculosis* among health care workers. *N Engl J Med* 1995;332:92–8.
75. Menzies D, Fanning A, Yuan L, FitzGerald JM, Canadian Collaborative Group in Nosocomial Transmission of Tuberculosis. Factors associated with tuberculin conversion in Canadian microbiology and pathology workers. *Am J Respir Crit Care Med* 2003;167:599–602.
76. Sepkowitz KA, Friedman CR, Hafner A, et al. Tuberculosis among urban health care workers: a study using restriction fragment length polymorphism typing. *Clin Infect Dis* 1995;21:1098–1012.
77. Templeton GL, Illing LA, Young L, Cave D, Stead WW, Bates JH. The risk for transmission of *Mycobacterium tuberculosis* at the bedside and during autopsy. *Ann Intern Med* 1995;122:922–5.
78. Zaza S, Blumberg HM, Beck-Sague C, et al. Nosocomial transmission of *Mycobacterium tuberculosis*: role of health care workers in outbreak propagation. *J Infect Dis* 1995;172:1542–9.
79. Anonymous. HazardAlert! Clusters of "positive PPD skin tests" due to intradermal injection of Td. *NurseAdvice-ERR* 2003;1:2.
80. Larson JL, Lambert L, Stricof RL, Driscoll J, McGarry MA, Ridzon R. Potential nosocomial exposure to *Mycobacterium tuberculosis* from a bronchoscope. *Infect Control Hosp Epidemiol* 2003;24:825–30.
81. Weber DJ, Rutala WA. Lessons from outbreaks associated with bronchoscopy. *Infect Control Hosp Epidemiol* 2001;22:403–8.
82. Srinivasan A, Wolfenden LL, Song X, Perl TM, Haponik EF. Bronchoscope reprocessing and infection prevention and control: bronchoscopy-specific guidelines are needed. *Chest* 2004;125:307–14.
83. D'Agata EM, Wise S, Stewart A, Lefkowitz LB Jr. Nosocomial transmission of *Mycobacterium tuberculosis* from an extrapulmonary site. *Infect Control Hosp Epidemiol* 2001;22:10–2.
84. Ball R, Van Wey M. *tuberculosis* skin test conversion among health care workers at a military medical center. *Military Medicine* 1997;162:338–43.
85. Menzies D, Fanning A, Yuan L, FitzGerald JM, Canadian Collaborative Group in Nosocomial Transmission of Tuberculosis. Hospital ventilation and risk for tuberculous infection in Canadian health care workers. Canadian Collaborative Group in Nosocomial Transmission of TB. *Ann Intern Med* 2000;133:779–89.
86. Williams J, Schneider N, Gilligan ME. Implementing a tuberculosis control program. *Am J Infect Control* 1995;23:152–5.
87. Beck-Sague C, Dooley SW, Hutton MD, et al. Hospital outbreak of multidrug-resistant *Mycobacterium tuberculosis* infections. Factors in transmission to staff and HIV-infected patients. *JAMA* 1992;268:1280–6.
88. CDC. *Mycobacterium tuberculosis* transmission in a health clinic—Florida, 1988. *MMWR* 1989;38:256–8, 263–4.
89. Nivin B, O'Flaherty T, Leibert E, Zhao BY, Driscoll J. Sputum induction problems identified through genetic fingerprinting. *Infect Control Hosp Epidemiol* 2002;23:580–3.
90. Pizzichini E, Pizzichini MM, Leigh R, Djukanovic R, Sterk PJ. Safety of sputum induction. *Eur Respir J* 2002;37(Suppl):9S–18S.
91. CDC. *Epidemiology Notes and Reports. Nosocomial transmission of multidrug-resistant tuberculosis to health-care workers and HIV-infected patients in an urban hospital—Florida. MMWR* 1990;39:718–22.
92. CDC. *Epidemiology Notes and Reports. Nosocomial transmission of multidrug-resistant tuberculosis among HIV-infected persons—Florida and New York, 1988–1991. MMWR* 1991;40:585–91.
93. Dooley SW, Jarvis WR, Martone WJ, Snider DE Jr. Multidrug-resistant tuberculosis. *Ann Intern Med* 1992;117:257–9.
94. Pearson ML, Jereb JA, Frieden TR, et al. Nosocomial transmission of multidrug-resistant *Mycobacterium tuberculosis*. A risk to patients and health care workers. *Ann Intern Med* 1992;117:191–6.
95. Larsen NM, Biddle CL, Sotir MJ, White N, Parrott P, Blumberg HM. Risk for tuberculin skin test conversion among health care workers: occupational versus community exposure and infection. *Clin Infect Dis* 2002;35:796–801.
96. Moro ML, Errante I, Infuso A, et al. Effectiveness of infection control measures in controlling a nosocomial outbreak of multidrug-resistant tuberculosis among HIV patients in Italy. *Int J Tuberc Lung Dis* 2000;4:61–8.

97. Panlilio AL, Burwen DR, Curtis AB, et al. Tuberculin skin testing surveillance of health care personnel. *Clin Infect Dis* 2002;35:219–27.
98. Fuss EP, Israel E, Baruch N, Roghmann MC. Improved tuberculosis infection control practices in Maryland acute care hospitals. *Am J Infect Control* 2000;28:133–7.
99. Stricof RL, DiFerdinando GT Jr, Osten WM, Novick LF. Tuberculosis control in New York City hospitals. *Am J Infect Control* 1998;26:270–6.
100. Lambert L, Rajbhandary S, Qualls N, et al. Costs of implementing and maintaining a tuberculin skin test program in hospitals and health departments. *Infect Control Hosp Epidemiol* 2003;24:814–20.
101. Askew GL, Finelli L, Hutton M, et al. Mycobacterium tuberculosis transmission from a pediatrician to patients. *Pediatrics* 1997;100:19–23.
102. Moore M, Schulte J, Valway SE, et al. Evaluation of transmission of Mycobacterium tuberculosis in a pediatric setting. *J Pediatr* 1998;133:108–12.
103. Schulte JM, Moore M, Kistler V, et al. Tuberculosis screening in private physicians' offices, Pennsylvania, 1996. *Am J Prev Med* 1999;16:178–81.
104. CDC. Drug-susceptible tuberculosis outbreak in a state correctional facility housing HIV-infected inmates—South Carolina, 1999–2000. MMWR 2000;49:1041–4.
105. Lobato MN, Roberts CA, Bazerman LB, Hammett TM. Public health and correctional collaboration in tuberculosis control. *Am J Prev Med* 2004;27:112–7.
106. Reichard AA, Lobato MN, Roberts CA, Bazerman LB, Hammett TM. Assessment of tuberculosis screening and management practices of large jail systems. *Public Health Rep* 2003;118:500–7.
107. Fennelly KP, Nardell EA. The relative efficacy of respirators and room ventilation in preventing occupational tuberculosis. *Infect Control Hosp Epidemiol* 1998;19:754–9.
108. Joint Commission on Accreditation of Healthcare Organizations. 2005 Critical access hospitals: surveillance, prevention, and control of infection. Oak Brook, IL: Joint Commission Resources; 2005.
109. Al Zahrani K, Al Jahdali H, Poirier L, Rene P, Menzies D. Yield of smear, culture and amplification tests from repeated sputum induction for the diagnosis of pulmonary tuberculosis. *Int J Tuberc Lung Dis* 2001;5:855–60.
110. Conde MB, Soares SL, Mello FC, et al. Comparison of sputum induction with fiberoptic bronchoscopy in the diagnosis of tuberculosis: experience at an acquired immune deficiency syndrome reference center in Rio de Janeiro, Brazil. *Am J Respir Crit Care Med* 2000;162:2238–40.
111. Bell D, Leckie V, McKendrick M. The role of induced sputum in the diagnosis of pulmonary tuberculosis. *J Infect* 2003;47:317–21.
112. Merrick ST, Sepkowitz KA, Walsh J, Damson L, McKinley P, Jacobs JL. Comparison of induced versus expectorated sputum for diagnosis of pulmonary tuberculosis by acid-fast smear. *Am J Infect Control* 1997;25:463–6.
113. CDC. Medical examiners, coroners, and biologic terrorism: a guidebook for surveillance and case management. MMWR 2004;53(No. RR-8).
114. CDC. Guidelines for environmental infection control in health-care facilities: recommendations of CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC). MMWR 2003;52(No. RR-10).
115. CDC. Effective TB interviewing for contact investigation. Atlanta, GA: US Department of Health and Human Services, CDC; 2004.
116. Food and Drug Administration. The selection of patients for x-ray examinations: chest x-ray screening examinations. Rockville, MD: US Department of Health and Human Services, Public Health Service, Food and Drug Administration; August 1983:26–9.
117. American Society of Heating, Refrigerating and Air-Conditioning Engineers, Inc. Health care facilities [Chapter 7]. 2003 ASHRAE handbook: HVAC applications. Atlanta, GA: American Society of Heating, Refrigerating and Air-Conditioning Engineers, Inc.; 2003:7.1–7.14.
118. American Institute of Architects. Guidelines for design and construction of hospital and health care facilities. Washington, DC: American Institute of Architects; 2001.
119. Francis J. Curry National Tuberculosis Center. Making the connection: an introduction to interpretation skills for TB control. San Francisco, CA: Francis J. Curry National Tuberculosis Center; 2003.
120. Lenehan GP. Universal respiratory etiquette: a modest proposal. *J Emerg Nurs* 2004;30:3.
121. Piotrowski J. Respiratory etiquette. CDC's SARS draft plan suggests masks for patients. *Mod Healthc* 2003;33:13.
122. CDC. Key facts about the flu and flu vaccine. Atlanta, GA: US Department of Health and Human Services, CDC; 2004.

123. Leonard MK, Osterholt D, Kourbatova EV, Del Rio C, Wang W, Blumberg HM. How many sputum specimens are necessary to diagnose pulmonary tuberculosis? *Am J Infect Control* 2005;33:58–61.
124. Toman K. How many bacilli are present in a sputum specimen found positive by smear microscopy [Chapter 4]. In: Frieden T, ed. *Toman's tuberculosis case detection, treatment, and monitoring: questions and answers*. 2nd ed. Geneva, Switzerland: World Health Organization; 2004:11–3.
125. CDC. Update: nucleic acid amplification tests for tuberculosis. *MMWR* 2000;49:593–4.
126. Willcox PA, Potgieter PD, Bateman ED, Benatar SR. Rapid diagnosis of sputum negative miliary tuberculosis using the flexible fiberoptic bronchoscope. *Thorax* 1986;41:681–4.
127. Abadco DL, Steiner P. Gastric lavage is better than bronchoalveolar lavage for isolation of *Mycobacterium tuberculosis* in childhood pulmonary tuberculosis. *Pediatr Infect Dis J* 1992;11:735–8.
128. Abadco DL, Amaro-Galvez R, Rao M, Steiner P. Experience with flexible fiberoptic bronchoscopy with bronchoalveolar lavage as a diagnostic tool in children with AIDS. *Am J Dis Child* 1992;146:1056–9.
129. Chan S, Abadco DL, Steiner P. Role of flexible fiberoptic bronchoscopy in the diagnosis of childhood endobronchial tuberculosis. *Pediatr Infect Dis J* 1994;13:506–9.
130. Lillehei JP. Sputum induction with heated aerosol inhalations for the diagnosis of tuberculosis. *Am Rev Respir Dis* 1961;84:276–8.
131. Willcox PA, Benatar SR, Potgieter PD. Use of the flexible fiberoptic bronchoscope in diagnosis of sputum-negative pulmonary tuberculosis. *Thorax* 1982;37:598–601.
132. Djukanovic R, Sterk PJ, Fahy JV, Hargreave FE. Standardised methodology of sputum induction and processing. *Eur Respir J* 2002;37(Suppl):1S–2S.
133. Paggiaro PL, Chanez P, Holz O, Ind PW, Djukanovic R, Maestrelli P, Sterk PJ. Sputum induction. *Eur Respir J* 2002;37(Suppl):3S–8S.
134. Gibson PG, Grootendor DC, Henry RL, et al. Sputum induction in children. *Eur Respir J* 2002;20(Suppl 4):44S–46S.
135. Curtis AB, Ridzon R, Vogel R, et al. Extensive transmission of *Mycobacterium tuberculosis* from a child. *N Engl J Med* 1999;341:1491–5.
136. American Academy of Pediatrics. *Tuberculosis*. 26 ed. Elk Grove Village, IL: American Academy of Pediatrics; 2003:642–80.
137. Rabalais G, Adams G, Stover B. PPD skin test conversion in health-care workers after exposure to *Mycobacterium tuberculosis* infection in infants. *Lancet* 1991;338:826.
138. CDC, National Institutes of Health. *Agent: Mycobacterium tuberculosis, M. bovis*. In: Richmond JY, McKinley RW, eds. *Biosafety in Microbiological and Biomedical Laboratories*. 4 ed. Washington, DC: US Government Printing Office; 1999:105–6.
139. Association of State and Territorial Public Health Laboratory Directors, CDC. *Mycobacterium tuberculosis: assessing your laboratory*. Atlanta, GA: US Department of Health and Human Services, CDC; 1995.
140. Tenover FC, Crawford JT, Huebner RE, Geiter LJ, Horsburgh CR Jr, Good RC. The resurgence of tuberculosis: is your laboratory ready? *J Clin Microbiol* 1993;31:767–70.
141. Klein NC, Duncanson FP, Lenox TH III, Pitta A, Cohen SC, Wormser GP. Use of mycobacterial smears in the diagnosis of pulmonary tuberculosis in AIDS/ARC patients. *Chest* 1989;95:1190–2.
142. Pitchenik AE, Robinson HA. The radiographic appearance of tuberculosis in patients with the acquired immune deficiency syndrome (AIDS) and pre-AIDS. *Am Rev Respir Dis* 1985;131:393–6.
143. Chaulk CP, Kazandjian VA. Directly observed therapy for treatment completion of pulmonary tuberculosis: consensus statement of the Public Health Tuberculosis Guidelines Panel. *JAMA* 1998;279:943–8. Erratum in: *JAMA* 1998;280:134.
144. Frieden TR, Fujiwara PI, Washko RM, Hamburg MA. Tuberculosis in New York City—turning the tide. *N Engl J Med* 1995;333:229–33.
145. Weis SE, Slocum PC, Blais FX, et al. The effect of directly observed therapy on the rates of drug resistance and relapse in tuberculosis. *N Engl J Med* 1994;330:1179–84.
146. Sokolove PE, Lee BS, Krawczyk JA, et al. Implementation of an emergency department triage procedure for the detection and isolation of patients with active pulmonary tuberculosis. *Ann Emerg Med* 2000;35:327–36.
147. Aranha-Creado H, Prince D, Greene K, Brandwein H. Removal of *Mycobacterium* species by breathing circuit filters. *Infect Control Hosp Epidemiol* 1997;18:252–4.
148. Berry AJ, Nolte FS. An alternative strategy for infection control of anesthesia breathing circuits: a laboratory assessment of the Pall HME Filter. *Anesth Analg* 1991;72:651–5.

149. Demers RR. Bacterial/viral filtration: let the breather beware! *Chest* 2001;120:1377-89.
150. Langevin PB, Rand KH, Layon AJ. The potential for dissemination of *Mycobacterium tuberculosis* through the anesthesia breathing circuit. *Chest* 1999;115:1107-14.
151. Tait AR. Occupational transmission of tuberculosis: implications for anesthesiologists. *Anesth Analg* 1997;85:444-51.
152. Teo DT, Lim TW. Transmission of tuberculosis from patient to healthcare workers in the anaesthesia context. *Ann Acad Med Singapore* 2004;33:95-9.
153. Kao AS, Ashford DA, McNeil MM, Warren NG, Good RC. Descriptive profile of tuberculin skin testing programs and laboratory-acquired tuberculosis infections in public health laboratories. *J Clin Microbiol* 1997;35:1847-51.
154. Peerbooms PG, van Doornum GJ, van Deutekom H, Coutinho RA, van Soolingen D. Laboratory-acquired tuberculosis. *Lancet* 1995;345:1311-2.
155. Garber E, San Gabriel P, Lambert L, Saiman L. A survey of latent tuberculosis infection among laboratory healthcare workers in New York City. *Infect Control Hosp Epidemiol* 2003;24:801-6.
156. Metchock BG, Nolte FS, Wallace RJ. *Mycobacterium*. In: Murray PR, Barron EJ, Pfaller MA, Tenover FC, Tenover FC, eds. *Manual of Clinical Microbiology*. 7 ed. Washington, DC: American Society for Microbiology; 1999:399-437.
157. Richmond JY. Anthology of biosafety: IV. Issues in public health. American Biological Safety Association; 2001.
158. CDC, National Institutes of Health. Primary containment for biohazards: selection, installation and use of biological safety cabinets. 2nd ed. Washington, DC: US Government Printing Office; 2000.
159. CDC, National Institutes of Health. Biosafety in microbiological and biomedical laboratories. 4th ed. Washington, DC: US Government Printing Office; 1999.
160. Mehta AC, Minai OA. Infection control in the bronchoscopy suite. A review. *Clin Chest Med* 1999;20:19-32.
161. Wang KP, Mehta AC. Flexible bronchoscopy. Blackwell Science, Inc.; 1995.
162. Jereb JA, Burwen DR, Dooley SW, et al. Nosocomial outbreak of tuberculosis in a renal transplant unit: application of a new technique for restriction fragment length polymorphism analysis of *Mycobacterium tuberculosis* isolates. *J Infect Dis* 1993;168:1219-24.
163. Agerton T, Valway S, Gore B, et al. Transmission of a highly drug-resistant strain (strain W1) of *Mycobacterium tuberculosis*. Community outbreak and nosocomial transmission via a contaminated bronchoscope. *JAMA* 1997;278:1073-7.
164. CDC. Bronchoscopy-related infections and pseudoinfections—New York, 1996 and 1998. *MMWR* 1999;48:557-60.
165. Leers WD. Disinfecting endoscopes: how not to transmit *Mycobacterium tuberculosis* by bronchoscopy. *Can Med Assoc J* 1980;123:275-80.
166. Michele TM, Cronin WA, Graham NM, et al. Transmission of *Mycobacterium tuberculosis* by a fiberoptic bronchoscope. Identification by DNA fingerprinting. *JAMA* 1997;278:1093-5.
167. Nelson KE, Larson PA, Schraufnagel DE, Jackson J. Transmission of tuberculosis by flexible fiberbronchoscopes. *Am Rev Respir Dis* 1983;127:97-100.
168. Ramsey AH, Oemig TV, Davis JP, Massey JP, Torok TJ. An outbreak of bronchoscopy-related *Mycobacterium tuberculosis* infections due to lack of bronchoscope leak testing. *Chest* 2002;121:976-81.
169. Spach DH, Silverstein FE, Stamm WE. Transmission of infection by gastrointestinal endoscopy and bronchoscopy. *Ann Intern Med* 1993;118:117-28.
170. Bar W, Marquez de Bar G, Naumann A, Rusch-Gerdes S. Contamination of bronchoscopes with *Mycobacterium tuberculosis* and successful sterilization by low-temperature hydrogen peroxide plasma sterilization. *Am J Infect Control* 2001;29:306-11.
171. Gershon RR, Vlahov D, Escamilla-Cejudo JA, et al. Tuberculosis risk in funeral home employees. *J Occup Environ Med* 1998;40:497-503.
172. Lauzardo M, Lee P, Duncan H, Hale Y. Transmission of *Mycobacterium tuberculosis* to a funeral director during routine embalming. *Chest* 2001;119:640-2.
173. McKenna MT, Hutton M, Cauthen G, Onorato IM. The association between occupation and tuberculosis. A population-based survey. *Am J Respir Crit Care Med* 1996;154:587-93.
174. Sterling TR, Pope DS, Bishai WR, Harrington S, Gershon RR, Chaisson RE. Transmission of *Mycobacterium tuberculosis* from a cadaver to an embalmer. *N Engl J Med* 2000;342:246-48.
175. Sugita M, Tsutsumi Y, Suchi M, Kasuga H, Ishiko T. Pulmonary tuberculosis. An occupational hazard for pathologists and pathology technicians in Japan. *Acta Pathol Jpn* 1990;40:116-27.
176. Ussery XT, Bierman JA, Valway SE, Seitz TA, DiFerdinando GT Jr, Ostroff SM. Transmission of multidrug-resistant *Mycobacterium tuberculosis* among persons exposed in a medical

- examiner's office, New York. *Infect Control Hosp Epidemiol* 1995;16:160–5.
177. Burton JL. Health and safety at necropsy. *J Clin Pathol* 2003;56:254–60.
 178. American Conference of Governmental Industrial Hygienists. *Industrial ventilation: a manual of recommended practice*. 24 ed. Cincinnati, OH: American Conference of Governmental Industrial Hygienists; 2001.
 179. Murthy BV, Pereira BJ. A 1990s perspective of hepatitis C, human immunodeficiency virus, and tuberculosis infections in dialysis patients. *Semin Nephrol* 1997;17:346–63.
 180. Tokars JI, Miller B. Tuberculin skin testing of ESRD patients. *Am J Kidney Dis* 1997;30:456–7.
 181. Ahmed AT, Karter AJ. Tuberculosis in California dialysis patients. *Int J Tuberc Lung Dis* 2004;8:341–5.
 182. Simon TA, Paul S, Wartenberg D, Tokars JI. Tuberculosis in hemodialysis patients in New Jersey: a statewide study. *Infect Control Hosp Epidemiol* 1999;20:607–9.
 183. Fang HC, Chou KJ, Chen CL, et al. Tuberculin skin test and anergy in dialysis patients of a tuberculosis-endemic area. *Nephron* 2002;91:682–7.
 184. Duell RC, Madden RM. Droplet nuclei produced during dental treatment of tubercular patients. A preliminary study. *Oral Surg Oral Med Oral Pathol* 1970;30:711–6.
 185. Naidoo S, Mahommed A. Knowledge, attitudes, behaviour and prevalence of TB infection among dentists in the western Cape. *SADJ* 2002;57:476–8.
 186. Cleveland JL, Kent J, Gooch BF, et al. Multidrug-resistant *Mycobacterium tuberculosis* in an HIV dental clinic. *Infect Control Hosp Epidemiol* 1995;16:7–11.
 187. Kohn WG, Harte JA, Malvitz DM, et al. Guidelines for infection control in dental health care settings—2003. *J Am Dent Assoc* 2004;135:33–47.
 188. CDC. Guidelines for infection control in dental health-care settings—2003. MMWR 2003;52(No. RR-17).
 189. CDC. Prevention and control of tuberculosis among homeless persons. Recommendations of the Advisory Council for the Elimination of Tuberculosis. MMWR 1992;41(No. RR-5):13–23.
 190. CDC. Tuberculosis outbreak in a homeless population—Portland, Maine, 2002–2003. MMWR 2003;52:1184–5.
 191. Asch S, Leake B, Knowles L, Gelberg L. Tuberculosis in homeless patients: potential for case finding in public emergency departments. *Ann Emerg Med* 1998;32:144–7.
 192. CDC. Tuberculosis transmission in a homeless shelter population—New York, 2000–2003. MMWR 2005;54:149–52.
 193. Prezant DJ, Kelly KJ, Mineo FP, et al. Tuberculin skin test conversion rates in New York City Emergency Medical Service health care workers. *Ann Emerg Med* 1998;32:208–13.
 194. Seitz TA, Decker J, Jensen PA. *Health Hazard Evaluation Report: University of Medicine and Dentistry of New Jersey, University Hospital, Newark, NJ*. Cincinnati, OH: US Department of Health and Human Services, Public Health Service, CDC, National Institute for Occupational Safety and Health; 1996. Publication no. HETA 95-0031-2601.
 195. Dickinson E. Exposures in EMS. An EMS medical director's 3-step plan to protect providers from TB exposure. *EMS* 1999;24:S6–7.
 196. CDC. Prevention and control of tuberculosis in correctional facilities. Recommendations of the Advisory Council for the Elimination of Tuberculosis. MMWR 1996;45(No. RR-8).
 197. McLaughlin SI, Spradling P, Drociuk D, Ridzon R, Pozsik CJ, Onorato I. Extensive transmission of *Mycobacterium tuberculosis* among congregated, HIV-infected prison inmates in South Carolina, United States. *Int J Tuberc Lung Dis* 2003;7:665–72.
 198. Mohle-Boetani JC, Miguelino V, Dewsnap DH, et al. Tuberculosis outbreak in a housing unit for human immunodeficiency virus-infected patients in a correctional facility: transmission risk factors and effective outbreak control. *Clin Infect Dis* 2002;34:668–76.
 199. Valway SE, Richards SB, Kovacovich J, Greifinger RB, Crawford JT, Dooley SW. Outbreak of multi-drug-resistant tuberculosis in a New York State prison, 1991. *Am J Epidemiol* 1994;140:113–22.
 200. Valway SE, Greifinger RB, Papania M, et al. Multidrug-resistant tuberculosis in the New York State prison system, 1990–1991. *J Infect Dis* 1994;170:151–6.
 201. Cone JE, Harrison R, Katz E, Chan J, Dewsnap D, Osorio AM. *tuberculosis* transmission to prison employees during an outbreak among prisoners at two California prisons. *Journal of Healthcare Safety, Compliance & Infection Control* 2004;4:75–9.
 202. Ijaz K, Yang Z, Templeton G, Stead WW, Bates JH, Cave MD. Persistence of a strain of *Mycobacterium tuberculosis* in a prison system. *Int J Tuberc Lung Dis* 2004;8:994–1000.
 203. Steenland K, Levine AJ, Sieber K, Schulte P, Aziz D. Incidence of tuberculosis infection among New York State prison employees. *Am J Public Health* 1997;87:2012–4.

204. March F, Coll P, Guerrero RA, Busquets E, Cayla JA, Prats G. Predictors of tuberculosis transmission in prisons: an analysis using conventional and molecular methods. *AIDS* 2000;14:525–35.
205. Stead WW. Undetected tuberculosis in prison. Source of infection for community at large. *JAMA* 1978;240:2544–7.
206. Jones TF, Craig AS, Valway SE, Woodley CL, Schaffner W. Transmission of tuberculosis in a jail. *Ann Intern Med* 1999;131:557–63.
207. Hammett TM, Harmon MP, Rhodes W. The burden of infectious disease among inmates of and releasees from US correctional facilities, 1997. *Am J Public Health* 2002;92:1789–94.
208. MacIntyre CR, Kendig N, Kummer L, Birago S, Graham NM. Impact of tuberculosis control measures and crowding on the incidence of tuberculous infection in Maryland prisons. *Clin Infect Dis* 1997;24:1060–7.
209. Tulskey JP, White MC, Dawson C, Hoynes TM, Goldenson J, Schecter G. Screening for tuberculosis in jail and clinic follow-up after release. *Am J Public Health* 1998;88:223–6.
210. Reyes H, Coninx R. Pitfalls of tuberculosis programmes in prisons. *BMJ* 1997;315:1447–50.
211. CDC. Tuberculosis outbreaks in prison housing units for HIV-infected inmates—California 1995–1996. *MMWR* 1999;48:79–82.
212. CDC. Tuberculosis transmission in multiple correctional facilities—Kansas, 2002–2003. *MMWR* 2004;53:734–8.
213. Ismeurt RL, Long CO. Tuberculosis. A new threat from an old nemesis. *Home Healthcare Nurse* 1993;11:16–23.
214. Stamp D, Arnold MS. Tuberculosis in home care. Complying with OSHA. *Caring* 1995;14:16–8, 20–2.
215. Lefrak S. Tuberculosis screening in a nursing home: indications for preventive therapy. *JAMA* 1991;266:2000–3.
216. Thrupp L, Bradley S, Smith P, et al. Tuberculosis prevention and control in long-term-care facilities for older adults. *Infect Control Hosp Epidemiol* 2004;25:1097–108.
217. Bentley DW. Tuberculosis in long-term care facilities. *Infect Control Hosp Epidemiol* 1990;11:42–6.
218. Malone JL, Ijaz K, Lambert L, et al. Investigation of healthcare-associated transmission of *Mycobacterium tuberculosis* among patients with malignancies at three hospitals and at a residential facility. *Cancer* 2004;101:2713–21.
219. Stead WW. Special problems in tuberculosis. Tuberculosis in the elderly and in residents of nursing homes, correctional facilities, long-term care hospitals, mental hospitals, shelters for the homeless, and jails. *Clin Chest Med* 1989;10:397–405.
220. Stead WW. Management of health care workers after inadvertent exposure to tuberculosis: a guide for the use of preventive therapy. *Ann Intern Med* 1995;122:906–12.
221. Linder JF, Enders SR, Craig E, Richardson J, Meyers FJ. Hospice care for the incarcerated in the United States: an introduction. *J Palliat Med* 2002;5:549–52.
222. McKeogh MM. *tuberculosis* in the hospice—a cause for concern? *Palliative Medicine* 1997;11:469–74.
223. CDC. Mantoux tuberculin skin test—training materials kit. Atlanta, GA: US Department of Health and Human Services, Public Health Service, CDC; 2003.
224. Snider DE Jr, Cauthen GM. Tuberculin skin testing of hospital employees: infection, "boosting," and two-step testing. *Am J Infect Control* 1984;12:305–11.
225. Duboczy BO, Brown BT. Multiple readings and determination of maximal intensity of tuberculin reaction. *Am Rev Respir Dis* 1961;84:60–8.
226. Cobelens F, van Deutekom H, Draayer-Jansen I, Schepp-Beelen A, Van Gerven P, Mensen M. Tuberculin skin test reactions by time of reading among Dutch travellers. *Int J Tuberc Lung Dis* 2003;7:758–63.
227. CDC. The role of BCG vaccine in the prevention and control of tuberculosis in the United States. A joint statement by the Advisory Council for the Elimination of Tuberculosis and the Advisory Committee on Immunization Practices. *MMWR* 1996;45(No. RR-4):1–18.
228. Huebner RE, Schein MF, Bass JB Jr. The tuberculin skin test. *Clin Infect Dis* 1993;17:968–75.
229. Karalliedde S, Katugaha LP, Uragoda CG. Tuberculin response of Sri Lankan children after BCG vaccination at birth. *Tubercle* 1987;68:33–8.
230. Mazurek GH, LoBue PA, Daley CL, et al. Comparison of a whole-blood interferon gamma assay with tuberculin skin testing for detecting latent *Mycobacterium tuberculosis* infection. *JAMA* 2001;286:1740–7.
231. Menzies R, Vissandjee B. Effect of Bacille Calmette-Guerin vaccination on tuberculin reactivity. *Am Rev Respir Dis* 1992;145:621–5.

232. Snider DE Jr. Bacille Calmette-Guerin vaccinations and tuberculin skin tests. *JAMA* 1985;253:3438–9.
233. Bugiani M, Borraccino A, Migliore E, et al. Tuberculin reactivity in adult BCG-vaccinated subjects: a cross-sectional study. *Int J Tuberc Lung Dis* 2003;7:320–6.
234. Aronson NE, Santosham M, Comstock GW, et al. Long-term efficacy of BCG vaccine in American Indians and Alaska Natives. A 60-year follow-up study. *JAMA* 2004;291:2086–91.
235. Dye C. A booster for tuberculosis vaccines. *JAMA* 2004;291:2127–8.
236. Fine PE, Carneiro IAM, Milstien JB, Clements CJ. Issues relating to the use of BCG in immunization programs. A discussion document. Geneva, Switzerland: World Health Organization, Department of Vaccines and Biologicals; 1999.
237. Aventis Pasteur. Tuberculin purified protein derivative (Mantoux) Tubersol(r) diagnostic antigen. Toronto, Ontario, Canada: Aventis Pasteur; 2001.
238. Parkdale Pharmaceuticals. APLISOL(r) (Tuberculin purified protein derivative, diluted [stabilized solution]). Diagnostic antigen for intradermal injection only. Rochester, MI: Parkdale Pharmaceuticals; 2002.
239. Froeschle JE, Ruben FL, Bloh AM. Immediate hypersensitivity reactions after use of tuberculin skin testing. *Clin Infect Dis* 2002;34:E12–3.
240. CDC. Update: adverse event data and revised American Thoracic Society/CDC recommendations against the use of rifampin and pyrazinamide for treatment of latent tuberculosis infection—United States, 2003. *MMWR* 2003;52:735–9.
241. Senate and House of Representatives of the United States of America. Americans with Disabilities Act of 1990, Titles I and V; 1990:12101–213.
242. Widdowson MA, Bosman A, van Straten E, et al. Automated, laboratory-based system using the internet for disease outbreak detection, the Netherlands. *Emerg Infect Dis* 2003;9:1046–52.
243. Malakmadze N, Gonzalez IM, Oemig T, et al. Unsuspected recent transmission of tuberculosis among high-risk groups: implications of universal tuberculosis genotyping in its detection. *Clin Infect Dis* 2005;40:366–73.
244. Nardell E, McInnis B, Thomas B, Weidhaas S. Exogenous reinfection with tuberculosis in a shelter for the homeless. *N Engl J Med* 1986;315:1570–5.
245. Occupational Safety and Health Administration. Recording and reporting occupational injuries and illnesses Title 29, Code of Federal Regulations 2003. Part 1904.
246. Sacks LV, Pendle S, Orlovic D, Blumberg L, Constantinou C. A comparison of outbreak- and nonoutbreak-related multidrug-resistant tuberculosis among human immunodeficiency virus–infected patients in a South African hospital. *Clin Infect Dis* 1999;29:96–101.
247. Aznar J, Safi H, Romero J, Alejo A, Gracia A, Palomares JC. Nosocomial transmission of tuberculosis infection in pediatrics wards. *Pediatr Infect Dis J* 1995;14:44–8.
248. Bauer J, Kok-Jensen A, Faurschou P, Thuesen J, Taudorf E, Andersen AB. A prospective evaluation of the clinical value of nation-wide DNA fingerprinting of tuberculosis isolates in Denmark. *Int J Tuberc Lung Dis* 2000;4:295–9.
249. Blazquez J, Espinosa de Los Monteros LE, Samper S, et al. Genetic characterization of multidrug-resistant *Mycobacterium bovis* strains from a hospital outbreak involving human immunodeficiency virus-positive patients. *J Clin Microbiol* 1997;35:1390–3. Erratum in: *J Clin Microbiol* 1998;36:2398.
250. Brown TJ, Tansel O, French GL. Simultaneous identification and typing of multi-drug-resistant *Mycobacterium tuberculosis* isolates by analysis of *pncA* and *rpoB*. *J Med Microbiol* 2000;49:651–6.
251. Cohn DL, O'Brien RJ. The use of restriction fragment length polymorphism (RFLP) analysis for epidemiological studies of tuberculosis in developing countries. *Int J Tuberc Lung Dis* 1998;2:16–26.
252. French AL, Welbel SF, Dietrich SE, et al. Use of DNA fingerprinting to assess tuberculosis infection control. *Ann Intern Med* 1998;129:856–61.
253. Garzelli C, Lari N, Nguon B, Falcone G. Evidence of nosocomial transmission of tuberculosis among AIDS patients by DNA fingerprinting. *New Microbiol* 1996;19:285–91.
254. Haas DW, Milton S, Kreiswirth BN, Brinsko VL, Bifani PJ, Schaffner W. Nosocomial transmission of a drug-sensitive W-variant *Mycobacterium tuberculosis* strain among patients with acquired immunodeficiency syndrome in Tennessee. *Infect Control Hosp Epidemiol* 1998;19:635–9.
255. Lambregts-van Weezenbeek CS, Keizer ST, Sebek MM, Schepp-Beelen JC, van der Loo CJ. Transmission of multiresistant tuberculosis in a Dutch hospital [Dutch]. *Ned Tijdschr Geneesk* 1996;140:2293–5.
256. Lemaitre N, Sougakoff W, Truffot-Pernot C, et al. Use of DNA fingerprinting for primary surveillance of nosocomial tuberculosis in a large urban hospital: detection of outbreaks in

- homeless persons and migrant workers. *Int J Tuberc Lung Dis* 1998;2:390–6.
257. Moro ML, Gori A, Errante I, et al. An outbreak of multidrug-resistant tuberculosis involving HIV-infected patients of two hospitals in Milan, Italy. *AIDS* 1998;12:1095–102.
 258. Moss AR, Alland D, Telzak E, et al. A city-wide outbreak of a multiple-drug-resistant strain of *Mycobacterium tuberculosis* in New York. *Int J Tuberc Lung Dis* 1997;1:115–21.
 259. Narvskaya O, Otten T, Limeschenko E, et al. Nosocomial outbreak of multidrug-resistant tuberculosis caused by a strain of *Mycobacterium tuberculosis* W-Beijing family in St. Petersburg, Russia. *Eur J Clin Microbiol Infect Dis* 2002;21:596–602.
 260. Samper S, Martin C, Pinedo A, et al. Transmission between HIV-infected patients of multidrug-resistant tuberculosis caused by *Mycobacterium bovis*. *AIDS* 1997;11:1237–42.
 261. van Soolingen D, Hermans PW. Epidemiology of tuberculosis by DNA fingerprinting. *Eur Respir J* 1995;20(Suppl):649S–56S.
 262. Behr MA, Warren SA, Salamon H, et al. Transmission of *Mycobacterium tuberculosis* from patients smear-negative for acid-fast bacilli. *Lancet* 1999;353:444–9. Erratum in: *Lancet* 1999;353:1714.
 263. CDC. Screening for tuberculosis and tuberculous infection in high-risk populations. Recommendations of the Advisory Committee for Elimination of Tuberculosis. MMWR 1990;39(No. RR-8).
 264. Reichler MR, Etkind S, Taylor Z, Castro KG. Tuberculosis contact investigations. *Int J Tuberc Lung Dis* 2003;7:S325–S327.
 265. Reichler MR, Reves R, Bur S, et al. Evaluation of investigations conducted to detect and prevent transmission of tuberculosis. *JAMA* 2002;287:991–5.
 266. Reichler M, Taylor Z, Castro KG. Factors in tuberculosis contact investigations. *JAMA* 2002;287:2944–5.
 267. Occupational Safety and Health Administration. Occupational exposure to tuberculosis: proposed rule. *Federal Register* 1997;62:54159–309.
 268. Occupational Safety and Health Administration. Occupational exposure to tuberculosis: proposed rule: termination of rulemaking respiratory protection for *M. tuberculosis*: final rule (revocation). *Federal Register* 2003;68:75767–75.
 269. Occupational Safety and Health Administration. Directive number: CPL 2.106. Enforcement procedures and scheduling for occupational exposure to tuberculosis; 1996:1–131.
 270. Occupational Safety and Health Administration. Occupational safety and health standards, subpart I—personal protective equipment. Respiratory protection for *M. tuberculosis*. Title 29, Code of Federal Regulations 2003. Section 1910.139.
 271. Occupational Safety and Health Administration. Occupational safety and health standards, subpart I—personal protective equipment. Respiratory protection. Title 29, Code of Federal Regulations 2003. Section 1910.134.
 272. CDC. Protect yourself against tuberculosis: a respiratory protection guide for health care workers. Cincinnati, OH: US Department of Health and Human Services, Public Health Service, CDC, National Institute for Occupational Safety and Health; 1996. DHHS (NIOSH) publication no. 96–102.
 273. CDC. Guide to the selection and use of particulate respirators certified under 42 CFR 84. Cincinnati, OH: US Department of Health and Human Services, Public Health Service, CDC, National Institute for Occupational Safety and Health; 1996. DHHS (NIOSH) publication no. 96–101.
 274. CDC. TB respiratory protection program in health care facilities: administrator's guide. Cincinnati, OH: US Department of Health and Human Services, Public Health Service, CDC, National Institute for Occupational Safety and Health; 1999. DHHS (NIOSH) publication no. 99–143.
 275. Ryan MG. Developing a respiratory protection program, Understanding the written elements. *AAOHN J* 2001;49:293–307.
 276. CDC. Guide to industrial respiratory protection. Morgantown, WV: US Department of Health and Human Services, Public Health Service, CDC, National Institute for Occupational Safety and Health; 1987. DHHS (NIOSH) publication no. 87–116.
 277. American National Standards Institute. American national standard practices for respiratory protection. ANSI Standard Number Z89.2–1992. New York, NY: American National Standards Institute; 1992.
 278. European Committee for Standardization. Respiratory protective devices: filtering half masks to protect against particles—Requirements, testing, marking. *Europaische Norm* 2001;149.
 279. Food and Drug Administration. Surgical masks—premarket notification [510(k)] submissions. Guidance for Industry and FDA. Rockville, MD: US Department of Health and Human Services, Food and Drug Administration; 2003.

280. Campbell DL, Coffey CC, Lenhart SW. Respiratory protection as a function of respirator fitting characteristics and fit-test accuracy. *AIHA Journal* 2001;62:36–44.
281. CDC. Laboratory performance evaluation of N95 filtering facepiece respirators, 1996. MMWR 1998;47:1045–9.
282. Coffey CC, Lawrence RB, Zhuang Z, Campbell DL, Jensen PA, Myers WR. Comparison of five methods for fit-testing N95 filtering-facepiece respirators. *Appl Occup Environ Hyg* 2002;17:723–30.
283. Coffey CC, Lawrence RB, Campbell DL, Zhuang Z, Calvert CA, Jensen PA. Fitting characteristics of eighteen N95 filtering-facepiece respirators. *J Occup Environ Health* 2004;1:262–71.
284. Hyatt EC, Pritchard JA, Haek AL. Respiratory studies for the National Institute for Occupational Safety and Health. Los Alamos, NM: Los Alamos Scientific Laboratory; 1974.
285. Lawrence RB, Campbell DL, Myers WR, Calvert CA, Jensen PA, Coffey CC. Determining the efficacy of fit-test protocols using N95 filtering-facepiece respirators—alternate approaches. *J Inter Soc Respir Protect* 2003;20:45–56.
286. Lee K, Slavcev A, Nicas M. Respiratory protection against Mycobacterium tuberculosis: quantitative fit test outcomes for five type N95 filtering-facepiece respirators. *J Occup Environ Health* 2004;1:22–8.
287. Martyny J, Glazer CS, Newman LS. Current concepts. Respiratory protection. *N Engl J Med* 2002;347:824–30.
288. Lowry PL, Hesck PR, Revoir WH. Performance of single-use respirators. *Am Industrial Hyg Assoc J* 1977;38:462–7.
289. Nicas M, Neuhaus J. Variability in respiratory protection and the assigned protection factor. *J Occup Environ Health* 2004;1:99–109.
290. Lenhart SW, Seitz T, Trout D, Bollinger N. Issues affecting respirator selection for workers exposed to infectious aerosols: emphasis on healthcare settings. *Applied Biosafety* 2004;9:20–36.
291. McWilliams T, Wells AU, Harrison AC, Lindstrom S, Cameron RJ, Foskin E. Induced sputum and bronchoscopy in the diagnosis of pulmonary tuberculosis. *Thorax* 2002;57:1010–4.
292. Riley RL, Mills CC, O'Grady F, Sultan LU, Wittstadt F, Shivpuri DN. Infectiousness of air from a tuberculosis ward: ultraviolet irradiation of infected air: comparative infectiousness of different patients. *Am Rev Respir Dis* 1962;85:511–25.
293. Noble RC. Infectiousness of pulmonary tuberculosis after starting chemotherapy: review of the available data on an unresolved question. *Am J Infect Control* 1981;9:6–10.
294. Coronado VG, Beck-Sague CM, Hutton MD, et al. Transmission of multidrug-resistant Mycobacterium tuberculosis among persons with human immunodeficiency virus infection in an urban hospital: epidemiologic and restriction fragment length polymorphism analysis. *J Infect Dis* 1993;168:1052–5.
295. Long R, Zielinski M, Kunimoto D, Manfreda J. The emergency department is a determinant point of contact of tuberculosis patients prior to diagnosis. *Int J Tuberc Lung Dis* 2002;6:332–9.
296. Luby S, Carmichael S, Shaw G, Horan J, Gamble W Jr, Jones J. A nosocomial outbreak of Mycobacterium tuberculosis. *J Fam Pract* 1994;39:21–5.
297. Nivin B, Nicholas P, Gayer M, Frieden TR, Fujiwara PI. A continuing outbreak of multidrug-resistant tuberculosis, with transmission in a hospital nursery. *Clin Infect Dis* 1998;26:303–7.
298. Mastorides SM, Oehler RL, Greene JN, Sinnott JT, Kranik M, Sandin RL. The detection of airborne Mycobacterium tuberculosis using micropore membrane air sampling and polymerase chain reaction. *Chest* 1999;115:19–25.
299. Sultan L, Nyka W, Mills C, O'Grady F, Wells W, Riley RL. Tuberculosis disseminators. A study of the variability of aerial infectivity of tuberculosis patients. *Am Rev Respir Dis* 1960;82:358–69.
300. Fennelly KP, Martyny JW, Fulton KE, Orme IM, Cave DM, Heifets LB. Cough-generated aerosols of Mycobacterium tuberculosis. A new method to study infectiousness. *Am J Respir Crit Care Med* 2004;169:604–9.
301. Keijman J, Tjhe J, Olde DS, Alink M. Unusual nosocomial transmission of Mycobacterium tuberculosis. *Eur J Clin Microbiol Infect Dis* 2001;20:808–9.
302. Hopewell PC. Mycobacterial diseases. In: Murray JF, Nadel JA, eds. Textbook of respiratory medicine. Philadelphia, PA: WB Saunders Company; 1988:856–915.
303. Ijaz K, Castro KG. Pediatric tuberculosis: all in the family? *Infect Control Hosp Epidemiol* 2002;23:562–3.
304. Munoz FM, Ong LT, Seavy D, Medina D, Correa A, Starke JR. Tuberculosis among adult visitors of children with suspected tuberculosis and employees at a children's hospital. *Infect Control Hosp Epidemiol* 2002;23:568–72.

305. Wallgren A. On contagiousness of childhood tuberculosis. *Acta Pediatr Scand* 1937;22:229–34.
306. CDC. Tuberculosis outbreak in a community hospital—District of Columbia, 2002. MMWR 2004;53:214–6.
307. Garcia-Garcia ML, Valdespino-Gomez JL, Garcia-Sancho C, et al. Underestimation of *Mycobacterium tuberculosis* infection in HIV-infected subjects using reactivity to tuberculin and anergy panel. *Int J Epidemiol* 2000;29:369–75.
308. Ridzon R, Kenyon T, Luskin-Hawk R, Schultz C, Valway S, Onorato IM. Nosocomial transmission of human immunodeficiency virus and subsequent transmission of multidrug-resistant tuberculosis in a healthcare worker. *Infect Control Hosp Epidemiol* 1997;18:422–3.
309. Snider DE Jr, Kelly GD, Cauthen GM, Thompson NJ, Kilburn JO. Infection and disease among contacts of tuberculosis cases with drug-resistant and drug-susceptible bacilli. *Am Rev Respir Dis* 1985;132:125–32.
310. Schaaf HS, Shean K, Donald PR. Culture confirmed multidrug resistant tuberculosis: diagnostic delay, clinical features, and outcome. *Arch Dis Child* 2003;88:1106–11.
311. Cauthen GM, Dooley SW, Onorato IM, et al. Transmission of *Mycobacterium tuberculosis* from tuberculosis patients with HIV infection or AIDS. *Am J Epidemiol* 1996;144:69–77.
312. Espinal MA, Perez EN, Baez J, et al. Infectiousness of *Mycobacterium tuberculosis* in HIV-1-infected patients with tuberculosis: a prospective study. *Lancet* 2000;355:275–80.
313. Klausner JD, Ryder RW, Baende E, et al. *Mycobacterium tuberculosis* in household contacts of human immunodeficiency virus type 1–eropositive patients with active pulmonary tuberculosis in Kinshasa, Zaire. *J Infect Dis* 1993;168:106–11. Erratum in: *J Infect Dis* 1993;168:802.
314. Nunn P, Mungai M, Nyamwaya J. The effect of human immunodeficiency virus type-1 on the infectiousness of tuberculosis. *Tubercle Lung Dis* 1994;75:25–32.
315. Selwyn PA, Hartel D, Lewis VA, et al. A prospective study of the risk for tuberculosis among intravenous drug users with human immunodeficiency virus infection. *N Engl J Med* 1989;320:545–50.
316. Rose DN, Schechter CB, Adler JJ. Interpretation of the tuberculin skin test. *J Gen Intern Med* 1995;10:635–42.
317. Menzies D. Interpretation of repeated tuberculin tests. Boosting, conversion, and reversion. *Am J Respir Crit Care Med* 1999;159:15–21.
318. CDC. Mantoux tuberculin skin test [Poster]. Atlanta, GA: US Department of Health and Human Services, Public Health Service, CDC; 2004.
319. Joseph HA, Shrestha-Kuwahara R, Lowry D, et al. Factors influencing healthcare workers' adherence to work site tuberculosis screening and treatment policies. *Am J Infect Control* 2004;32:456–61.
320. Mantoux C, Roux E. Report of intradermal reaction of tuberculin [French]. *The Academy of Sciences* 1908;147:355–7.
321. Mendel F. The intravenous application of medicine. *Therapeutic Monthly* 1902;17:177–93.
322. CDC. Guideline for hand hygiene in health-care settings. Recommendations of the Healthcare Infection Control Practices Advisory Committee and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force. MMWR 2002;51(No. RR-16).
323. Mendel F. von Pirquet's skin reaction and intravenous tuberculosis treatment. *Medical Clinical Hospital* 1908;4:402–4
324. National Tuberculosis Controllers Association, National Tuberculosis Nurse Consultant Coalition. Tuberculosis nursing: a comprehensive guide to patient care. Smyrna, GA: National Tuberculosis Controllers Association; 1997.
325. CDC. Inadvertent intradermal administration of tetanus toxoid-containing vaccines instead of tuberculosis skin tests. MMWR 2004;53:662–4.
326. CDC. National Health and Nutrition Examination Survey (NHANES). Tuberculosis skin test procedures manual. Atlanta, GA: US Department of Health and Human Services, Public Health Service, CDC; 2000.
327. Occupational Safety and Health Administration. Occupational safety and health standards, subpart Z—toxic and hazardous substances. Bloodborne pathogens Title 29, Code of Federal Regulations 2003. Section 1910.1030.
328. Sokal JE. Measurement of delayed skin-test responses [Editorial]. *N Engl J Med* 1975;293:501–2.
329. Lee E, Holzman RS. Evolution and current use of the tuberculin test. *Clin Infect Dis* 2002;34:365–70.
330. Snider DE Jr. The tuberculin skin test. *Am Rev Respir Dis* 1982;125:108–18.
331. Marsh BJ, San Vicente J, von Reyn F. Utility of dual skin tests to evaluate tuberculin skin test reactions of 10 to 14 mm in healthcare workers. *Infect Control Hosp Epidemiol* 2003;24:821–4.

332. Winthrop KL, Siegel JN, Jereb J, Taylor Z, Iademarco MF. Tuberculosis associated with therapy against tumor necrosis factor alpha. *Arthritis Rheum* 2005;52:2968–74.
333. Potter PA, Perry AG. *Fundamentals of nursing*. 5th ed. St. Louis, MO: Mosby, Inc.; 2001.
334. Canessa PA, Fasano L, Lavecchia MA, Torraca A, Schiattone ML. Tuberculin skin test in asymptomatic HIV seropositive carriers. *Chest* 1989;96:1215–6.
335. CDC. Purified protein derivative (PPD) Tuberculin anergy and HIV infection. Guidelines for anergy testing and management of anergic persons at risk for tuberculosis. MMWR 1991;40(No. RR-5):27–33.
336. CDC. Anergy skin testing and preventive therapy for HIV-infected persons: revised recommendations. MMWR 1997;46(No. RR-15):1–10. Erratum in: MMWR 1997;46:880.
337. Huebner RE, Schein MF, Hall CA, Barnes SA. Delayed-type hypersensitivity anergy in human immunodeficiency virus–infected persons screened for infection with *Mycobacterium tuberculosis*. *Clin Infect Dis* 1994;19:26–32.
338. CDC. General recommendations on immunization. Recommendations of the Advisory Committee on Immunization Practices (ACIP) and the American Academy of Family Physicians (AAFP). MMWR 2002;51(No. RR-2).
339. Slovis BS, Plitman JD, Haas DW. The case against anergy testing as a routine adjunct to tuberculin skin testing. *JAMA* 2000;283:2003–7.
340. Narita M, Ashkin D, Hollender ES, Pitchenik AE. Paradoxical worsening of tuberculosis following antiretroviral therapy in patients with AIDS. *Am J Respir Crit Care Med* 1998;158:157–61.
341. Snider DE. Pregnancy and tuberculosis. *Chest* 1984;86:10S–13S.
342. Addis A, Blowey D, Koren G. Tuberculosis during pregnancy. *Can Fam Physician* 1996;42:1461–2.
343. American College of Obstetricians and Gynecologists. ACOG technical bulletin. Pulmonary disease in pregnancy. Number 224–June 1996. *Int J Gynecol Obstet* 1996;54:187–96.
344. Cauthen GM, Snider DE Jr, Onorato IM. Boosting of tuberculin sensitivity among Southeast Asian refugees. *Am J Respir Crit Care Med* 1994;149:1597–600.
345. Menzies D. What does tuberculin reactivity after Bacille Calmette-Guerin vaccination tell us? *Clin Infect Dis* 2000;31(Suppl 3):S71–4.
346. Moreno S, Blazquez R, Novoa A, et al. The effect of BCG vaccination on tuberculin reactivity and the booster effect among hospital employees. *Arch Intern Med* 2001;161:1760–5.
347. Villarino ME, Burman W, Wang YC, et al. Comparable specificity of 2 commercial tuberculin reagents in persons at low risk for tuberculous infection. *JAMA* 1999;281:169–71.
348. Blumberg HM, White N, Parrott P, Gordon W, Hunter M, Ray S. False-positive tuberculin skin test results among health care workers. *JAMA* 2000;283:2793.
349. Greenberg SD, Frager D, Suster B, Walker S, Stavropoulos C, Rothpearl A. Active pulmonary tuberculosis in patients with AIDS: spectrum of radiographic findings (including a normal appearance). *Radiology* 1994;193:115–9.
350. Havlir DV, Barnes PF. Tuberculosis in patients with human immunodeficiency virus infection. *N Engl J Med* 1999;340:367–73.
351. Jones BE, Ryu R, Yang Z, et al. Chest radiographic findings in patients with tuberculosis with recent or remote infection. *Am J Respir Crit Care Med* 1997;155:1270–3.
352. Tattevin P, Casalino E, Fleury L, Egmann G, Ruel M, Bouvet E. The validity of medical history, classic symptoms, and chest radiographs in predicting pulmonary tuberculosis: derivation of a pulmonary tuberculosis prediction model. *Chest* 1999;115:1248–53.
353. Chintu C, Mwaba P. Is there a role for chest radiography in identification of asymptomatic tuberculosis in HIV-infected persons? *Lancet* 2003;362:1516.
354. Mosimaneotsile B, Talbot EA, Moeti TL, et al. Value of chest radiography in a tuberculosis prevention programme for HIV-infected people, Botswana. *Lancet* 2003;362:1551–2.
355. Siddiqui AH, Perl TM, Conlon M, Donegan N, Roghmann MC. Preventing nosocomial transmission of pulmonary tuberculosis: when may isolation be discontinued for patients with suspected tuberculosis? *Infect Control Hosp Epidemiol* 2002;23:141–4.
356. Shata AM, Coulter JB, Parry CM, Ching'ani G, Broadhead RL, Hart CA. Sputum induction for the diagnosis of tuberculosis. *Arch Dis Child* 1996;74:535–7.
357. Anderson C, Inhaber N, Menzies D. Comparison of sputum induction with fiber-optic bronchoscopy in the diagnosis of tuberculosis. *Am J Respir Crit Care Med* 1995;152:1570–4.
358. CDC. Performance evaluation programs for determining HIV-1 viral loads, testing for HIV p24 antigen, and identifying *Mycobacterium tuberculosis* using nucleic acid amplification tests. MMWR 1997;46:155–6.
359. Burnens AP, Vurma-Rapp U. Mixed mycobacterial cultures—occurrence in the clinical laboratory. *Int J Med Microbiol* 1989;271:85–90.

360. Malasky C, Jordan T, Potulski F, Reichman LB. Occupational tuberculous infections among pulmonary physicians in training. *Am Rev Respir Dis* 1990;142:505–7.
361. Carr DT, Karlson AG, Stilwell GG. A comparison of cultures of induced sputum and gastric washings in the diagnosis of tuberculosis. *Mayo Clin Proc* 1967;42:23–5.
362. Hensler NM, Spivey Jr CG, Dees TM. The use of hypertonic aerosol in production of sputum for diagnosis of tuberculosis. Comparison with gastric specimens. *Dis Chest* 1961;40:639–42.
363. Makkar H, Mallampalli A, Matthew M, et al. Improved yield of *Mycobacterium tuberculosis* with sputum induction in addition to three expectorated sputa. *Am J Respir Crit Care Med* 2000;161:A298.
364. Yajko DM, Nassos PS, Sanders CA, Madej JJ, Hadley WK. High predictive value of the acid-fast smear for *Mycobacterium tuberculosis* despite the high prevalence of *Mycobacterium avium* complex in respiratory specimens. *Clin Infect Dis* 1994;19:334–6.
365. Khilnani GC. Tuberculosis and pregnancy. *Indian J Chest Dis Allied Sci* 2004;46:105–11.
366. CDC. Update: fatal and severe liver injuries associated with rifampin and pyrazinamide for latent tuberculosis infection, and revisions in American Thoracic Society/CDC recommendations—United States, 2001. MMWR 2001;50:733–5.
367. CDC. Fatal and severe hepatitis associated with rifampin and pyrazinamide for the treatment of latent tuberculosis infection—New York and Georgia, 2000. MMWR 2001;50:289–91.
368. CDC. Update: fatal and severe liver injuries associated with rifampin and pyrazinamide treatment for latent tuberculosis infection. MMWR 2002;51:998–9.
369. Edwards LB, Palmer CE, Magnus K, eds. Response to BCG vaccination [Chapter 3]. In: BCG Vaccination Studies by the WHO Tuberculosis Research Office, Copenhagen. Geneva, Switzerland: World Health Organization; 1953:51–64.
370. Menzies RI. Tuberculin skin testing. In: Reichman LB, Hershfield ES, eds. Tuberculosis. A comprehensive international approach. 2nd ed. New York, NY: Marcel Dekker, Inc.; 2000:279–322.
371. Youmans GP. Pathogenesis of tuberculosis [Chapter 14]. In: Tuberculosis. Philadelphia, PA: W.B. Sanders Co.; 1979:317–26.
372. Caminero JA, Pena MJ, Campos-Herrero MI, et al. Exogenous reinfection with tuberculosis on a European island with a moderate incidence of disease. *Am J Respir Crit Care Med* 2001;163:717–20.
373. de Viedma DG, Marin M, Hernangomez S, et al. Tuberculosis recurrences: reinfection plays a role in a population whose clinical/epidemiological characteristics do not favor reinfection. *Arch Intern Med* 2002;162:1873–9.
374. Small PM, Shafer RW, Hopewell PC, et al. Exogenous reinfection with multidrug-resistant *Mycobacterium tuberculosis* in patients with advanced HIV infection. *N Engl J Med* 1993;328:1137–44.
375. van Rie A, Warren R, Richardson M, et al. Exogenous reinfection as a cause of recurrent tuberculosis after curative treatment. *N Engl J Med* 1999;341:1174–9.
376. Iseman MD, Madsen LA. Drug-resistant tuberculosis. *Clin Chest Med* 1989;10:341–53.
377. Iseman MD. Drug therapy: treatment of multidrug-resistant tuberculosis. *N Engl J Med* 1993;329:784–91. Erratum in: *N Engl J Med* 1993;329:1435.
378. CDC. Acquired rifamycin resistance in persons with advanced HIV disease being treated for active tuberculosis with intermittent rifamycin-based regimens. MMWR 2002;51:214–5.
379. Goble M. Drug-resistant tuberculosis. *Semin Respir Infect* 1986;1:220–9.
380. Goble M, Iseman MD, Madsen LA, Waite D, Ackerson L, Horsburgh CR Jr. Treatment of 171 patients with pulmonary tuberculosis resistant to isoniazid and rifampin. *N Engl J Med* 1993;328:527–32.
381. Simone PM, Iseman MD. Drug-resistant tuberculosis: a deadly — and growing — danger. *J Respir Dis* 1992;13:960–71.
382. CDC. Initial therapy for tuberculosis in the era of multidrug resistance. Recommendations of the Advisory Council for the Elimination of Tuberculosis. MMWR 1993;42(No. RR-7):1–8. Erratum in: MMWR 1993;42:536.
383. Cellestis Limited. QuantiFERON(r)-TB Gold [Package insert]. Carnegie, Victoria, Australia: Cellestis Limited; 2005.
384. Riley RL, Knight M, Middlebrook G. Ultraviolet susceptibility of BCG and virulent tubercle bacilli. *Am Rev Respir Dis* 1976;113:413–8.
385. Riley RL, Nardell EA. Clearing the air. The theory and application of ultraviolet air disinfection. *Am Rev Respir Dis* 1989;139:1286–94.
386. American National Standards Institute, American Society of Heating, Refrigerating and Air-Conditioning Engineers, Inc. ANSI/ASHRAE Standard 62.1-2004: ventilation for acceptable

- indoor air quality. Atlanta, GA: American Society of Heating, Refrigerating and Air-Conditioning Engineers, Inc.; 2004.
387. Hayden II CS, Fischbach TJ, Johnston OE, Hughes RT, Jensen PA. A model for calculating leakage areas into negative pressure isolation rooms. Cincinnati, OH: US Department of Health and Human Services, CDC; 1996.
 388. Rice N, Streifel A, Vesley D. An evaluation of hospital special-ventilation-room pressures. *Infect Control Hosp Epidemiol* 2001;22:19–23.
 389. Streifel AJ, Marshall JW. Parameters for ventilation controlled environments in hospitals. In: Moschandreas DJ, ed. *Design, construction, and operation of healthy buildings: solutions to global and regional concerns*. Atlanta, GA: American Society of Heating, Refrigerating and Air-Conditioning Engineers Press; 1998:305–9.
 390. DeLuga GF. Designing laboratory ventilation. In: Richmond JY, ed. *Designing a modern microbiological/biomedical laboratory. Lab design process & technology*. Washington, DC: American Public Health Association; 1997:234.
 391. Jensen PA, Hayden II CS, Burroughs E, Hughes RT. Assessment of the health hazard associated with the use of smoke tubes in healthcare facilities. *Appl Occup Environ Hyg* 1998;13:172–6.
 392. Pavelchak N, DePersis RP, London M, et al. Identification of factors that disrupt negative air pressurization of respiratory isolation rooms. *Infect Control Hosp Epidemiol* 2000;21:191–5.
 393. Hayden II CS. Positive advice on negative pressure for TB isolation rooms. *Health Facil Manage* 1997;10:43–5.
 394. Hayden II CS, Johnston OE, Hughes RT, Jensen PA. Air volume migration from negative pressure isolation rooms during entry/exit. *Appl Occup Environ Hyg* 1998;13:518–27.
 395. American Society of Heating, Refrigerating and Air-Conditioning Engineers, Inc. *Airflow around buildings [Chapter 16]. 2005 ASHRAE handbook: 2005 fundamentals*. Atlanta, GA: American Society of Heating, Refrigerating and Air-Conditioning Engineers, Inc.; 2005:16.1–16.12.
 396. CDC. *Health hazard evaluations: tuberculosis 1990–1999*. Cincinnati, OH: US Department of Health and Human Services, Public Health Service, CDC, National Institute for Occupational Safety and Health; 2001. DHHS (NIOSH) publication no. 2001-116.
 397. Esterhai JL Jr, Reynolds MR, Chou L. Hazards to the orthopaedic trauma surgeon: occupational exposure to tuberculosis. Risk reduction, testing, and treatment (a review article). *J Orthop Trauma* 1996;10:366–70.
 398. Seitz T, Decker J. Health hazard evaluation report. Onondaga County Medical Examiner's Office, Syracuse, New York. Cincinnati, OH: US Department of Health and Human Services, Public Health Service, CDC, National Institute for Occupational Safety and Health; 1992; report no. HETA 92-171-2255.
 399. Opal SM, Asp AA, Cannady PB Jr, Morse PL, Burton LJ, Hammer II PG. Efficacy of infection control measures during a nosocomial outbreak of disseminated aspergillosis associated with hospital construction. *J Infect Dis* 1986;153:634–7.
 400. Rhame FS, Streifel AJ, Kersey JH Jr, McGlave PB. Extrinsic risk factors for pneumonia in the patient at high risk of infection. *Am J Med* 1984;76:42–52.
 401. Sherertz RJ, Belani A, Kramer BS, et al. Impact of air filtration on nosocomial aspergillus infections. Unique risk for bone marrow transplant recipients. *Am J Med* 1987;83:709–18.
 402. Rippon JW, Gerhold R, Heath M. Thermophilic and thermotolerant fungi isolated from the thermal effluent of nuclear power generating reactors: dispersal of human opportunistic and veterinary pathogenic fungi. *Mycopathologia* 1980;70:169–79.
 403. Brown RC. *Air filtration. An integrated approach to the theory and applications of fibrous filters*. 1st ed. Tarrytown, NY: Pergamon Press; 1993.
 404. Woods JE. *Cost avoidance and productivity in owning and operating buildings*. 4th ed. Philadelphia, PA: Hanley & Belfus, Inc.; 1989:753–70.
 405. Cheng YS, Lu JC, Chen TR. Efficiency of a portable indoor air cleaner in removing pollens and fungal spores. *Aerosol Science and Technology* 1998;29:92–101.
 406. ECRI. *TB engineering controls: mobile high-efficiency-filter air cleaners*. *Health Devices* 1995;24:370–418.
 407. Marier RL, Nelson T. A ventilation-filtration unit for respiratory isolation. *Infect Control Hosp Epidemiol* 1993;14:700–5.
 408. Miller-Leiden S, Lobascio C, Nazaroff WW, Macher JM. Effectiveness of in-room air filtration and dilution ventilation for tuberculosis infection control. *J Air Waste Manag Assoc* 1996;46:869–82.
 409. Miller SL, Hernandez M. *Evaluating portable air cleaner removal efficiencies for bioaerosols*. Boulder, CO: University of Colorado at Boulder; 2002; NIOSH contract report PO-36755-R-00077B5D.

410. Rutala WA, Jones SM, Worthington JM, Reist PC, Weber DJ. Efficacy of portable filtration units in reducing aerosolized particles in the size range of *Mycobacterium tuberculosis*. *Infect Control Hosp Epidemiol* 1995;16:391–8.
411. Woods JE, Rask DR. Heating, ventilation, air-conditioning systems: the engineering approach to methods of control. In: Kundsinn RB, ed. *Architectural design and indoor microbial pollution*. New York, NY: Oxford University Press; 1988:123–53.
412. American Society of Heating, Refrigerating and Air-Conditioning Engineers, Inc. Air cleaners for particulate contaminants. 2004 ASHRAE handbook: HVAC systems and equipment. Atlanta, GA: American Society of Heating, Refrigerating and Air-Conditioning Engineers, Inc.; 2004:24.1–24.13.
413. National Sanitation Foundation (NSF). Class II (laminar flow) biohazard cabinetry—NSF/ANSI standard 49-2002. Ann Arbor, MI: National Sanitation Foundation International; 2001.
414. Ko G, Burge HA, Muilenberg M, Rudnick S, First M. Survival of mycobacteria on HEPA filter material. *J Amer Biologic Safety Assoc* 1998;3:65–78.
415. Qian Y, Willeke K, Grinshpun SA, Donnelly J. Performance of N95 respirators: reaerosolization of bacteria and solid particles. *AIHA Journal* 1997;58:876–80.
416. Reponen TA, Wang Z, Willeke K, Grinshpun SA. Survival of mycobacteria on N95 personal respirators. *Infect Control Hosp Epidemiol* 1999;20:237–41.
417. Rutala WA, Cole EC, Wannamaker NS, Weber DJ. Inactivation of *Mycobacterium tuberculosis* and *Mycobacterium bovis* by 14 hospital disinfectants. *Am J Med* 1991;91(Suppl 3B):267S–71S.
418. Illuminating Engineering Society of North America. The IESNA lighting handbook—reference and application. 9th ed. New York, NY: Illuminating Engineering Society of North America; 2000.
419. Riley RL, Wells WF, Mills CC, Nyka W, McLean RL. Air hygiene in tuberculosis: quantitative studies of infectivity and control in a pilot ward. *Am Rev Tuberc* 1957;75:420–31.
420. Riley RL. Ultraviolet air disinfection for control of respiratory contagion. In: Kundsinn RB, ed. *Architectural design and indoor microbial pollution*. New York, NY: Oxford University Press; 1988:174–97.
421. Stead WW. Clearing the air: the theory and application of ultraviolet air disinfection. *Am Rev Respir Dis* 1989;140:1832.
422. Xu P. Ultraviolet germicidal irradiation for preventing infectious disease transmission. Boulder, CO: University of Colorado, Department of Civil, Environmental, and Architectural Engineering; 2001.
423. Xu P, Peccia J, Fabian P, et al. Efficacy of ultraviolet germicidal irradiation of upper-room air in inactivating airborne bacterial spores and mycobacteria in full-scale studies. *Atmospheric Environment* 2003;37:405–19.
424. McLean RL. Mechanisms of spread. The mechanism of spread of Asian influenza. *Am Rev Respir Dis* 1961;83:29–40.
425. Willmon TL, Hollaender A, Langmuir AD. Studies of the control of acute respiratory diseases among naval recruits. I. A review of a four-year experience with ultraviolet irradiation and dust suppressive measures, 1943 to 1947. *Am J Hyg* 1948;48:227–32.
426. Perkins JE, Bahlke AM, Silverman HF. Effect of ultra-violet irradiation of classrooms on spread of measles in large rural central schools. *Am J Public Health* 1947;37:529–37.
427. Wells WF, Wells MW, Wilder TS. The environmental control of epidemic contagion: I. An epidemiologic study of radiant disinfection of air in day schools. *Am J Hyg* 1942;35:97–121.
428. Wells WF, Holla WA. Ventilation in the flow of measles and chickenpox through a community. Progress report, January 1, 1946 to June 15, 1949, Airborne Infection Study, Westchester County Department of Health. *JAMA* 1950;142:1337–44.
429. Collins FM. Relative susceptibility of acid-fast and non-acid-fast bacteria to ultraviolet light. *Appl Microbiol* 1971;21:411–3.
430. David HL, Jones WD Jr, Newman CM. Ultraviolet light inactivation and photoreactivation in the mycobacteria. *Infect Immun* 1971;4:318–9.
431. David HL. Response of mycobacteria to ultraviolet light radiation. *Am Rev Respir Dis* 1973;108:1175–85.
432. Lurie MB. Resistance to tuberculosis: experimental studies in native and acquired defensive mechanisms. Cambridge, MA: Harvard University Press; 1964.
433. National Tuberculosis and Respiratory Disease Association. Guidelines for the general hospital in the admission and care of tuberculous patients. *Am Rev Respir Dis* 1969;99:631–3.
434. Schieffelbein CW Jr, Snider DE Jr. Tuberculosis control among homeless populations. *Arch Intern Med* 1988;148:1843–6.
435. First MW, Nardell EA, Chaisson RE, Riley R. Guidelines for the application of upper-room ultraviolet germicidal irradiation for preventing transmission of airborne contagion—part 1:

basic principles. ASHRAE Transactions: Symposia 1999;105:869–76.

436. First MW, Nardell EA, Chaisson RE, Riley R. Guidelines for the application of upper-room ultraviolet germicidal irradiation for preventing transmission of airborne contagion—part 2: design and operation guidance. ASHRAE Transactions: Symposia 1999;105:877–87.
437. Miller SL, Macher JM. Evaluation of a methodology for quantifying the effect of room air ultraviolet germicidal irradiation on airborne bacteria. *Aerosol Science and Technology* 2000;33:274–95.
438. Kowalski WJ, Bahnfleth WP. UVGI design basics for air and surface disinfection. Ultraviolet germicidal irradiation lamps can help clean coils and improve indoor air quality. *HPAC* 2000;100–10.
439. Green CF, Scarpino PV. The use of ultraviolet germicidal irradiation (UVGI) in disinfection of airborne bacteria. *Environ Eng Policy* 2002;3:101–7.
440. Riley RL, Permutt S, Kaufman JE. Convection, air mixing, and ultraviolet air disinfection in rooms. *Arch Environ Health* 1971;22:200–7.
441. Riley RL, Permutt S, Kaufman JE. Room air disinfection by ultraviolet irradiation of upper air. Further analysis of convective air exchange. *Arch Environ Health* 1971;23:35–9.
442. Riley RL, Permutt S. Room air disinfection by ultraviolet irradiation of upper air. Air mixing and germicidal effectiveness. *Arch Environ Health* 1971;22:208–19.
443. Riley RL, Kaufman JE. Air disinfection in corridors by upper air irradiation with ultraviolet. *Arch Environ Health* 1971;22:551–3.
444. Ko G, First MW, Burge HA. The characterization of upper-room ultraviolet germicidal irradiation in inactivating airborne microorganisms. *Environmental Health Perspectives* 2002;110:95–101.
445. Xu P, Peccia J, Hernandez M, Miller SL. The efficacy of upper room ultraviolet germicidal irradiation in inactivating airborne microorganisms under incomplete mixing conditions. *Proceedings of Engineering Solutions to Indoor Air Quality Problems*, Raleigh, NC; July 17–19, 2000.
446. Memarzadeh F, Jiang J. Methodology for minimizing risk from airborne organisms in hospital isolation rooms. ASHRAE Transactions: Symposia 2000;733–49.
447. Ko G, First MW, Burge HA. Influence of relative humidity on particle size and UV sensitivity of *Serratia marcescens* and *Mycobacterium bovis* BCG aerosols. *Tubercle Lung Dis* 2000;80:217–28.
448. Peccia J, Werth HM, Miller S, Hernandez M. Effects of relative humidity on the ultraviolet induced inactivation of airborne bacteria. *Aerosol Science and Technology* 2001;35:728–40.
449. Riley RL, O'Grady F. *Airborne infection: transmission and control*. New York, NY: MacMillan; 1961.
450. Riley RL, Kaufman JE. Effect of relative humidity on the inactivation of airborne *Serratia marcescens* by ultraviolet radiation. *Appl Microbiol* 1972;23:1113–20.
451. American National Standards Institute, American Society of Heating, Refrigerating and Air-Conditioning Engineers, Inc. Standard 55–2004. Thermal environmental conditions for human occupancy. Atlanta, GA: American Society of Heating, Refrigerating and Air-Conditioning Engineers, Inc.; 2004.
452. Kethley TW, Branch K. Ultraviolet lamps for room air disinfection. Effect of sampling location and particle size of bacterial aerosol. *Arc Environ Health* 1972;25:205–14.
453. National Institute for Occupational Safety and Health. Criteria for a recommended standard. Occupational exposure to ultraviolet radiation. Atlanta, GA: US Department of Health, Education, and Welfare, Public Health Service, Health Services and Mental Health Administration; 1972.
454. International Agency for Research on Cancer. IARC monographs on the evaluation of carcinogenic risks to humans: solar and ultraviolet radiation. Lyon, France: World Health Organization; 1992.
455. Clerici M, Shearer GM. UV light exposure and HIV replication. *Science* 1992;258:1070–1.
456. Stein B, Rahmsdorf HJ, Steffen A, Litfin M, Herrlich P. UV-induced DNA damage is an intermediate step in UV-induced expression of human immunodeficiency virus type 1, collagenase, c-fos, and metallothionein. *Mol Cell Biol* 1989;9:5169–81.
457. Valerie K, Delers A, Bruck C, et al. Activation of human immunodeficiency virus type 1 by DNA damage in human cells. *Nature* 1988;333:78–81.
458. Valerie K, Rosenberg M. Chromatin structure implicated in activation of HIV-1 gene expression by ultraviolet light. *New Biol* 1990;2:712–8.
459. Wallace BM, Lasker JS. Awakenings... UV light and HIV gene activation. *Science* 1992;257:1211–2.

460. Zmudzka BZ, Beer JZ. Activation of human immunodeficiency virus by ultraviolet radiation. *Photochem Photobiol* 1990;52:1153–62.
461. Everett MA, Sayre RM, Olson RL. Physiologic response of human skin to ultraviolet light. In: Urbach F, ed. *The biologic effects of ultraviolet radiation (with emphasis on the skin)*. Oxford, England: Pergamon Press; 1969:181–6.
462. Boudreau Y, Decker J, Burton N, Moss CE, Mortimer V, Deitchman S. Health hazard evaluation report. Jackson Memorial Hospital, Miami, Florida. Cincinnati, OH: US Department of Health and Human Services, Public Health Service, CDC, National Institute for Occupational Safety and Health; 1995; report no. HETA 91-187-2544.
463. Moss CE, Seitz T. Health Hazard Evaluation Report. John C. Murphy Family Health Center, Berkeley, Missouri. Cincinnati, OH: US Department of Health and Human Services, Public Health Service, CDC, National Institute for Occupational Safety and Health; 1992; HETA 91-148-2236.
464. Brubacher J, Hoffman RS. Hazards of ultraviolet lighting used for tuberculosis control. *Chest* 1996;109:582–3.
465. Talbot EA, Jensen P, Moffat HJ, Wells CD. Occupational risk from ultraviolet germicidal irradiation (UVGI) lamps. *Int J Tuberc Lung Dis* 2002;6:738–41.
466. American Conference of Governmental Industrial Hygienists. 2004 TLVs(r) and BEIs(r). Based on the documentation of the threshold limit values for chemical substances and physical agents & biological exposure indices. Cincinnati, OH: American Conference of Governmental Industrial Hygienists; 2004.
467. Dumyahn T, First M. Characterization of ultraviolet upper room air disinfection devices. *AIHA Journal* 1999;60:219–27.
468. Rahn RO, Xu P, Miller SL. Dosimetry of room-air germicidal (254 nm) radiation using spherical actinometry. *Photochem Photobiol* 1999;70:314–8.
469. Ikeda RM, Birkhead GS, DiFerdinando GT Jr, et al. Nosocomial tuberculosis: an outbreak of a strain resistant to seven drugs. *Infect Control Hosp Epidemiol* 1995;16:152–9.
470. Fraser VJ, Johnson K, Primack J, Jones M, Medoff G, Dunagan WC. Evaluation of rooms with negative pressure ventilation used for respiratory isolation in seven midwestern hospitals. *Infect Control Hosp Epidemiol* 1993;14:623–8.
471. Sutton PM, Nicas M, Reinisch F, Harrison RJ. Evaluating the control of tuberculosis among healthcare workers: adherence to CDC guidelines of three urban hospitals in California. *Infect Control Hosp Epidemiol* 1998;19:487–93.
472. Streifel AJ. Design and maintenance of hospital ventilation systems and the prevention of airborne nosocomial infections. In: Mayall CG, ed. *Hospital Epidemiology and Infection Control*. 2 ed. Philadelphia, PA: Lippincot Williams and Wilkins; 1999:1211–21.
473. Bloom BR, Murray CJ. Tuberculosis: commentary on a reemergent killer. *Science* 1992;257:1055–64.
474. Nardell EA. Dodging droplet nuclei. Reducing the probability of nosocomial tuberculosis transmission in the AIDS era. *Am Rev Respir Dis* 1990;142:501–3.
475. Public Health Service, US Department of Health and Human Services. Approval of respiratory protective devices. Title 42, Code of Federal Regulations 2004. Part 84.
476. Occupational Safety and Health Administration. Respiratory protection program guidelines. Washington, DC: Occupational Safety and Health Administration; 2000. Directive number CPL 2-2.54A.
477. Hyatt EC. Current problems and new developments in respiratory protection. *AIHA Journal* 1963;24:295–304.
478. Rikimaru T, Kondo M, Kajimura K, et al. Efficacy of common antiseptics against multidrug-resistant *Mycobacterium tuberculosis*. *Int J Tuberc Lung Dis* 2002;6:763–70.
479. George RH. The prevention and control of mycobacterial infections in hospitals. *J Hosp Infect* 1988;11(Suppl A):386–92.
480. Johnson KR, Braden CR, Cairns KL, et al. Transmission of *Mycobacterium tuberculosis* from medical waste. *JAMA* 2000;284:1683–8.
481. Alvarado CJ, Reichelderfer M. APIC guideline for infection prevention and control in flexible endoscopy. *Am J Infect Control* 2000;28:138–55.
482. American Society for Gastrointestinal Endoscopy. Reprocessing of flexible gastrointestinal endoscopes. *Gastrointest Endosc* 1996;43:540–6.
483. American Society for Testing and Materials. Standard practice for cleaning and disinfection of flexible fiberoptic and video endoscopes used in the examination of the hollow viscera. West Conshohocken, PA: American Society for Testing and Materials; 2000.
484. Society of Gastroenterology Nurses and Associates, Inc. SGNA monograph series. Standards for infection control and reprocessing of flexible gastrointestinal endoscopes. Chicago, IL: Society
A48946859

- of Gastroenterology Nurses and Associates, Inc.; 1997.
485. Axon ATR. World Congress of Gastroenterology. Working party report to the World Congress of Gastroenterology, Sydney, 1990. Disinfection and endoscopy: summary and recommendations. *J Gastroenterol Hepatol* 1991;6:23–4.
 486. Favero MS, Bond WW. Chemical disinfection of medical and surgical materials [Chapter 35]. In: Block SS, ed. *Disinfection, sterilization, and preservation*. 4th ed. Philadelphia, PA: Lea & Febiger; 1991:617–41.
 487. Food and Drug Administration, CDC. FDA and CDC Public Health Advisory: infections from endoscopes inadequately reprocessed by an automated endoscope reprocessing system. Rockville, MD: US Food and Drug Administration, Center for Devices and Radiological Health; 1999:1–5.

Terms and Abbreviations Used in this Report

ACET	Advisory Council for the Elimination of Tuberculosis
ACGIH	American Conference of Governmental Industrial Hygienists
ACGIH	American Conference of Governmental Industrial Hygienists
ACGIH	American Conference of Governmental Industrial Hygienists
ACH	Air changes per hour
ACOG	American College of Obstetricians and Gynecologists
AERS	Adverse event reporting system
AFB	Acid-fast bacilli
AIA	American Institute of Architects
AIDS	Acquired immunodeficiency syndrome
AII	Airborne infection isolation
ALA	American Lung Association
ALT	Alanine aminotransferase
ANSI	American National Standards Institute
APF	Assigned protection factor
APIC	Association for Professionals in Infection Control and Epidemiology, Inc.
ART	Antiretroviral therapy
ASHRAE	American Society of Heating, Refrigerating, and Air-Conditioning Engineers, Inc.
AST	Aspartate aminotransferase
ATS	American Thoracic Society
BAMT	Blood assay for <i>Mycobacterium tuberculosis</i>
BCG	Bacille Calmette-Guérin
BIDR	Blinded independent duplicate reading
BMBL	Biosafety in Microbiological and Biomedical Laboratories
BSL	Biosafety level
BSC	Biological safety cabinet
CAV	Constant air volume
CDC	Centers for Disease Control and Prevention
CEL	Certified equipment list
CFM	Cubic feet per minute
CFR	Code of Federal Regulations
CoV	Coronavirus
CPL	Compliance policy directive

CT	Computed tomography
DHHS	U.S. Department of Health and Human Services
DNA	Deoxyribonucleic acid
DTBE	Division of Tuberculosis Elimination
DOT	Directly observed therapy
DTH	Delayed-type hypersensitivity
ED	Emergency department
EMS	Emergency medical service
EPA	Environmental Protection Agency
ESRD	End-stage renal disease
ETL	Electrical Testing Laboratories
FDA	U.S. Food and Drug Administration
FGI	Facility Guideline Institute
FPM	Feet per minute
HAART	Highly active antiretroviral therapy
HCW	Health-care worker
HEPA	High-efficiency particulate air
HIV	Human immunodeficiency virus
HMO	Health maintenance organization
HPLC	High-pressure liquid chromatograph
HVAC	Heating, ventilation, air conditioning
ICU	Intensive care unit
IDSA	Infectious Diseases Society of America
IFN- γ	Inteferon-gamma
IGRA	Interferon gamma release assay
INH	Isoniazid
IUATLD	International Union Against Tuberculosis and Lung Disease
JCAHO	Joint Commission on Accreditation of Healthcare Organizations
LTBI	Latent tuberculosis infection
MDR	TB Multidrug-resistant tuberculosis
MOTT	Mycobacterium other than tuberculosis
NAA	Nucleic acid amplification
NCID	National Center for Infectious Diseases
NIAID	National Institute of Allergy and Infectious Diseases
NIH	National Institutes of Health
NIOSH	National Institute for Occupational Safety and Health
NM	Nanometer
NNRTI	Nonnucleoside reverse transcriptase inhibitors
NPIN	National Prevention Information Network
NTCA	National Tuberculosis Controllers Association
NTM	Nontuberculous mycobacteria
OR	Operating room
OSHA	Occupational Safety and Health Administration
PAPR	Powered air-purifying respirator
PCP	Pneumocystis pneumonia

PCR	Polymerase chain reaction
PE	Protective environment
PET	Permissible exposure time
PI	Protease inhibitor
PPD	Purified protein derivative
PPE	Personal protective equipment
QC	Quality control
QFT	QuantiFERON®-TB test
QFT-G	QuantiFERON®-TB Gold test
QLFT	Qualitative fit test
QNFT	Quantitative fit test
REL	Recommended exposure limit
RFLP	Restriction fragment length polymorphism
RNA	Ribonucleic acid
RZ	Rifampin and pyrazinamide
SARS	Severe acute respiratory syndrome
SGOT	Serum glutamic-oxalacetic transaminase*
SGPT	Serum glutamic-pyruvic transaminase†
SWPF	Simulated workplace protection factor
TB	Tuberculosis
TNF-α	Tumor necrosis factor-alpha
TU	Tuberculin unit
TST	Tuberculin skin test
UL	Underwriters Laboratories
UV	Ultraviolet
UVGI	Ultraviolet germicidal irradiation
VAV	Variable air volume
WHO	World Health Organization
WPF	Workplace protection factor

* Older term for AST.

† Older term for ALT.

Glossary of Definitions

acid-fast bacilli (AFB) examination	A laboratory test that involves microscopic examination of a stained smear of a patient specimen (usually sputum) to determine if mycobacteria are present. A presumptive diagnosis of pulmonary tuberculosis (TB) can be made with a positive AFB sputum smear result; however, approximately 50% of patients with TB disease of the lungs have negative AFB sputum smear results. The diagnosis of TB disease is usually not confirmed until Mycobacterium tuberculosis is identified in culture or by a positive nucleic acid amplification (NAA) test result.
administrative controls	Managerial measures that reduce the risk for exposure to persons who might have TB disease. Examples include coordinating efforts with the local or state health department; conducting a TB risk assessment for the setting; developing and instituting a written TB infection-control plan to ensure prompt detection, airborne infection isolation (AII), and treatment of persons with suspected or confirmed TB disease; and

	screening and evaluating health-care workers (HCWs) who are at risk for TB disease or who might be exposed to <i>M. tuberculosis</i> .
aerosol	Dispersions of particles in a gaseous medium (e.g., air). Droplet nuclei are an example of particles that are expelled by a person with an infectious disease (e.g., by coughing, sneezing, or singing). For <i>M. tuberculosis</i> , the droplet nuclei are approximately 1–5 μm . Because of their small size, the droplet nuclei can remain suspended in the air for substantial periods and can transmit <i>M. tuberculosis</i> to other persons.
air change rate	Ratio of the airflow in volume units per hour to the volume of the space under consideration in identical volume units, usually expressed in air changes per hour (ACH).
air change rate (equivalent)	Ratio of the volumetric air loss rate associated with an environmental control (or combination of controls) (e.g., an air cleaner or ultraviolet germicidal irradiation [UVGI] system) divided by the volume of the room where the control has been applied. The equivalent air change rate is useful for describing the rate at which bioaerosols are removed by means other than ventilation.
air change rate (mechanical)	Ratio of the airflow to the space volume per unit time, usually expressed in air changes per hour (ACH).
air changes per hour (ACH)	Air change rate expressed as the number of air exchange units per hour.
airborne infection isolation (AII) precautions	The isolation of patients infected with organisms spread through airborne droplet nuclei 1–5 μm in diameter. This isolation area receives substantial ACH (≥ 12 ACH for new construction since 2001 and ≥ 6 ACH for construction before 2001) and is under negative pressure (i.e., the direction of the air flow is from the outside adjacent space [e.g., the corridor] into the room). The air in an AII room is preferably exhausted to the outside, but can be recirculated if the return air is filtered through an high efficiency particulate respirator (HEPA) filter.
AII room	A room designed to maintain AII. Formerly called negative pressure isolation room, an AII room is a single-occupancy patient-care room used to isolate persons with suspected or confirmed infectious TB disease. Environmental factors are controlled in AII rooms to minimize the transmission of infectious agents that are usually spread from person-to-person by droplet nuclei associated with coughing or aerosolization of contaminated fluids. AII rooms should provide negative pressure in the room (so that air flows under the door gap into the room), an air flow rate of 6–12 ACH, and direct exhaust of air from the room to the outside of the building or recirculation of air through a HEPA filter.
American Institute of Architects/Facility Guideline Institute (AIA/FGI)	A professional organization that develops standards for building design and construction, including ventilation parameters, and enforced by the Joint Commission on Accreditation of Healthcare Organizations.
American Society of Heating, Refrigerating, and Air-Conditioning Engineers, Inc. (ASHRAE)	A professional organization that develops guidelines for building ventilation.
aminotransaminases	Also called transaminases. Used to assess for hepatotoxicity in persons taking antituberculosis medications and include aspartate amino transferase (AST), serum glutamic oxalacetic transaminase, formerly SGOT, and amino alanine transferase, formerly ALT.

aminotransferases	Also called transaminases. Used to assess for hepatotoxicity in persons taking antituberculosis medications and include aspartate amino transferase (AST) (formerly serum glutamic oxalacetic transaminase) and amino alanine transferase (ALT) (formerly serum glutamic pyruvic transaminase).
anaphylactic shock	An often severe and sometimes fatal systemic reaction upon a second exposure to a specific antigen (as wasp venom or penicillin) after previous sensitization that is characterized especially by respiratory symptoms, fainting, itching, and hives.
anemometer	An instrument used to measure the velocity (speed) of air.
anergy	A condition in which a person has a diminished ability to exhibit delayed T-cell hypersensitivity to antigens because of a condition or situation resulting in altered immune function. An inability to react to a skin test is called cutaneous anergy. Skin tests for anergy (i.e., control antigens) have poor predictive value and are not recommended.
anteroom	Small room leading from a corridor into an AII room. An anteroom is separated from both the AII room and the corridor by doors. An anteroom can act as an airlock, preventing the escape of contaminants from the AII room into the corridor.
apical	Relating to or located at the tip (an apex).
assigned protection factor (APF)	The minimum anticipated protection provided by a properly worn and functioning respirator or class of respirators.
asymptomatic	Neither causing nor exhibiting signs or symptoms of disease.
Bacille Calmette-Guérin (BCG)	A vaccine for TB named after the French scientists Calmette and Guérin used in most countries where TB disease is endemic. The vaccine is effective in preventing disseminated and meningeal TB disease in infants and young children. It may have approximately 50% efficacy for preventing pulmonary TB disease in adults.
baseline TB screening	Screening HCWs for LTBI and TB disease at the beginning of employment. TB screening includes a symptom screen for all HCWs, and tuberculin skin tests (TSTs) or blood assay for <i>Mycobacterium tuberculosis</i> (BAMT) for those with previous negative test results for <i>M. tuberculosis</i> infection.
baseline TST or baseline BAMT	The TST or BAMT is administered at the beginning of employment to newly hired HCWs. If the TST method is used, for HCWs who have not had a documented negative test result for <i>M. tuberculosis</i> during the preceding 12 months, the baseline TST result should be obtained by using the two-step method. BAMT baseline testing does not need the two-step method.
biological safety cabinet (BSC)	A ventilated box that provides HCWs with a degree of protection against hazardous aerosols that are generated within it. BSC is the principal device used to contain infectious splashes or aerosols generated by multiple microbiology processes. BSC provides physical barriers and directional airflow to carry hazards away from the HCW. Maintenance is an essential part of ensuring proper BCS function.
Biosafety in Microbiological and Biomedical Laboratories (BMBL)	A publication of the U.S. Public Health Service that describes the combinations of standard and special microbiology practices, safety equipment, and facilities constituting biosafety levels (BSLs) 1–4, which are recommended for work with various infectious agents in laboratory settings. The recommendations are advisory and intended to provide a voluntary guide or code of practice.

biosafety levels (BSLs)	Four BSLs are described in Section III of BMBL that comprise combinations of laboratory practices and techniques, safety equipment, and laboratory settings.
blinded independent duplicate reading (BIDR)	Process in which two or more TST readers immediately measure the same TST result by standard procedures, without consulting or observing one another's readings, and record results. BIDRs help ensure that TST readers continue to read TST results correctly.
blood assay for Mycobacterium tuberculosis (BAMT)	A general term to refer to recently developed in vitro diagnostic tests that assess for the presence of infection with <i>M. tuberculosis</i> . This term includes, but is not limited to, IFN- γ release assays (IGRA). In the United States, the currently available test is QuantiFERON®-TB Gold test (QFT-G).
BAMT converter	A change from a negative to a positive BAMT result over a 2-year period.
boosting	When nonspecific or remote sensitivity to tuberculin purified protein derivative (PPD) in the skin test wanes or disappears over time, subsequent TSTs can restore the sensitivity. This process is called boosting or the booster phenomenon. An initially small TST reaction size is followed by a substantial reaction size on a later test, and this increase in millimeters of induration can be confused with a conversion or a recent <i>M. tuberculosis</i> infection. Two-step testing is used to distinguish new infections from boosted reactions in infection-control surveillance programs.
bronchoscopy	A procedure for examining the lower respiratory tract in which the end of the endoscopic instrument is inserted through the mouth or nose (or tracheostomy) and into the respiratory tree. Bronchoscopy can be used to obtain diagnostic specimens. Bronchoscopy also creates a high risk for <i>M. tuberculosis</i> transmission to HCWs if it is performed on an untreated patient who has TB disease (even if the patient has negative AFB smear results) because it is a cough-inducing procedure.
case	A particular instance of a disease (e.g., TB). A case is detected, documented, and reported.
cavity (pulmonary)	A hole in the lung parenchyma, usually not involving the pleural space. Although a lung cavity can develop from multiple causes, and its appearance is similar regardless of its cause, in pulmonary TB disease, cavitation results from the destruction of pulmonary tissue by direct bacterial invasion and an immune interaction triggered by <i>M. tuberculosis</i> . A TB cavity substantial enough to see with a normal chest radiograph predicts infectiousness.
clinical examination	A physical evaluation of the clinical status of a patient by a physician or equivalent practitioner.
close contact (TB)	A person who has shared the same air space in a household or other enclosed environment for a prolonged period (days or weeks, not minutes or a couple hours) with a person with suspected or confirmed TB disease. Close contacts have also been referred to as high-priority contacts because they have the highest risk for infection with <i>M. tuberculosis</i> .
cluster (TB)	A group of patients with LTBI or TB disease that are linked by epidemiologic, location, or genotyping data. Two or more TST conversions within a short period can be a cluster of TB disease and might suggest transmission within the setting. A genotyping cluster is

	two or more cases with isolates that have an identical genotyping pattern.
combination product surgical mask/N95 disposable respirator	Product certified by CDC's National Institute for Occupational Safety and Health (NIOSH) and cleared by the Food and Drug Administration (FDA) that provides both respiratory protection and bloodborne pathogen protection.
constant air volume (CAV)	A descriptor for an air-handling system which, as the name implies, supplies and exhausts air at a constant flow rate. The flow rate does not change over time based on temperature load or other parameters.
contact (TB)	Refers to someone who was exposed to <i>M. tuberculosis</i> infection by sharing air space with an infectious TB patient.
contact investigation	Procedures that occur when a case of infectious TB is identified, including finding persons (contacts) exposed to the case, testing and evaluation of contacts to identify LTBI or TB disease, and treatment of these persons, as indicated.
contagious	Describes a characteristic of a disease that can be transmitted from one living being to another through direct contact or indirect contact; communicable. The agent responsible for the contagious character of a disease is also described as being infectious; the usual culprits are microorganisms.
contraindication	Any condition, especially any condition of disease, which renders a certain line of treatment improper or undesirable.
conversion	See TST conversion.
conversion rate	The percentage of a population with a converted test result (TST or BAMT) for <i>M. tuberculosis</i> within a specified period. This is calculated by dividing the number of conversions among eligible HCWs in the setting in a specified period (numerator) by the number of HCWs who received tests in the setting over the same period (denominator) multiplied by 100.
culture	Growth of microorganisms in the laboratory performed for detection and identification in sputum or other body fluids and tissues. This test usually takes 2–4 weeks for mycobacteria to grow (2–4 days for most other bacteria).
cough etiquette	See respiratory hygiene and cough etiquette.
cross contamination	When organisms from one sample are introduced into another sample, causing a false-positive result.
delayed-type hypersensitivity (DTH)	Cell-mediated inflammatory reaction to an antigen, which is recognized by the immune system usually because of previous exposure to the same antigen or similar ones. Cell-mediated reactions are contrasted with an antibody (or humoral) response. DTH typically peaks at 48–72 hours after exposure to the antigen.
deoxyribonucleic acid	DNA fingerprinting is a clinical laboratory technique used to distinguish between different strains of <i>M. tuberculosis</i> and to help assess the likelihood of TB transmission.
differential pressure	A measurable difference in air pressure that creates a directional airflow between adjacent compartmentalized spaces.
directly observed therapy (DOT)	Adherence-enhancing strategy in which an HCW or other trained person watches a patient swallow each dose of medication. DOT is the standard care for all patients with TB disease and is a preferred option for patients treated for LTBI.

disposable respirator	A respirator designed to be used and then discarded; also known as a filtering-facepiece respirator. Respirators should be discarded after excessive resistance, physical damage, or hygiene considerations.
droplet nuclei	Microscopic particles produced when a person coughs, sneezes, shouts, or sings. These particles can remain suspended in the air for prolonged periods and can be carried on normal air currents in a room and beyond to adjacent spaces or areas receiving exhaust air.
drug-susceptibility test	A laboratory determination to assess whether an <i>M. tuberculosis</i> complex isolate is susceptible or resistant to antituberculosis drugs that are added to mycobacterial growth medium or are detected genetically. The results predict whether a specific drug is likely to be effective in treating TB disease caused by that isolate.
environmental control measures	Physical or mechanical measures (as opposed to administrative control measures) used to reduce the risk for transmission of <i>M. tuberculosis</i> . Examples include ventilation, filtration, ultraviolet lamps, AII rooms, and local exhaust ventilation devices.
epidemiologic cluster	A closely grouped series of cases in time or place.
erythema	Abnormal redness of the skin. Erythema can develop around a TST site but should not be read as part of the TST result.
expert TST trainer	A designated instructor who has documented TST training experience. This may include having received training on placing and reading multiple TST results.
exposed cohorts	Groups of persons (e.g., family members, co-workers, friends, club, team or choir members, persons in correctional facilities, or homeless shelter residents) who have shared the same air space with the suspected patient with TB disease during the infectious period. A person in the exposed cohort is a contact. See also contact and close contact.
exposure	The condition of being subjected to something (e.g., an infectious agent) that could have an adverse health effect. A person exposed to <i>M. tuberculosis</i> does not necessarily become infected. See also transmission.
exposure period	The coincident period when a contact shared the same air space as the index TB patient during the infectious period.
exposure site	A location that the index patient visited during the infectious period (e.g., school, bar, bus, or residence).
extrapulmonary TB	TB disease in any part of the body other than the lungs (e.g., kidney, spine, or lymph nodes). The presence of extrapulmonary disease does not exclude pulmonary TB disease.
false-negative TST or BAMT result	A TST or BAMT result that is interpreted as negative in a person who is actually infected with <i>M. tuberculosis</i> .
false-positive TST or BAMT result	A TST or BAMT result that is interpreted as positive in a person who is not actually infected with <i>M. tuberculosis</i> . A false-positive TST result is more likely to occur in persons who have been vaccinated with BCG or who are infected with nontuberculous mycobacteria (NTM).
facility	A physical building or set of buildings.
filtering-facepiece respirator	A type of air purifying respirator that uses a filter as an integral part of the facepiece or with the entire facepiece composed of the filtering medium.
fit check	See user-seal check.

fit factor	A quantitative estimate of the fit of a particular respirator to a specific person; typically estimates the ratio of the concentration of a substance in ambient air to its concentration inside the respirator when worn.
fit test	The use of a protocol to qualitatively or quantitatively evaluate the fit of a respirator on a person. See also QLFT and QNFT.
flutter strips	Physical indicators used to provide a continuous visual sign that a room is under negative pressure. These simple and inexpensive devices are placed directly in the door and can be useful in identifying a pressure differential problem.
genotype	The DNA pattern of <i>M. tuberculosis</i> used to discriminate among different strains.
health-care–associated	Broader term used instead of "nosocomial."
health-care setting	A place where health care is delivered.
health-care workers (HCWs)	All paid and unpaid persons working in health-care settings.
heating, ventilating, or air conditioning (HVAC)	Mechanical systems that provide either collectively or individually heating, ventilating, or air conditioning for comfort within or associated with a building.
high efficiency particulate air (HEPA) filter	A filter that is certified to remove $\geq 99.97\%$ of particles $0.3 \mu\text{m}$ in size, including <i>M. tuberculosis</i> –containing droplet nuclei; the filter can be either portable or stationary. Use of HEPA filters in building ventilation systems requires expertise in installation and maintenance.
high-pressure liquid chromatograph (HPLC)	Laboratory method used to identify Mycobacterium species by analysis of species-specific fatty acids called mycolic acids, which are present in the cell walls of mycobacteria.
human immunodeficiency virus (HIV) infection	Infection with the virus that causes acquired immunodeficiency syndrome (AIDS). A person with both LTBI and HIV infection is at high risk for developing TB disease.
hemoptysis	The expectoration or coughing up of blood or blood-tinged sputum; one of the symptoms of pulmonary TB disease. Hemoptysis can also be observed in other pulmonary conditions (e.g., lung cancer).
hypersensitivity	A state in which the body reacts with an exaggerated immune response to a foreign substance. Hypersensitivity reactions are classified as immediate or delayed, types I and IV, respectively. See also delayed-type hypersensitivity.
immunocompromised and immunosuppressed	Describes conditions in which at least part of the immune system is functioning at less than normal capacity. According to certain style experts, "immunocompromised" is the broader term, and "immunosuppressed" is restricted to conditions with iatrogenic causes, including treatments for another condition.
incentive	A gift given to patients to encourage or acknowledge their adherence to treatment.
incidence	The number of new events or cases of disease that develop during a specified period.
index case	The first person with TB disease who is identified in a particular setting. This person might be an indicator of a potential public health problem and is not necessarily the source case. See also source case or patient.

induration	The firmness in the skin test reaction; produced by immune-cell infiltration in response to the tuberculin antigen that was introduced into the skin. Induration is measured transversely by palpation, and the result is recorded in millimeters. The measurement is compared with guidelines to determine whether the test result is classified as positive or negative.
infection with <i>M. tuberculosis</i>	In some persons who are exposed to and who inhale <i>M. tuberculosis</i> bacteria, the bacteria are not promptly cleared by respiratory defense systems, and the bacteria multiply and are spread throughout the body, thereby infecting the exposed person. In the majority of persons who become infected, the body is able to fight the bacteria to stop the bacteria from growing, further establishing a latent state. The bacteria are inactive, but they remain alive in the body and can become active later. In other persons, the infection with <i>M. tuberculosis</i> can progress to TB disease more promptly. <i>M. tuberculosis</i> infection encompasses both latent TB infection and TB disease. See also latent TB infection and reinfection.
infectious	See contagious.
infectious droplet nuclei	Droplet nuclei produced by an infectious TB patient that can carry tubercle bacteria and be inhaled by others. Although usually produced from patients with pulmonary TB through coughing, aerosol-generating procedures can also generate infectious droplet nuclei.
infectious period	The period during which a person with TB disease might have transmitted <i>M. tuberculosis</i> organisms to others. For patients with positive AFB sputum smear results, the infectious period begins 3 months before the collection date of the first positive smear result or the symptom onset date (whichever is earlier) and ends when the patient is placed into AII or the date of collection for the first of consistently negative smear results. For patients with negative AFB sputum smear results, the infectious period extends from 1 month before the symptom onset date and ends when the patient is placed into AII (whichever was earlier).
interferon- γ release assays (IGRA)	A type of an ex vivo test that detects cell-mediated immune response to this cytokine. In the United States, QFT-G is a currently available IGRA.
isoniazid (INH)	A highly active antituberculosis chemotherapeutic agent that is a cornerstone of treatment for TB disease and the cornerstone of treatment for LTBI.
laryngeal TB	A form of TB disease that involves the larynx and can be highly infectious.
latent TB infection (LTBI)	Infection with <i>M. tuberculosis</i> without symptoms or signs of disease have manifested. See also Infection with <i>M. tuberculosis</i> .
manometer	An instrument used to measure pressure differentials (i.e., pressure inside an AII room relative to the corridor of the room).
Mantoux method	A skin test performed by intradermally injecting 0.1 mL of PPD tuberculin solution into the volar or dorsal surface of the forearm. This method is the recommended method for TST.
mask	A device worn over the nose and mouth of a person with suspected or confirmed infectious TB disease to prevent infectious particles from being released into room air.
mechanical ACH	Air change rate based on only the mechanical ventilation flowrates.

medical evaluation	An examination to diagnose TB disease or LTBI, to select treatment, and to assess response to therapy. A medical evaluation can include medical history and TB symptom screen, clinical or physical examination, screening and diagnostic tests (e.g., TSTs, chest radiographs, bacteriologic examination, and HIV testing), counseling, and treatment referrals.
meningeal TB	A serious form of TB disease involving the meninges, the covering of the brain. Meningeal TB can result in serious neurologic complications.
miliary TB	A serious form of TB disease sometimes referred to as disseminated TB. A dangerous and difficult form to diagnose of rapidly progressing TB disease that extends throughout the body. Uniformly fatal if untreated; in certain instances, it is diagnosed too late to save a life. Certain patients with this condition have normal findings or ordinary infiltrates on the chest radiograph.
mitogen	A substance that stimulates the growth of certain white blood cells. Mitogen is used as a positive control in BAMT tests.
multidrug-resistant tuberculosis (MDR TB)	TB disease caused by <i>M. tuberculosis</i> organisms that are resistant to at least INH and rifampin.
mycobacteria other than tuberculosis (MOTT)	See NTM.
Mycobacterium tuberculosis	The namesake member organism of <i>M. tuberculosis</i> complex and the most common causative infectious agent of TB disease in humans. In certain instances, the species name refers to the entire <i>M. tuberculosis</i> complex, which includes <i>M. bovis</i> , <i>M. african</i> , <i>M. microti</i> , <i>M. canettii</i> , <i>M. caprae</i> , and <i>M. pinnipedii</i> .
<i>M. tuberculosis</i> culture	A laboratory test in which the organism is grown from a submitted specimen (e.g., sputum) to determine the presence of <i>M. tuberculosis</i> . In the absence of cross-contamination, a positive culture confirms the diagnosis of TB disease.
N95 disposable respirator	An air-purifying, filtering-facepiece respirator that is $\geq 95\%$ efficient at removing 0.3 μm particles and is not resistant to oil. See also respirator.
negative pressure	The difference in air-pressure between two areas. A room that is under negative pressure has a lower pressure than adjacent areas, which keeps air from flowing out of the room and into adjacent rooms or areas. Also used to describe a nonpowered respirator. See also AII and AII room.
nontuberculous mycobacteria (NTM)	Refers to mycobacterium species other than those included as part of <i>M. tuberculosis</i> complex. Although valid from a laboratory perspective, the term can be misleading because certain types of NTM cause disease with pathologic and clinical manifestations similar to TB disease. Another term for NTM is mycobacterium other than tuberculosis (MOTT). NTM are environmental mycobacteria.
nosocomial	Acquired in a hospital. The broader term "health-care-associated" is used in this report.
nucleic acid amplification (NAA)	Laboratory method used to target and amplify a single DNA or RNA sequence usually for detecting and identifying a microorganism. The NAA tests for <i>M. tuberculosis</i> complex are sensitive and specific and can accelerate the confirmation of pulmonary TB disease.
periodic fit testing	Repetition of fit testing performed in accordance with local, state, and federal regulations. Additional fit testing should be used when 1) a new model of respirator is used, 2) a physical characteristic of the user

	changes, or 3) when the user or respiratory program administrator is uncertain that the HCW is obtaining an adequate fit.
pleural effusion	Abnormal accumulation of fluid between the lining of the lung and the chest wall. Persons with TB pleural effusions might also have concurrent unsuspected pulmonary or laryngeal TB disease. These patients should be considered contagious until infectious TB disease is excluded.
polymerase chain reaction (PCR)	A system for in vitro amplification of DNA that can be used for diagnosis of infections.
positive predictive value of a TST	The probability that a person with a positive TST result is actually infected with <i>M. tuberculosis</i> . The positive predictive value is dependent on the prevalence of infection with <i>M. tuberculosis</i> in the population being tested and on the sensitivity and specificity of the test.
potential ongoing transmission	A risk classification for TB screening, including testing for <i>M. tuberculosis</i> infection when evidence of ongoing transmission of <i>M. tuberculosis</i> is apparent in the setting. Testing might need to be performed every 8–10 weeks until lapses in infection controls have been corrected, and no further evidence of ongoing transmission is apparent. Use potential ongoing transmission as a temporary risk classification only. After corrective steps are taken, reclassify the setting as medium risk. Maintaining the classification of medium risk for at least 1 year is recommended.
powered air-purifying respirator (PAPR)	A respirator equipped with a tight-fitting facepiece (rubber facepiece) or loose-fitting facepiece (hood or helmet), breathing tube, air-purifying filter, cartridge or canister, and a fan. Air is drawn through the air-purifying element and pushed through the breathing tube and into the facepiece, hood, or helmet by the fan. Loose-fitting PAPRs (e.g., hoods or helmets) might be useful for persons with facial hair because they do not require a tight seal with the face.
prevalence	The proportion of persons in a population who have a disease at a specific time.
protection factor	A general term for three specific terms: 1) APF, 2) SWPF, and 3) WPF. These terms refer to different methods of defining adequacy of respirator fit. See also APF, SWPF, and WPF.
pulmonary TB	TB disease that occurs in the lung parenchyma, usually producing a cough that lasts ≥ 3 weeks.
purified protein derivative (PPD) tuberculin	A material used in diagnostic tests for detecting infection with <i>M. tuberculosis</i> . In the United States, PPD solution is approved for administration as an intradermal injection (5 TU per 0.1 mL), a diagnostic aid for LTBI (see TST). In addition, PPD tuberculin was one of the antigens in the first-generation QFT.
qualitative fit test (QLFT)	A pass-fail fit test to assess the adequacy of respirator fit that relies on the response of the person to the test agent.
quality control (QC)	A function to ensure that project tools and procedures are reviewed and verified according to project standards.
QFT and QFT-G	Types of BAMT that are in vitro cytokine assays that detects cell-mediated immune response (see also DTH) to <i>M. tuberculosis</i> in heparinized whole blood from venipuncture. This test requires only a single patient encounter, and the result can be ready within 1 day. In 2005, QuantiFERON(r)-TB was replaced by QuantiFERON(r)-TB Gold (QFT-G), which has greater specificity because of antigen selection.

	QFT-G appears to be capable of distinguishing between the sensitization caused by <i>M. tuberculosis</i> infection and that caused by BCG vaccination.
quantitative fit test (QNFT)	An assessment of the adequacy of respirator fit by numerically measuring the amount of leakage into the respirator.
recirculation	Ventilation in which all or the majority of the air exhausted from an area is returned to the same area or other areas of the setting.
recommended exposure limit (REL)	The occupational exposure limit established by CDC/NIOSH. RELs are intended to suggest levels of exposure to which the majority of HCWs can be exposed without experiencing adverse health effects.
reinfection	A second infection that follows from a previous infection by the same causative agent. Frequently used when referring to an episode of TB disease resulting from a subsequent infection with <i>M. tuberculosis</i> and a different genotype.
resistance	The ability of certain strains of mycobacteria, including <i>M. tuberculosis</i> , to grow and multiply in the presence of certain drugs that ordinarily kill or suppress them. Such strains are referred to as drug-resistant strains and cause drug-resistant TB disease. See also multidrug-resistant TB.
respirator	A CDC/NIOSH-approved device worn to prevent inhalation of airborne contaminants.
respiratory hygiene and cough etiquette	Procedures by which patients with suspected or confirmed infectious TB disease can minimize the spread of infectious droplet nuclei by decreasing the number of infectious particles that are released into the environment. Patients with a cough should be instructed to turn their heads away from persons and to cover their mouth and nose with their hands or preferably a cloth or tissue when coughing or sneezing.
respiratory protection	The third level in the hierarchy of TB infection-control measures after administrative and environmental controls is used because of the risk for exposure.
restriction fragment length polymorphism (RFLP)	A technique by which organisms can be differentiated by analysis of patterns derived from cleavage of their DNA. The similarity of the patterns generated can be used to differentiate strains from one another. See also genotype.
reversion	A subsequent TST or BAMT result that is substantially smaller than a previous test; reversion has been observed to be more likely when the intervening time between TSTs increases.
Rifampin	A highly active antituberculosis chemotherapeutic agent that is a cornerstone of treatment for TB disease.
screening (TB)	Measures used to identify persons who have TB disease or LTBI. See also symptom screen.
secondary (TB) case	A new case of TB disease that is attributed to recent transmission as part of the scenario under investigation. The period for "recent" is not defined but usually will be briefer than 2 years. Technically, all cases are secondary, in that they originate from other contagious cases.
simulated workplace protection factor (SWPF)	A surrogate measure of the workplace protection provided by a respirator.
smear (AFB smear)	A laboratory technique for preparing a specimen so that bacteria can be visualized microscopically. Material from the specimen is spread onto a glass slide and usually dried and stained. Specific smear, stain, and microscopy methods for mycobacteria are designed to optimally detect members of this genus. The slide can be scanned by light or fluorescent

high-power microscopy. These methods require ongoing quality assurance for prompt and reliable results. The results for sputum smears usually are reported as numbers of AFB per high-powered microscopy field or as a graded result, from +1 to +4. The quantity of stained organisms predicts infectiousness. See also AFB.

source case or patient	The person or the case that was the original source of infection for secondary cases or contacts. The source case can be, but is not necessarily, the index case.
source case investigation	An investigation to determine the source case could be conducted in at least two circumstances: 1) when a health-care setting detects an unexplained cluster of TST conversions among HCWs or 2) when TB infection or disease is diagnosed in a young child. The purposes of a source case investigation are to ascertain that the source case has been diagnosed and treated, to prevent further <i>M. tuberculosis</i> transmission, and to ensure that other contacts of that source case are also evaluated and, if indicated, provided treatment.
source control	A process for preventing or minimizing emission (e.g., aerosolized <i>M. tuberculosis</i>) at the place of origin. Examples of source-control methods are booths in which a patient coughs and produces sputum, BSCs in laboratories, and local exhaust ventilation.
spirometry	A procedure used to measure time expired and the volume inspired, and from these measurements, calculations can be made on the effectiveness of the lungs.
sputum	Mucus containing secretions coughed up from inside the lungs. Tests of sputum (e.g., smear and culture) can confirm pulmonary TB disease. Sputum is different from saliva or nasal secretions, which are unsatisfactory specimens for detecting TB disease. However, specimens suspected to be inadequate should still be processed because positive culture results can still be obtained and might be the only bacteriologic indication of disease.
sputum induction	A method used to obtain sputum from a patient who is unable to cough up a specimen spontaneously. The patient inhales a saline mist, which stimulates coughing from deep inside the lungs.
supervised TST administration	A procedure in which an expert TST trainer supervises a TST trainee who performs all procedures on the procedural observation checklist for administering TSTs.
supervised TST reading	A procedure in which an expert TST trainer supervises a TST trainee who performs all procedures on the procedural observation checklist for reading TST results.
suspected TB	A tentative diagnosis of TB that will be confirmed or excluded by subsequent testing. Cases should not remain in this category for longer than 3 months.
symptomatic	A term applied to a patient with health-related complaints (symptoms) that might indicate the presence of disease. In certain instances, the term is applied to a medical condition (e.g., symptomatic pulmonary TB).
symptom screen	A procedure used during a clinical evaluation in which patients are asked if they have experienced any departure from normal in function, appearance, or sensation related to TB disease (e.g., cough).
targeted testing	A strategy to focus testing for infection with <i>M. tuberculosis</i> in persons at high risk for LTBI and for those at high risk for progression to TB disease if infected.

tuberculosis (TB) disease	Condition caused by infection with a member of the <i>M. tuberculosis</i> complex that has progressed to causing clinical (manifesting symptoms or signs) or subclinical (early stage of disease in which signs or symptoms are not present, but other indications of disease activity are present [see below]) illness. The bacteria can attack any part of the body, but disease is most commonly found in the lungs (pulmonary TB). Pulmonary TB disease can be infectious, whereas extrapulmonary disease (occurring at a body site outside the lungs) is not infectious, except in rare circumstances. When the only clinical finding is specific chest radiographic abnormalities, the condition is termed "inactive TB" and can be differentiated from active TB disease, which is accompanied by symptoms or other indications of disease activity (e.g., the ability to culture reproducing TB organisms from respiratory secretions or specific chest radiographic finding).
TB case	A particular episode of clinical TB disease. Refers only to the disease, not to the person with the disease. According to local laws and regulation, TB cases and suspect TB cases must be reported to the local or state health department.
TB contact	A person who has shared the same air space with a person who has TB disease for a sufficient amount of time to allow possible transmission of <i>M. tuberculosis</i>.
TB exposure incident	A situation in which persons (e.g., HCWs, visitors, and inmates) have been exposed to a person with suspected or confirmed infectious TB disease (or to air containing <i>M. tuberculosis</i>), without the benefit of effective infection-control measures.
TB infection	See LTBI.
TB infection-control program	A program designed to control transmission of <i>M. tuberculosis</i> through early detection, isolation, and treatment of persons with infectious TB. A hierarchy of control measures are used, including 1) administrative controls to reduce the risk for exposure to persons with infectious TB disease and screening for HCWs for LTBI and TB disease, 2) environmental controls to prevent the spread and reduce the concentration of infectious droplet nuclei in the air, and 3) respiratory protection in areas where the risk for exposure to <i>M. tuberculosis</i> is high (e.g., AII rooms). A TB infection-control plan should include surveillance of HCWs who have unprotected high-risk exposure to TB patients or their environment of care.
TB screening	An administrative control measure in which evaluation for LTBI and TB disease are performed through initial and serial screening of HCWs, as indicated. Evaluation might comprise TST, BAMT, chest radiograph, and symptom screening. See also symptom screen.
TB screening program	A plan that health-care settings should implement to provide information that is critical in caring for HCWs and information and that facilitates detection of <i>M. tuberculosis</i> transmission. The TB screening program comprises four major components: 1) baseline testing for <i>M. tuberculosis</i> infection, 2) serial testing for <i>M. tuberculosis</i> infection, 3) serial screening for signs or symptoms of TB disease, and 4) TB training and education.
TB risk assessment	An initial and ongoing evaluation of the risk for transmission of <i>M. tuberculosis</i> in a particular health-care setting. To perform a risk assessment, the following factors should be considered: the community rate of TB, number of TB patients encountered in the setting, and the speed with which patients with TB disease are suspected, isolated, and

evaluated. The TB risk assessment determines the types of administrative and environmental controls and respiratory protection needed for a setting.

transmission	Any mode or mechanism by which an infectious agent is spread from a source through the environment or to a person (or other living organism). In the context of health-care–associated TB infection control, transmission is the airborne conveyance of aerosolized <i>M. tuberculosis</i> contained in droplet nuclei from a person with TB disease, usually from the respiratory tract, to another person, resulting in infection.
treatment for LTBI	Treatment that prevents the progression of infection into disease.
tuberculin skin test (TST)	A diagnostic aid for finding <i>M. tuberculosis</i> infection. A small dose of tuberculin is injected just beneath the surface of the skin (in the United States by the Mantoux method), and the area is examined for induration by palpation 48–72 hours after the injection. The indurated margins should be read transverse (perpendicular) to the long axis of the forearm. See also Mantoux method and PPD.
TST conversion	A change in the result of a test for <i>M. tuberculosis</i> infection wherein the condition is interpreted as having progressed from uninfected to infected. An increase of ≥ 10 mm in induration during a maximum of 2 years is defined as a TST conversion for the purposes of a contact investigation. A TST conversion is presumptive evidence of new <i>M. tuberculosis</i> infection and poses an increased risk for progression to TB disease. See also conversion rate.
tubercle bacilli	<i>M. tuberculosis</i> organisms.
tuberculin	A precipitate made from a sterile filtrate of <i>M. tuberculosis</i> culture medium.
tumor necrosis factor-alpha (TNF- α)	A small molecule (called a cytokine) discovered in the blood of animals (and humans) with tumors but which has subsequently been determined to be an essential host mediator of infection and inflammation. TNF- α is released when humans are exposed to bacterial products (e.g., lipopolysaccharide) or BCG. Drugs (agents) that block human TNF- α have been demonstrated to increase the risk for progression to TB disease in persons who are latently infected.
two-step TST	Procedure used for the baseline skin testing of persons who will receive serial TSTs (e.g., HCWs and residents or staff of correctional facilities or long-term-care facilities) to reduce the likelihood of mistaking a boosted reaction for a new infection. If an initial TST result is classified as negative, a second step of a two-step TST should be administered 1–3 weeks after the first TST result was read. If the second TST result is positive, it probably represents a boosted reaction, indicating infection most likely occurred in the past and not recently. If the second TST result is also negative, the person is classified as not infected. Two-step skin testing has no place in contact investigations or in other circumstances in which ongoing transmission of <i>M. tuberculosis</i> is suspected.
ulceration (TST)	A break in the skin or mucosa with loss of surface tissue.
ultraviolet germicidal radiation (UVGI)	Use of ultraviolet germicidal irradiation to kill or inactivate microorganisms.
UVGI lamp	An environmental control measure that includes a lamp that kills or inactivates microorganisms by emitting ultraviolet germicidal

irradiation, predominantly at a wavelength of 254 nm (intermediate light waves between visible light and radiographs). UVGI lamps can be used in ceiling or wall fixtures or within air ducts of ventilation systems as an adjunct to other environmental control measures.

user-seal check

Formerly called "fit check." A procedure performed after every respirator is donned to check for proper seal of the respirator.

variable air volume (VAV)

VAV ventilation systems are designed to vary the quantity of air delivered to a space while maintaining a constant supply air temperature to achieve the desired temperature in the occupied space. Minimum levels are mechanical, and outside air is maintained.

vesiculation

An abnormal elevation of the outer layer of skin enclosing a watery liquid; blister.

wheel

A small bump that is produced when a TST is administered. The wheal disappears in approximately 10 minutes after TST placement.

workplace protection factor (WPF) A measure of the protection provided in the workplace by a properly functioning respirator when correctly worn and used.

Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health-Care Settings, 2005

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TABLE 1. Air changes per hour (ACH) and time required for removal efficiencies of 99% and 99.9% of airborne contaminants*

ACH	Minutes required for removal efficiency†	
	99%	99.9%
2	138	207
4	69	104
6	46	69
12	23	35
15	18	28
20	14	21
50	6	8
400	<1	1

* This table can be used to estimate the time necessary to clear the air of airborne *Mycobacterium tuberculosis* after the source patient leaves the area or when aerosol-producing procedures are complete.

† Time in minutes to reduce the airborne concentration by 99% or 99.9%.

BOX 1. Indications for two-step tuberculin skin tests (TSTs)

Situation	Recommended testing
No previous TST result	Two-step baseline TSTs
Previous negative TST result (documented or not) >12 months before new employment	Two-step baseline TSTs
Previous documented negative TST result ≤12 months before new employment	Single TST needed for baseline testing; this test will be the second-step
≥2 previous documented negative TSTs but most recent TST >12 months before new employment	Single TST; two-step testing is not necessary (result would have already boosted)
Previous documented positive TST result	No TST
Previous undocumented positive TST result*	Two-step baseline TST(s)
Previous BCG [†] vaccination	Two-step baseline TST(s)
Programs that use serial BAMT, [§] including QFT [¶] (or the previous version QFT ^{**})	See Supplement, Use of QFT-G ^{**} for Diagnosing <i>M. tuberculosis</i> Infections in Health-Care Workers (HCWs)

* For newly hired health-care workers and other persons who will be tested on a routine basis (e.g., residents or staff of correctional or long-term-care facilities), a previous TST is not a contraindication to a subsequent TST, unless the test was associated with severe ulceration or anaphylactic shock, which are substantially rare adverse events. If the previous positive TST result is not documented, administer two-step TSTs or offer BAMT. **SOURCES:** Aventis Pasteur. Tuberculin purified protein derivative (Mantoux) Tubersol[®] diagnostic antigen. Toronto, Ontario, Canada: Aventis Pasteur; 2001. Parkdale Pharmaceuticals. APLISOL (Tuberculin purified protein derivative, diluted [stabilized solution]). Diagnostic antigen for intradermal injection only. Rochester, ME: Parkdale Pharmaceuticals; 2002. Froeschle JE, Ruben FL, Bloh AM. Immediate hypersensitivity reactions after use of tuberculin skin testing. Clin Infect Dis 2002;34:E12-3.

[†] Bacille Calmette-Guérin.

[§] Blood assay for *Mycobacterium tuberculosis*.

[¶] QuantiFERON[®]-TB test.

^{**} QuantiFERON[®]-TB Gold test.

TABLE 2. Ventilation recommendations for selected areas in new or renovated health-care settings

Health-care setting	Minimum mechanical ACH*	Minimum outdoor ACH*	Air movement relative to adjacent areas	Air exhausted directly outdoors [†]
Microbiology laboratory	6	§	In	Yes
Anteroom to All [‡] room	10	§	In/Out	Yes
All room ^{**††}	12	2	In	Yes
Autopsy suite	12	§	In	Yes
Bronchoscopy room	12	2	In	Yes
Emergency department and radiology waiting rooms	12–15 ^{§§}	2	In	Yes
Operating room or surgical room	15 ^{¶¶} 25 ^{***}	3 ^{§§} 15 ^{¶¶} 5 ^{***}	Out	§

SOURCES: CDC. Guidelines for preventing the transmission of *Mycobacterium tuberculosis* in health-care facilities, 1994. MMWR 1994;43(No. RR-13). American Society of Heating, Refrigerating, and Air-Conditioning Engineers, Inc. Health care facilities [Chapter 7]. 2003 ASHRAE handbook: HVAC applications. Atlanta, GA: American Society of Heating, Refrigerating, and Air-Conditioning Engineers, Inc.; 2003:7.1–7.14.

- * Air changes per hour.
- [†] If it is not possible to exhaust all the air to the outdoors in existing or renovated facilities, the air can be recirculated after passing through high efficiency particulate air (HEPA) filtration.
- [§] American National Standards Institute (ANSI)/American Society of Heating, Refrigerating, and Air-Conditioning Engineers, Inc. (ASHRAE). Standard 62.1-2004, Ventilation for Acceptable Indoor Air Quality, should be consulted for outside air recommendations in areas that are not specified. **SOURCE:** ANSI/ASHRAE. Standard 62.1-2004—ventilation for acceptable indoor air quality. Atlanta, GA: ASHRAE; 2004.
- [¶] Airborne infection isolation.
- ^{**} Settings with existing All rooms should have an airflow of ≥6 mechanical ACH; air-cleaning devices can be used to increase the equivalent ACH.
- ^{††} Patients requiring a protective environment room (e.g., severely immunocompromised patients) who also have TB disease require protection from common airborne infectious microorganisms.
- ^{§§} Recommendation of the American Institute of Architects (AIA) (air is recirculated through HEPA filters). **SOURCE:** AIA. Guidelines for design and construction of hospital and health care facilities. Washington, DC: AIA; 2001.
- ^{¶¶} Recommendation of ASHRAE (100% exhaust). **SOURCE:** ANSI/ASHRAE. Standard 62.1-2004—ventilation for acceptable indoor air quality. Atlanta, GA: ASHRAE; 2004.
- ^{***} Recommendation of ASHRAE (air is recirculated through HEPA filters). **SOURCE:** ANSI/ASHRAE. Standard 62.1-2004—ventilation for acceptable indoor air quality. Atlanta, GA: ASHRAE; 2004.

BOX 2. Interpretation of QuantiFERON(r)-TB Gold test (QFT-G) results

QFT-G result	Interpretation
Positive	
ESAT-6 or CFP-10* responsiveness detected	<i>Mycobacterium tuberculosis</i> infection probable
Negative	
No ESAT-6 and CFP-10 responsiveness detected	<i>M. tuberculosis</i> infection unlikely, but cannot be excluded, especially when
	1. any illness is consistent with TB disease, and
	2. the likelihood of progression to TB disease is increased (e.g., because of immunosuppression)
Indeterminate	Test not interpretable

* ESAT-6 is a 6-kDa early secretory antigenic target, and CFP-10 is 10-kDa culture filtrate protein.

FIGURE 1. The tuberculin skin test result in this picture should be recorded as 16 mm. The "0" mm ruler line is inside the edge of the left dot.

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BOX 3. Interpretations of tuberculin skin test (TST) and QuantiFERON(r)-TB test (QFT) results according to the purpose of testing for Mycobacterium tuberculosis infection in a health-care setting

Purpose of testing	TST	QFT
1. Baseline	1. ≥ 10 mm is considered a positive result (either first- or second-step); 0–9 mm is considered a negative result	1. Positive (only one-step)
2. Serial testing without known exposure	2. Increase of ≥ 10 mm is considered a positive result (TST conversion)	2. Change from negative to positive (QFT conversion)
3. Known exposure (close contact)	3. ≥ 5 mm is considered a positive result in persons who have a baseline TST result of 0 mm; an increase of ≥ 10 mm is considered a positive result in persons with a negative baseline TST result or previous follow-up screening TST result of >0 mm	3. Change to positive

TABLE 3. Standard drug regimens for treatment of latent TB infection (LTBI)*

Drugs	Months of duration	Interval	Minimum no. of standard doses*
Isoniazid (INH)	9 [†]	Daily	270
		Twice weekly	76
INH	6	Daily	180
		Twice weekly	52
Rifampin (RIF)	4	Daily	120
Rifampin/Pyrazinamide (RIF/PZA or RZ)	§	§	§

* **SOURCE:** American Thoracic Society, CDC. Targeted tuberculin testing and treatment of latent tuberculosis infection. MMWR 2000;49(No. RR-6).

[†]Nine months of INH is preferred, but 6 months of INH or 4 months of rifampin are acceptable alternatives.

§ Generally should not be offered for treatment of LTBI. **SOURCE:** CDC. Update: adverse event data and revised American Thoracic Society/CDC recommendations against the use of rifampin and pyrazinamide for treatment of latent tuberculosis infection—United States, 2003. MMWR 2003;52:735–9.

BOX 4. Conditions requiring caution in interpreting QuantiFERON(r)-TB Gold test results

- Human immunodeficiency virus infection or acquired immunodeficiency syndrome
- Immunosuppressive drugs, including those used for managing organ transplantation
- TNF*- α
- Diabetes mellitus
- Silicosis
- Chronic renal failure
- Certain hematological disorders (e.g., leukemias and lymphomas)
- Other specific malignancies (e.g., carcinoma of the head, neck, or lung)

* Tumor necrosis factor.

BOX 5. Factors affecting treatment decisions during the medical and diagnostic evaluation, by tuberculin skin test (TST) result

TST result ≥ 5 mm is positive	TST result ≥ 10 mm is positive	TST result ≥ 15 mm is positive*
- Persons infected with HIV[†] - Recent contacts of a person with tuberculosis (TB) disease - Persons with fibrotic changes on chest radiograph consistent with previous TB disease - Organ transplant recipients and other immunosuppressed persons (e.g., persons receiving ≥ 15 mg/day of prednisone for ≥ 1 month)[‡] - TB suspects[§]	- Recent immigrants (i.e., within the previous 5 years) from countries with a high incidence of TB disease - Persons who inject illicit drugs - Residents and employees (including health-care workers [HCWs])** of the following congregate settings - hospitals and other health-care facilities - long-term-care facilities (e.g., hospices and skilled nursing facilities) - residential facilities for patients with AIDS^{††} or other immunocompromising conditions - correctional facilities - homeless shelters - Mycobacteriology laboratory personnel - Persons with any of the following clinical conditions or immunocompromising conditions that place them at high risk for TB disease - diabetes mellitus - silicosis - chronic renal failure - certain hematologic disorders (e.g., leukemias and lymphomas) - other specific malignancies (e.g., carcinoma of the head, neck, or lung) - unexplained weight loss of $\geq 10\%$ of ideal body weight - gastrectomy - jejunoileal bypass - Persons living in areas with high incidence of TB disease - Children aged <4 years - Infants, children, and adolescents exposed to adults at high risk for developing TB disease - Locally identified groups at high risk	- Persons with no known risk factors for TB disease - HCWs who are otherwise at low risk for TB disease and who received baseline testing at the beginning of employment as part of a TB screening program**

* TST results ≥ 15 mm is positive in anyone. These persons should receive a symptom screen and do not need to be tested again. They should be evaluated for TB disease, and if disease is excluded, they should be offered treatment for latent TB infection (LTBI) if they have no contraindication to treatment.

[†] Human immunodeficiency virus.

[‡] The risk for TB disease in persons treated with corticosteroids increases with higher doses and longer duration of corticosteroid use.

[§] Persons with suspected TB disease can be treated based on the medical and diagnostic evaluation, regardless of the TST results.

** For HCWs who are otherwise at low risk for LTBI and progression to TB disease if infected and who received baseline testing at the beginning of employment as part of a TB infection-control screening program, a TST result of ≥ 15 mm (instead of ≥ 10 mm) is considered to be positive. Although a result of ≥ 10 mm on baseline or follow-up testing is considered a positive result for HCWs for the purposes of referral for medical and diagnostic evaluation, if the TST result is 10–14 mm on baseline or follow-up testing, the referring clinician might not recommend treatment of LTBI. SOURCE: Marsh BJ, SanVicente J, vonReyn E. Utility of dual skin tests to evaluate tuberculin skin test reactions of 10 to 14 mm in health-care workers. *Infect Control Hosp Epidemiol* 2003;24:821–4.

^{††} Acquired immunodeficiency syndrome.

FIGURE 2. An enclosing booth designed to sweep air past a patient with tuberculosis disease and collect the infectious droplet nuclei on a high efficiency particulate air (HEPA) filter

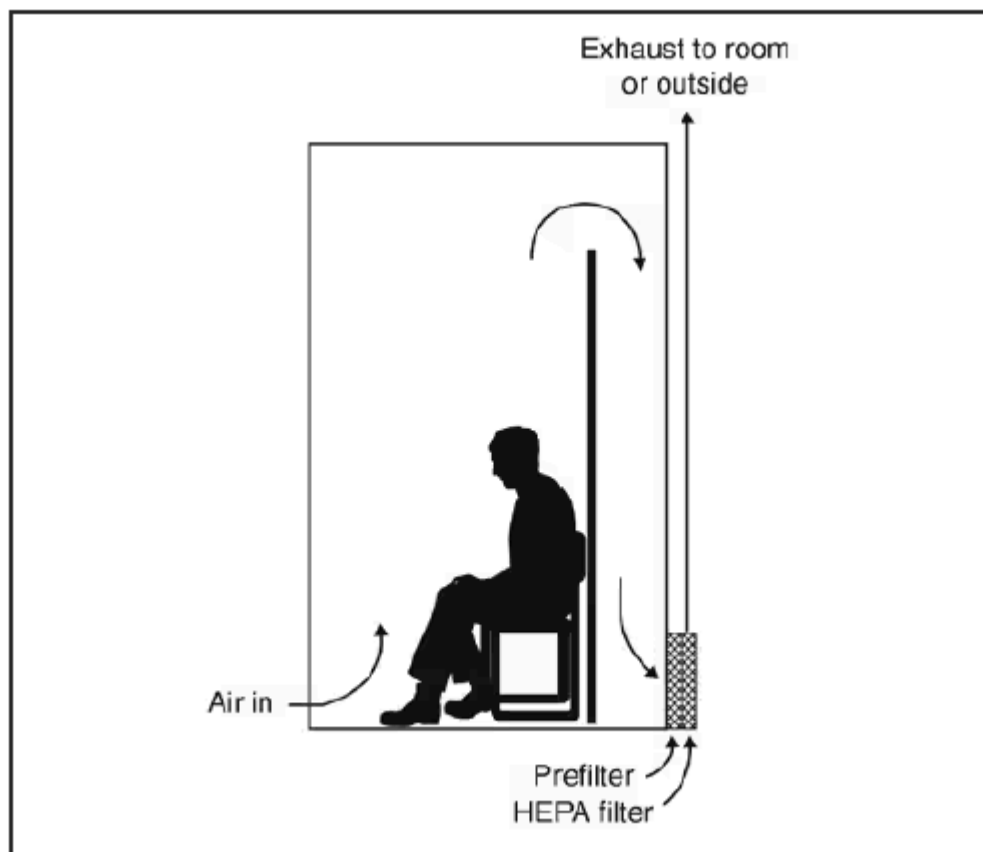
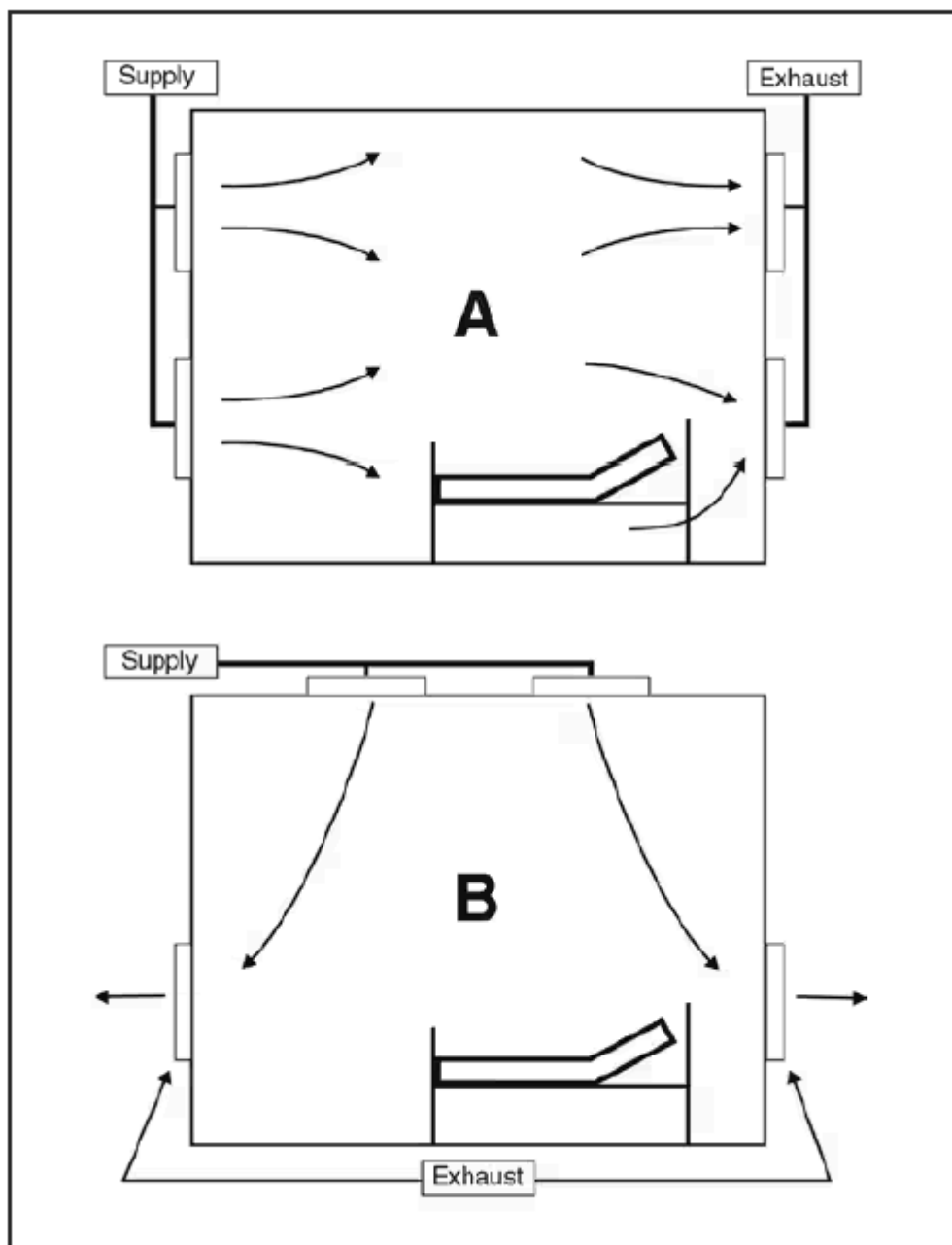
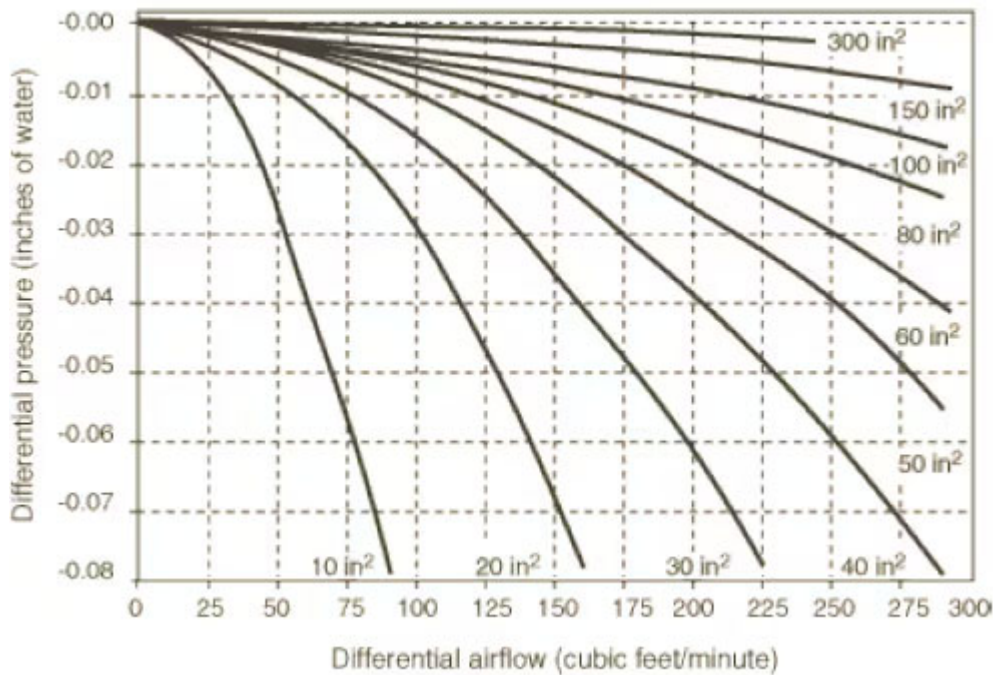


FIGURE 3. Room airflow patterns designed to provide mixing of air and prevent short-circuiting*



* Short-circuiting is the passage of air directly from the air supply to the exhaust.

FIGURE 4. Empirical relation between differential airflow, differential pressure, and leakage areas*



* Black solid lines indicate leakage areas. **SOURCE:** Hayden II CS, Fischbach TJ, Johnston OE, Hughes RT, Jensen PA. A model for calculating leakage areas into negative pressure isolation rooms. Cincinnati, OH: US Department of Health and Human Services, CDC; 1996.

FIGURE 5. Smoke tube testing and manometer placement to determine the direction of airflow into and out of a room

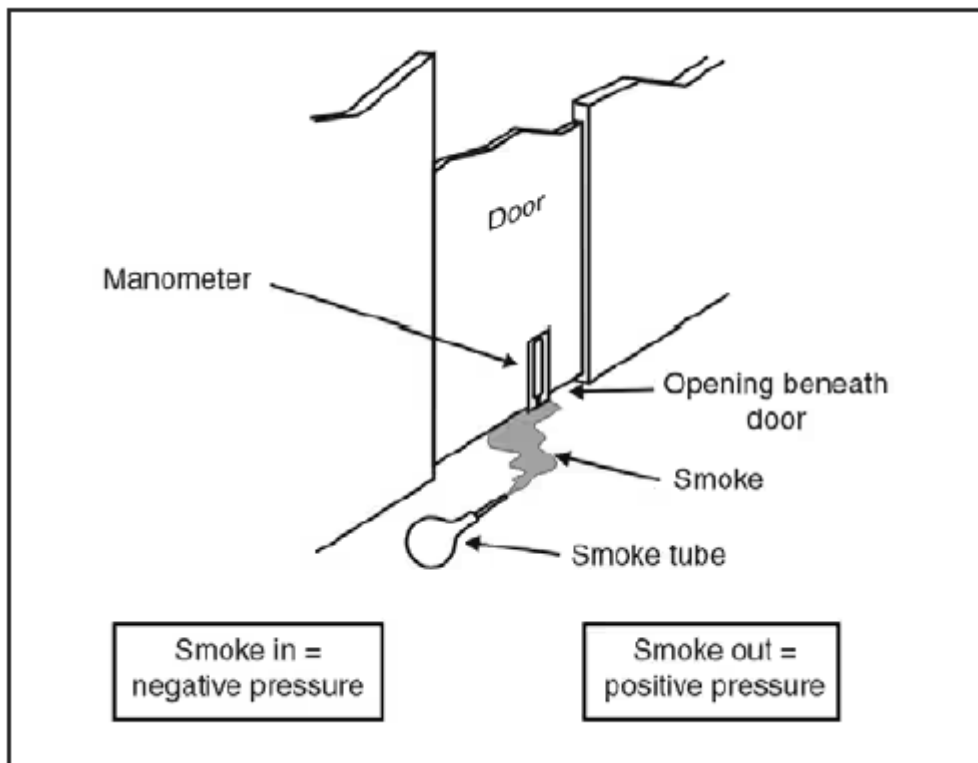
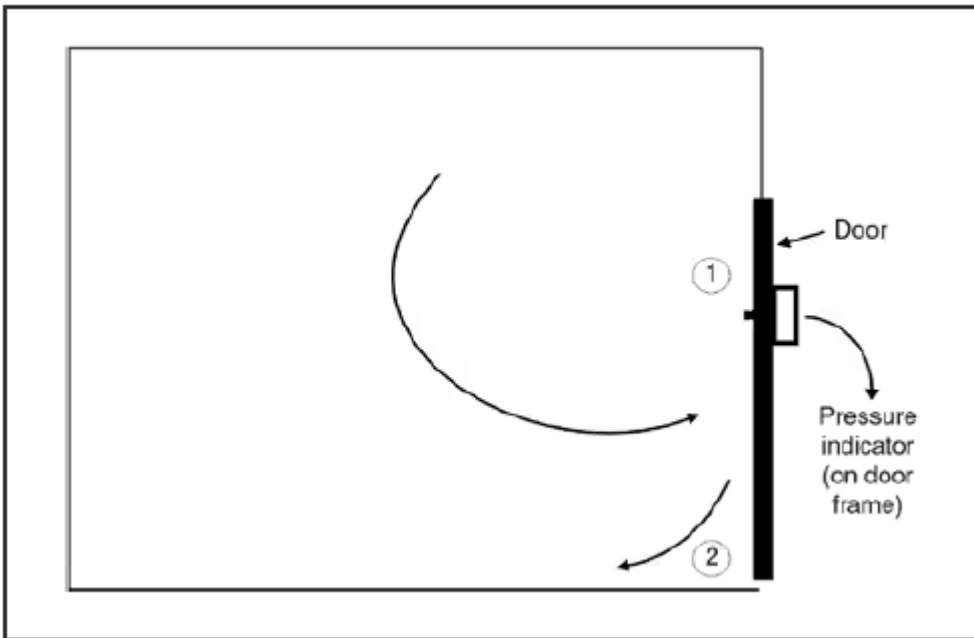


FIGURE 6. Cross-sectional view of a room indicating the location of negative pressure measurement*



* Airflow pressure at location 1 might differ from that at location 2. Measure pressure at location 2 for correct indication of negative pressure.

FIGURE 7. Fixed ducted room-air recirculation system using a high efficiency particulate air (HEPA) filter inside an air duct

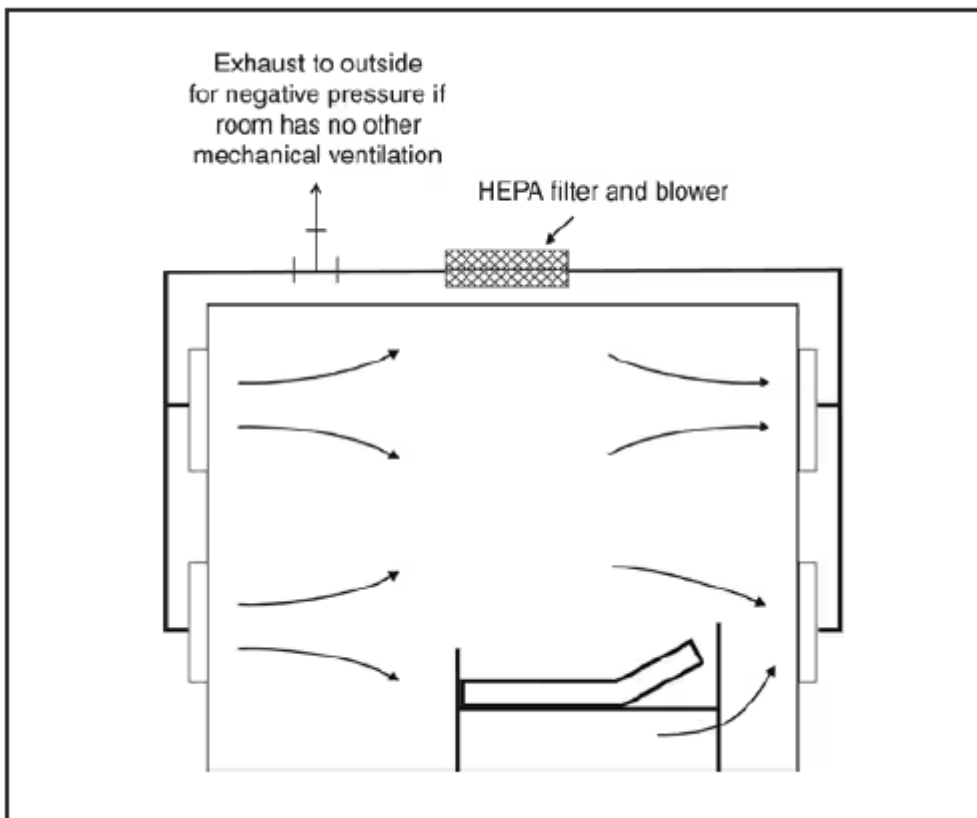
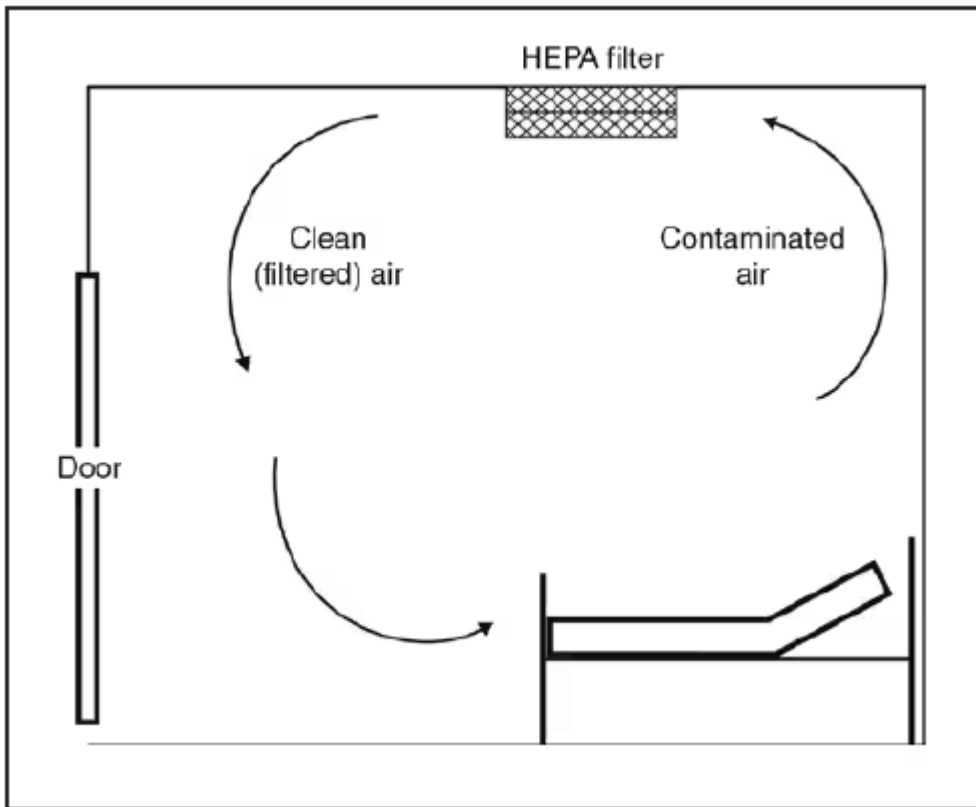


FIGURE 8. Fixed ceiling-mounted room-air recirculation system using a high efficiency particulate air (HEPA) filter



BOX 6. Examples of ultraviolet germicidal irradiation (UVGI) signs

- Wall sign for upper-air UVGI

CAUTION
ULTRAVIOLET ENERGY
SWITCH OFF LAMPS BEFORE
ENTERING UPPER ROOM

- General warning posted near UVGI lamps

CAUTION
ULTRAVIOLET ENERGY
PROTECT EYES AND SKIN

- Warning posted on the door of air handlers where UVGI is present in ductwork

CAUTION
ULTRAVIOLET ENERGY IN DUCT
DO NOT SWITCH OFF SAFETY BUTTON
OR ACTIVATE LAMPS WITH DOOR OPEN

TABLE 4. Nonpowered air-purifying respirator filter classes certified in 42 CFR* 84

Resistance to efficiency filter degradation	Filter efficiencies [†]		
	95 (95%)	99 (99%)	100 (99.97%)
N (Not resistant to oil)	N95	N99	N100
R (Resistant to oil)	R95	R99	R100
P (Oil proof)	P95	P99	P100

* Code of Federal Regulations.

[†] The percentages in parenthesis indicate the minimum allowable laboratory filter efficiency value when challenged with 0.3 μ m particles.

Appendix A. Administrative, environmental, and respiratory-protection controls for selected health-care settings

Setting	Administrative controls [*]	Environmental controls [†]	Respiratory-protection controls [§]
Settings in Which Patients with Suspected or Confirmed Infectious Tuberculosis (TB) Disease are not Expected to be Encountered			
Triage only: Initial evaluation of patients who will transfer to another setting	- Implement a written infection-control plan for triage of patients with suspected or confirmed TB disease. Update annually. - Promptly recognize and transfer patients with suspected or confirmed TB disease to a facility that treats persons with TB disease. - Before transferring the patient out of this setting, hold the patient in an area separate from health-care workers (HCWs) and other persons.	- Settings in which patients with suspected or confirmed TB disease are rarely seen and not treated do not need an airborne infection isolation (AII) room. - Place any patient with suspected or confirmed TB disease in an AII room if available or in a separate room with the door closed, away from others and not in a waiting area. - Air-cleaning technologies (e.g., high efficiency particulate air [HEPA] filtration and ultraviolet germicidal irradiation [UVGI]) can be used to increase the number of equivalent air changes per hour (ACH) (see Supplement, Environmental Controls).	- Settings in which patients with suspected or confirmed TB disease are rarely seen and not treated do not need a respiratory-protection program. - If the patient has signs or symptoms of infectious TB disease (positive acid-fast bacilli [AFB] sputum smear result), consider having the patient wear a surgical or procedure mask (if possible) during transport, in waiting areas, or when others are present.
Inpatient Settings in Which Patients with Suspected or Confirmed Infectious TB Disease are Expected to be Encountered			
	- Perform an annual risk assessment for the setting. - Implement a written infection-control plan for the setting and evaluate and update annually. - Provide TB training, education, and screening for HCWs as part of the infection-control plan. - Establish protocols for problem evaluation. - When possible, postpone nonurgent procedures that might put HCWs at risk for possible exposure to <i>M. tuberculosis</i> until patients are determined to not have TB disease or are noninfectious. - Collaborate with state or local health departments when appropriate.	- In settings with a high volume of patients with suspected or confirmed TB disease, at least one room should meet requirements for an AII room (see Supplement, Environmental Controls). - Air-cleaning technologies (e.g., HEPA filtration and UVGI) can be used to increase the number of equivalent ACH (see Supplement, Environmental Controls).	- For HCWs, visitors,[¶] and others entering the AII room of a patient with suspected or confirmed infectious TB disease, at least N95 disposable respirators should be worn. - If the patient has signs or symptoms of infectious TB disease consider having the patient wear a surgical or procedure mask, if possible, (e.g., if patient is not using a breathing circuit) during transport, in waiting areas, or when others are present.
Patient rooms	- Place patients with suspected or confirmed TB disease in an AII room. - Persons infected with human immunodeficiency virus (HIV) or who have other immunocompromising conditions should especially avoid exposure to persons with TB disease.	- At least one inpatient room should meet requirements for an AII room to be used for patients with suspected or confirmed infectious TB disease (see Supplement, Environmental Controls). - Air-cleaning technologies (e.g., HEPA filtration and UVGI) can be used to increase the number of equivalent ACH (Table 2).	- For HCWs, visitors,[¶] and others entering the AII room of a patient with suspected or confirmed infectious TB disease, at least N95 disposable respirators should be worn. - If the patient has signs or symptoms of infectious TB disease (positive AFB sputum smear result), consider having the patient wear a surgical or procedure mask, if possible, (e.g., if patient is not using a breathing circuit) during transport, in waiting areas, or when others are present.

Appendix A. (Continued) Administrative, environmental, and respiratory-protection controls for selected health-care settings

Setting	Administrative controls [*]	Environmental controls [†]	Respiratory-protection controls [‡]
Inpatient Settings in Which Patients with Suspected or Confirmed Infectious TB Disease are Expected to be Encountered			
Emergency departments (EDs)	- Implement a written infection-control plan for triage of patients with suspected or confirmed TB disease. Update annually. - Patients with signs or symptoms of infectious TB disease should be moved to an All room as soon as possible.	- In settings classified as medium risk or potential ongoing transmission, at least one room should meet requirements for an All room to be used for patients with suspected or confirmed infectious TB disease (see Supplement, Environmental Controls; Table 2). - Air-cleaning technologies (e.g., HEPA filtration and UVGI) can be used to increase the number of equivalent ACH (see Supplement, Environmental Controls).	- For HCWs, visitors,[¶] and others entering the All room of a patient with suspected or confirmed TB disease, at least N95 disposable respirators should be worn. - If the patient has signs or symptoms of infectious TB disease (positive AFB sputum smear result), consider having the patient wear a surgical or procedure mask, if possible. (e.g., if patient is not using a breathing circuit) during transport, in waiting areas, or when others are present.
Intensive care units (ICUs)	Place patients with suspected or confirmed infectious TB disease in an All room, separate from HCWs and other patients, if possible.	- In settings with a high volume of patients with suspected or confirmed TB disease, at least one room should meet requirements for an All room to be used for such patients (see Supplement, Environmental Controls; Table 2). - Bacterial filters should be used routinely in breathing circuits of patients with suspected or confirmed TB disease and should filter particles 0.3 µm in size in unloaded and loaded situations with a filter efficiency of ≥95%.	- For HCWs, visitors,[¶] and others entering the All room of a patient with suspected or confirmed infectious TB disease, at least N95 disposable respirators should be worn. - If the patient has signs or symptoms of infectious TB disease and is suspected of being contagious (positive AFB sputum smear result), consider having the patient wear a surgical or procedure mask, if possible (e.g., if patient is not using a breathing circuit) during transport, in waiting areas, or when others are present.
Surgical suites	Schedule a patient with suspected or confirmed TB disease for surgery when a minimum number of HCWs and other patients are present, and as the last surgical case of the day to maximize the time available for removal of airborne contamination (see Supplement, Environmental Controls; Table 1). For postoperative recovery, place patients in a room that meets requirements for an All room.	- If a surgical suite has an operating room (OR) with an anteroom, that room should be used for TB cases. - If surgery is needed, use a room or suite of rooms that meet requirements for All rooms (see Supplement, Environmental Controls). - If an All or comparable room is not available for surgery or postoperative recovery, air-cleaning technologies (e.g., HEPA filtration and UVGI) can be used to increase the number of equivalent ACH (see Supplement, Environmental Controls). - If the health-care setting has an anteroom, reversible flow rooms (OR or isolation) are not recommended by the American Institute of Architects or American Society of Heating, Refrigerating and Air-conditioning Engineers, Inc. - Bacterial filters should be used routinely in breathing circuits of patients with suspected or confirmed TB disease and should filter particles 0.3 µm in size in an unloaded and loaded situation with a filter efficiency of ≥95%.	- For HCWs present during surgery of a patient with suspected or confirmed infectious TB disease, at least N95 disposable respirators, unvalved, should be worn. - Standard surgical or procedure masks for HCWs might not have fitting or filtering capacity for adequate protection. - If the patient has signs or symptoms of infectious TB disease (positive AFB sputum smear result), consider having the patient wear a surgical or procedure mask, if possible, before and after the procedure. - Valved or positive-pressure respirators should not be used because they do not protect the sterile surgical field.

Appendix A. (Continued) Administrative, environmental, and respiratory-protection controls for selected health-care settings

Setting	Administrative controls [*]	Environmental controls [†]	Respiratory-protection controls [‡]
Inpatient Settings in Which Patients with Suspected or Confirmed Infectious TB Disease are Expected to be Encountered			
Laboratories ^{**}	- Conduct a laboratory-specific risk assessment. - In general, biosafety level (BSL)-2 practices, procedures, containment equipment, and facilities are required for nonaerosol-producing manipulations of clinical specimens. BSL-3 practices, procedures, and containment equipment might be necessary for certain aerosol-generating or aerosol-producing manipulations.	- Environmental controls should meet requirements for clinical microbiology laboratories in accordance with guidelines by Biosafety in Microbiological and Biomedical Laboratories (BMBL) and the AIA. - Perform all manipulation of clinical specimens that could result in aerosolization in a certified class I or II biosafety cabinet (BSC).	For laboratory workers who manipulate clinical specimens (from patients with suspected or confirmed infectious TB disease) outside of a BSC, at least N95 disposable respirators should be worn.
Bronchoscopy suites ^{††}	- Use a dedicated room to perform bronchoscopy procedures. - If a patient with suspected or confirmed infectious TB disease must undergo bronchoscopy, schedule the procedure when a minimum number of HCWs and other patients are present, and schedule the patient at the end of the day. - Do not allow another procedure to be performed in the bronchoscopy suite until sufficient time has elapsed for adequate removal of <i>M. tuberculosis</i>-contaminated air (Table 1).	- Bronchoscopy suites should meet requirements for an AII room to be used for patients with suspected or confirmed infectious TB disease (Table 2). - Air-cleaning technologies (e.g., HEPA filtration and UVGI) can be used to increase the number of equivalent ACH (see Supplement, Environmental Controls). - Closing ventilatory circuitry and minimizing opening of such circuitry of intubated and mechanically ventilated patients might minimize exposure. - Keep patients with suspected or confirmed infectious TB disease in the bronchoscopy suite until coughing subsides.	- For HCWs present during bronchoscopic procedures of a patient with suspected or confirmed infectious TB disease, at least N95 disposable respirators should be worn. Protection greater than an N95 (e.g., a full-facepiece elastomeric respirator or powered air-purifying respirator [PAPR]) should be considered. - If the patient has signs or symptoms of infectious TB disease (positive AFB sputum smear result), consider having the patient wear a surgical or procedure mask, if possible, before and after the procedure.
Sputum induction and inhalation therapy rooms	- Implement a written infection-control plan in the setting. Update annually. - Use a dedicated room to perform sputum induction and inhalation therapy. - Schedule sputum induction and inhalation therapy when a minimum number of HCWs and other patients are present, and schedule the patient at the end of the day. - Do not perform another procedure in a booth or room where sputum induction or inhalation therapy on a patient with suspected or confirmed infectious TB disease was performed until sufficient time has elapsed for adequate removal of <i>M. tuberculosis</i>-contaminated air (Table 1).	- Perform sputum induction and inhalation therapy in booths with special ventilation, if possible. If booths are not available, sputum induction or inhalation therapy rooms should meet requirements for an AII room to be used for patients with suspected or confirmed infectious TB disease (Table 2). - Air-cleaning technologies (e.g., HEPA filtration and UVGI) can be used to increase the number of equivalent ACH (see Supplement, Environmental Controls). - Keep patients with suspected or confirmed infectious TB disease in the sputum induction or inhalation therapy room after sputum collection or inhalation therapy until coughing subsides.	- For HCWs present during sputum induction and inhalation therapy of a patient with suspected or confirmed infectious TB disease, a respirator with a level of protection of at least N95 disposable respirators should be worn. Respiratory protection greater than an N95 (e.g., a full-facepiece elastomeric respirator or PAPR) should be considered (see Supplement, Respiratory Protection). - If the patient has signs or symptoms of infectious TB disease (positive AFB sputum smear result), consider having the patient wear a surgical or procedure mask, if possible, before and after the procedure.

Appendix A. (Continued) Administrative, environmental, and respiratory-protection controls for selected health-care settings

Setting	Administrative controls [*]	Environmental controls [†]	Respiratory-protection controls [‡]
Inpatient Settings in Which Patients with Suspected or Confirmed Infectious TB Disease are Expected to be Encountered			
Autopsy suites	• Ensure proper coordination between attending physician(s) and pathologist(s) for proper infection control and specimen collection during autopsies performed on bodies with suspected or confirmed infectious TB disease. • Allow sufficient time to elapse for adequate removal of <i>M. tuberculosis</i>-contaminated air (Table 1) before performing another procedure.	• Autopsy suites should meet ACH requirements for an All room to be used for bodies with suspected or confirmed TB disease (Table 2). • Air-cleaning technologies (e.g., HEPA filtration and UVGI) can be used to increase the number of equivalent ACH (see Supplement, Environmental Controls). • Consider using local exhaust ventilation to reduce exposures to infectious aerosols and vapors from embalming fluids.	• For those present during autopsy on bodies with suspected or confirmed infectious TB disease, a respirator with a level of protection of at least an N95 should be worn. Protection greater than an N95 (e.g., a full-facepiece elastomeric respirator or PAPR) should be considered (see Supplement, Respiratory Protection), especially if aerosol generation is likely. • If another procedure cannot be delayed until sufficient time has elapsed for adequate removal of <i>M. tuberculosis</i>-contaminated air, staff should continue wearing respiratory protection while in the room (Table 1).
Embalming rooms	• Implement a written infection-control plan in the setting. Update annually.	• Embalming rooms should meet ACH requirements for an All room to be used for bodies with suspected or confirmed TB disease (Table 2). • Air-cleaning technologies (e.g., HEPA filtration and UVGI) can be used to increase the number of equivalent ACH (see Supplement, Environmental Controls).	• For staff present during embalming procedures on bodies with suspected or confirmed infectious TB disease, a respirator with a level of protection of at least N95 should be worn. Protection greater than an N95 (e.g., a full-facepiece elastomeric respirator or PAPR) should be considered (see Supplement, Respiratory Protection), especially if aerosol generation is likely. • If another procedure cannot be delayed until sufficient time has elapsed for adequate removal of <i>M. tuberculosis</i>-contaminated air, staff should continue wearing respiratory protection while in the room.
Outpatient Settings^{§§} in Which Patients with Suspected or Confirmed Infectious TB Disease are Expected to be Encountered			
	• Perform an annual risk assessment for the setting. • Develop and implement a written infection-control plan for the setting and evaluate and update annually. • Provide TB training, education, and screening for HCWs as part of the infection-control plan. • Establish protocols for problem evaluation. • Collaborate with state or local health departments when appropriate.	• Environmental controls should be implemented based on the types of activities that are performed. • Patients with suspected or confirmed infectious TB disease requiring transport should be transported as discussed below under Emergency Medical Services (EMS).	• For HCWs, visitors,[¶] and others entering an All room of a patient with suspected or confirmed infectious TB disease, at least N95 disposable respirators should be worn. • If the patient has signs or symptoms of infectious TB disease (positive AFB sputum smear result), consider having the patient wear a surgical or procedure mask, if possible (e.g., if patient is not using a breathing circuit), during transport, in waiting areas, or when others are present. • If risk assessment indicates that respiratory protection is needed, drivers or HCWs who are transporting patients with suspected or confirmed infectious TB disease in an enclosed vehicle should wear at least an N95 disposable respirator. The risk assessment should consider the potential for shared air.

Appendix A. (Continued) Administrative, environmental, and respiratory-protection controls for selected health-care settings

Setting	Administrative controls [*]	Environmental controls [†]	Respiratory-protection controls [‡]
Outpatient Settings in Which Patients with Suspected or Confirmed Infectious TB Disease are Expected to be Encountered			
TB treatment facilities ^{¶¶}	- Physically separate immunosuppressed patients from those with suspected or confirmed infectious TB. - Schedule appointments to avoid exposing HIV-infected or other severely immunocompromised persons to <i>M. tuberculosis</i>.	- If patients with TB disease are treated in the clinic, at least one room should meet requirements for an All room (Table 2). - Air-cleaning technologies (e.g., HEPA filtration and UVGI) can be used to increase the number of equivalent ACH (see Supplement, Environmental Controls). - Perform all cough-inducing or aerosol-generating procedures by using environmental controls (e.g., booth) or in an All room. - Keep patients in the booth or All room until coughing subsides. - Do not allow another patient to enter the booth or All room until sufficient time has elapsed for adequate removal of <i>M. tuberculosis</i>-contaminated air (see Supplement, Environmental Controls; Table 1).	- For HCWs, visitors,[¶] and others entering the All room of a patient with suspected or confirmed infectious TB disease, at least N95 disposable respirators should be worn. - If the patient has signs or symptoms of infectious TB disease (positive AFB sputum smear result), consider having the patient wear a surgical or procedure mask, if possible, during transport, in waiting areas, or when others are present.
Medical offices and ambulatory-care settings	Implement a written infection-control plan in the setting. Update annually.	In medical offices or ambulatory-care settings where patients with TB disease are treated, at least one room should meet requirements for an All room to be used for patients with suspected or confirmed infectious TB disease (Table 2).	- For HCWs in medical offices or ambulatory care settings with patients with suspected or confirmed infectious TB disease, at least N95 disposable respirators should be worn. - If the patient has signs or symptoms of infectious TB disease (positive AFB sputum smear result), consider having the patient wear a surgical or procedure mask, if possible, during transport, in waiting areas, or when others are present.
Dialysis units	Schedule dialysis for patients with TB disease when a minimum number of HCWs and other patients are present and at the end of the day to maximize the time available for removal of airborne contamination (Table 1).	- Perform dialysis for patients with suspected or confirmed infectious TB disease in a room that meets requirements for an All room (Table 2). - Air-cleaning technologies (e.g., HEPA filtration and UVGI) can be used to increase the number of equivalent ACH (see Supplement, Environmental Controls).	- For HCWs, visitors,[¶] and others entering the All room of a patient with suspected or confirmed infectious TB disease, at least N95 disposable respirators should be worn. - If the patient has signs or symptoms of infectious TB disease (positive AFB sputum smear result), consider having the patient wear a surgical or procedure mask, if possible, during transport, in waiting areas, or when others are present. - If risk assessment indicates the need for respiratory protection, drivers or HCWs who are transporting patients with suspected or confirmed infectious TB disease in an enclosed vehicle should wear at least an N95 disposable respirator. The risk assessment should consider the potential for shared air.

Appendix A. (Continued) Administrative, environmental, and respiratory-protection controls for selected health-care settings

Setting	Administrative controls [*]	Environmental controls [†]	Respiratory-protection controls [‡]
Outpatient Settings in Which Patients with Suspected or Confirmed Infectious TB Disease are Expected to be Encountered			
Dental-care settings	If possible, postpone dental procedures of patients with suspected or confirmed infectious TB disease until the patient is determined not to have TB disease or to be noninfectious.	- Treat patients with suspected or confirmed infectious TB disease in a room that meets requirements for an All room (Table 2). - Air-cleaning technologies (e.g., HEPA filtration and UVGI) can be used to increase the number of equivalent ACH (see Supplement, Environmental Controls).	For dental staff performing procedures on a patient with suspected or confirmed infectious TB disease, at least N95 disposable respirators should be worn.
Nontraditional Facility-Based Settings			
	- Perform an annual risk assessment for the setting. - Develop and implement a written infection-control plan for the setting and evaluate and update annually. - Provide TB training, education, and screening for HCWs as part of the infection-control plan. - Establish protocols for problem evaluation. - Collaborate with state or local health departments when appropriate.	- Environmental controls should be implemented based on the types of activities that are performed (see Supplement, Environmental Controls). - Patients with suspected or confirmed infectious TB disease requiring transport should be transported as discussed in the EMS section.	- For HCWs, visitors,[§] and others entering the All room of a patient with suspected or confirmed infectious TB disease, at least N95 disposable respirators should be worn. - If the patient has signs or symptoms of infectious TB disease (positive AFB sputum smear result), consider having the patient wear a surgical or procedure mask, if possible (e.g., if patient is not using a breathing circuit), during transport, in waiting areas, or when others are present.
EMS	Include exposed emergency medical HCWs in the contact investigation of patients with TB disease if administrative, environmental, and respiratory-protection controls for TB infection control were not followed.	- Patients with suspected or confirmed infectious TB disease requiring transport should be transported in an ambulance whenever possible. The ambulance ventilation system should be operated in the non-recirculating mode, and the maximum amount of outdoor air should be provided to facilitate dilution. If the vehicle has a rear exhaust fan, use this fan during transport. Airflow should be from the cab (front of vehicle), over the patient, and out the rear exhaust fan. - If an ambulance is not used, the ventilation system for the vehicle should bring in as much outdoor air as possible, and the system should be set to non-recirculating. If possible, physically isolate the cab from the rest of the vehicle and have the patient sit in the back.	- If risk assessment indicates the need for respiratory protection, drivers or HCWs who are transporting patients with suspected or confirmed infectious TB disease in an enclosed vehicle should wear at least an N95 disposable respirator. The risk assessment should consider the potential for shared air. - If the patient has signs or symptoms of infectious TB disease (positive AFB sputum smear result), consider having the patient wear a surgical or procedure mask, if possible, during transport, in waiting areas, or when others are present.

Appendix A. (Continued) Administrative, environmental, and respiratory-protection controls for selected health-care settings

Setting	Administrative controls*	Environmental controls†	Respiratory-protection controls‡
Nontraditional Facility-Based Settings			
Medical settings in correctional facilities	- Follow recommendations for inpatient and outpatient settings as appropriate. In waiting rooms or areas, follow recommendations for TB treatment facilities. - If possible, postpone transporting patients with suspected or confirmed infectious TB disease until they are determined not to have TB disease or to be noninfectious.	- At least one room should meet requirements for an AII room (Table 2). - Air-cleaning technologies (e.g., HEPA filtration and UVGI) can be used to increase the number of equivalent ACH (see Supplement, Environmental Controls). - When transporting patients with suspected or confirmed infectious TB disease in a vehicle (ideally an ambulance), if possible, physically isolate the cab (the front seat) from rest of the vehicle, have the patient sit in the back seat, and open the windows.	- For HCWs or others entering the AII room of a patient with suspected or confirmed infectious TB disease, at least N95 disposable respirators should be worn. - If the patient has signs or symptoms of infectious TB disease (positive AFB sputum smear result), consider having the patient wear a surgical or procedure mask, if possible, during transport, in waiting areas, or when others are present.
Home-based health-care and outreach settings	- Patients and household members should be educated regarding the importance of taking medications, respiratory hygiene and cough etiquette procedures, and proper medical evaluation. - If possible, postpone transporting patients with suspected or confirmed infectious TB disease until they are determined not to have TB disease or to be noninfectious. - Certain patients can be instructed to remain at home until they are determined not to have TB disease or to be noninfectious.	Do not perform cough-inducing or aerosol-generating procedures unless appropriate environmental controls are in place (see Supplement, Environmental Controls), or perform those procedures outside, if possible.	- For HCWs entering the homes of patients with suspected or confirmed infectious TB disease, at least N95 disposable respirators should be worn. - For HCWs transporting patients with suspected or confirmed infectious TB disease in a vehicle, consider at least an N95 disposable respirator. - If the patient has signs or symptoms of infectious TB disease (positive AFB sputum smear result), consider having the patient wear a surgical or procedure mask, if possible, during transport, in waiting areas, or when others are present.
Long-term-care settings (e.g., hospices and skilled nursing facilities)	Patients with suspected or confirmed infectious TB disease should not be treated in a long-term-care setting, unless proper administrative and environmental controls and a respiratory-protection program are in place.	Do not perform cough-inducing or aerosol-generating procedures unless appropriate infection controls are in place (see Supplement, Environmental Controls), or perform those procedures outside, if possible.	If the patient has signs or symptoms of infectious TB disease (positive AFB sputum smear result), consider having the patient wear a surgical or procedure mask, if possible, during transport, in waiting areas, or when others are present.

* Administrative controls must be implemented to ensure the effectiveness of environmental controls and respiratory-protection programs, and should be in place for all settings where patients with suspected or confirmed TB disease are expected to be encountered. Administrative controls include a written TB infection-control plan (which should be reassessed at least annually), assignment of responsibility for the plan, setting risk assessment, HCW risk classification, HCW training and education, and a TB screening program to test HCWs for infection with *M. tuberculosis*.

† Environmental controls include local exhaust and general ventilation (i.e., achieving negative pressure), using AII rooms, and air-cleaning methods (i.e., HEPA filtration and UVGI).

‡ All settings where patients with suspected or confirmed TB disease will be encountered need to have a respiratory-protection program. A respiratory-protection program might not be necessary for settings where patients with TB disease are not encountered or where a procedure exists for the prompt transfer of patients with suspected or confirmed TB disease to a setting where they can be evaluated.

§ Visitors with suspected or confirmed TB disease should not have contact with patients, including contact with those who have suspected or confirmed TB disease.

** Laboratories that are not based in inpatient settings should observe the same TB infection-control measures as laboratories in inpatient settings.

†† Certain bronchoscopy suites are built to have positive pressure.

§§ Although the majority of these settings are routinely considered "outpatient," they might be part of inpatient services in certain settings. If so, follow the recommendations for inpatient settings for patient rooms.

¶¶ TB treatment facilities can include TB clinics, infectious disease clinics, or pulmonary clinics.

Appendix B. Tuberculosis (TB) risk assessment worksheet

This model worksheet should be considered for use in performing TB risk assessments for health-care settings and nontraditional facility-based settings. Facilities with more than one type of setting will need to apply this table to each setting.

Scoring: ✓ or Y = Yes X or N = No NA = Not Applicable

1. Incidence of TB

- a. What is the incidence of TB in your community (county or region served by the health-care setting), and how does it compare with the state and national average?
- b. What is the incidence of TB in your facility and specific settings, and how do those rates compare? (Incidence is the number of TB cases in your community during the previous year. A rate of TB cases per 100,000 persons should be obtained for comparison.)^{*} This information can be obtained from the state or local health department.

Rate

Community _____
 State _____
 National _____
 Facility _____
 Department 1 _____
 Department 2 _____
 Department 3 _____

- c. Are patients with suspected or confirmed TB disease encountered in your setting (inpatient and outpatient)?

- 1) If yes, how many are treated in your health-care setting in 1 year? (Review laboratory data, infection-control records, and databases containing discharge diagnoses for this information.)

No. patients

Year	No. patients	
	Suspected	Confirmed
1 year ago	_____	_____
2 years ago	_____	_____
5 years ago	_____	_____

- 2) If no, does your health-care setting have a plan for the triage of patients with suspected or confirmed TB disease?

- d. Currently, does your health-care setting have a cluster of persons with confirmed TB disease that might be a result of ongoing transmission of *Mycobacterium tuberculosis*?

2. Risk Classification

a. Inpatient settings

- 1) How many inpatient beds are in your inpatient setting?
- 2) How many patients with TB disease are encountered in the inpatient setting in 1 year? (Review laboratory data, infection-control records, and databases containing discharge diagnoses.)
- 3) Depending on the number of beds and TB patients encountered in 1 year, what is the risk classification for your inpatient setting?

Quantity _____

Previous year _____

5 years ago _____

___ Low risk
 ___ Medium risk
 ___ Potential ongoing transmission

- 4) Does your health-care setting have a plan for triaging patients with suspected or confirmed TB disease?

b. Outpatient settings

- 1) How many TB patients are evaluated at your outpatient setting in 1 year? (Review laboratory data, infection-control records, and databases containing discharge diagnoses for this information.)

Previous year _____

5 years ago _____

- 2) Is your health-care setting a TB clinic? (If yes, a classification of at least medium risk is recommended.)

- 3) Does evidence exist that a high incidence of TB disease has been observed in the community that the health-care setting serves?

- 4) Does evidence exist of person-to-person transmission of *M. tuberculosis* in the health-care setting? (Use information from case reports. Determine if any TST or blood assay for *M. tuberculosis* [BAMT] conversions have occurred among health-care workers [HCWs].)

- 5) Does evidence exist that ongoing or unresolved health-care-associated transmission has occurred in the health-care setting (based on case reports)?

- 6) Does a high incidence of immunocompromised patients or HCWs in the health-care setting exist?

- 7) Have patients with drug-resistant TB disease been encountered in your health-care setting within the previous 5 years?

Year encountered _____

- 8) When was the first time a risk classification was done for your health-care setting?

Date of classification _____

- 9) Considering the items above, would your health-care setting need a higher risk classification?

Appendix B. (Continued) Tuberculosis (TB) risk assessment worksheet

_____ 10) Depending on the number of TB patients evaluated in 1 year, what is the risk classification for your outpatient setting (Appendix C)?

_____ 11) Does your health-care setting have a plan for the triage of patients with suspected or confirmed TB disease?

c. Nontraditional facility-based settings

_____ 1) How many TB patients are encountered at your setting in 1 year?

_____ 2) Does evidence exist that a high incidence of TB disease has been observed in the community that the setting serves?

_____ 3) Does evidence exist of person-to-person transmission of *M. tuberculosis* in the setting?

_____ 4) Have any recent TST or BAMT conversions occurred among staff or clients?

_____ 5) Is there a high incidence of immunocompromised patients or HCWs in the setting?

_____ 6) Have patients with drug-resistant TB disease been encountered in your health-care setting within the previous 5 years?

_____ 7) When was the first time a risk classification was done for your setting?

_____ 8) Considering the items above, would your setting require a higher risk classification?

_____ 9) Does your setting have a plan for the triage of patients with suspected or confirmed TB disease?

_____ 10) Depending on the number of patients with TB disease who are encountered in a nontraditional setting in 1 year, what is the risk classification for your setting (Appendix C)?

3. Screening of HCWs for *M. tuberculosis* infection

_____ a. Does the health-care setting have a TB screening program for HCWs?

If yes, which HCWs are included in the TB screening program? (check all that apply)

_____ Physicians	_____ Service workers
_____ Mid-level practitioners (nurse practitioners [NP] and physician's assistants [PA])	_____ Janitorial staff
_____ Nurses	_____ Maintenance or engineering staff
_____ Administrators	_____ Transportation staff
_____ Laboratory workers	_____ Dietary staff
_____ Respiratory therapists	_____ Receptionists
_____ Physical therapists	_____ Trainees and students
_____ Contract staff	_____ Volunteers
_____ Construction or renovation workers	_____ Others _____

_____ b. Is baseline skin testing performed with two-step TST for HCWs?

_____ c. Is baseline testing performed with QuantiFERON®-TB or other BAMT for HCWs?

_____ d. How frequently are HCWs tested for *M. tuberculosis* infection?

_____ e. Are *M. tuberculosis* infection test records maintained for HCWs?

_____ f. Where are test records for HCWs maintained?

_____ g. Who maintains the records?

_____ h. If the setting has a serial TB screening program for HCWs to test for *M. tuberculosis* infection, what are the conversion rates for the previous years?†

_____ i. Has the test conversion rate for *M. tuberculosis* infection been increasing or decreasing, or has it remained the same over the previous 5 years? (check one)

_____ Low risk
_____ Medium risk
_____ Potential ongoing transmission

Previous year _____
5 years ago _____

Year encountered _____

Date of classification _____

_____ Low risk
_____ Medium risk
_____ Potential ongoing transmission

Frequency _____

Location _____

Name _____

1 year ago _____
2 years ago _____
3 years ago _____
4 years ago _____
5 years ago _____

_____ Increasing
_____ Decreasing
_____ No change in previous 5 years

Appendix B. (Continued) Tuberculosis (TB) risk assessment worksheet

_____ j. Do any areas of the health-care setting (e.g., waiting rooms or clinics) or any group of HCWs (e.g., laboratory workers, emergency department staff, respiratory therapists, and HCWs who attend bronchoscopies) have a test conversion rate for *M. tuberculosis* infection that exceeds the health-care setting's annual average? Rate _____
If yes, list. _____

_____ k. For HCWs who have positive test results for *M. tuberculosis* infection and who leave employment at the health setting, are efforts made to communicate test results and recommend follow-up of latent TB infection treatment with the local health department or their primary physician? _____ Not applicable

4. TB Infection-Control Program

_____ a. Does the health-care setting have a written TB infection-control plan? Name _____

_____ b. Who is responsible for the infection-control program? Date _____

_____ c. When was the TB infection-control plan first written? Date _____

_____ d. When was the TB infection-control plan last reviewed or updated?

_____ e. Does the written infection-control plan need to be updated based on the timing of the previous update (i.e., >1 year, changing TB epidemiology of the community or setting, the occurrence of a TB outbreak, change in state or local TB policy, or other factors related to a change in risk for transmission of *M. tuberculosis*)?

_____ f. Does the health-care setting have an infection-control committee (or another committee with infection-control responsibilities)?

1) If yes, which groups are represented on the infection-control committee? (check all that apply)

_____ Physicians	_____ Health and safety staff
_____ Nurses	_____ Administrator
_____ Epidemiologists	_____ Risk assessment
_____ Engineers	_____ Quality control
_____ Pharmacists	_____ Others (specify)
_____ Laboratory personnel	

2) If no, what committee is responsible for infection control in the setting? Committee _____

5. Implementation of TB Infection-Control Plan Based on Review by Infection-Control Committee

_____ a. Has a person been designated to be responsible for implementing an infection-control plan in your health-care setting? If yes, list the name. Name _____

_____ b. Based on a review of the medical records, what is the average number of days for the following:

- _____ Presentation of patient until collection of specimen.
- _____ Specimen collection until receipt by laboratory.
- _____ Receipt of specimen by laboratory until smear results are provided to health-care provider.
- _____ Diagnosis until initiation of standard antituberculosis treatment.
- _____ Receipt of specimen by laboratory until culture results are provided to health-care provider.
- _____ Receipt of specimen by laboratory until drug-susceptibility results are provided to health-care provider.
- _____ Receipt of drug-susceptibility results until adjustment of antituberculosis treatment, if indicated.
- _____ Admission of patient to hospital until placement in airborne infection isolation (AII).

_____ c. Through what means (e.g., review of TST or BAMT conversion rates, patient medical records, and time analysis) are lapses in infection control recognized? Means _____

_____ d. What mechanisms are in place to correct lapses in infection control? Mechanisms _____

_____ e. Based on measurement in routine QC exercises, is the infection-control plan being properly implemented?

_____ f. Is ongoing training and education regarding TB infection-control practices provided for HCWs?

Appendix B. (Continued) Tuberculosis (TB) risk assessment worksheet

6. Laboratory Processing of TB-Related Specimens, Tests, and Results Based on Laboratory Review

- a. Which of the following tests are either conducted in-house at your health-care setting's laboratory or sent out to a reference laboratory? (check all that apply)

In-house **Sent out**

- _____ Acid-fast bacilli (AFB) smears
 _____ Culture using liquid media (e.g., Bactec and MB-BacT)
 _____ Culture using solid media
 _____ Drug-susceptibility testing
 _____ Nucleic acid amplification testing

- b. What is the usual transport time for specimens to reach the laboratory for the following tests?

AFB smears _____
 Culture using liquid media (e.g., Bactec, MB-BacT) _____
 Culture using solid media _____
 Drug-susceptibility testing _____
 Nucleic acid amplification testing _____
 Other (specify) _____

- c. Does the laboratory at your health-care setting or the reference laboratory used by your health-care setting report AFB smear results for all patients within 24 hours of receipt of specimen? What is the procedure for weekends?

7. Environmental Controls

- a. Which environmental controls are in place in your health-care setting? (check all that apply and describe)

<u>Environmental control</u>	<u>Description</u>
_____ All rooms	_____
_____ Local exhaust ventilation (enclosing devices and exterior devices)	_____
_____ General ventilation (e.g., single-pass system, recirculation system)	_____
_____ Air-cleaning methods (e.g., high efficiency particulate air [HEPA] filtration and ultraviolet germicidal irradiation [UVGI])	_____

- b. What are the actual air changes per hour (ACH) and design for various rooms in the setting?

<u>Room</u>	<u>ACH</u>	<u>Design</u>
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

- c. Which of the following local exterior or enclosing devices such as exhaust ventilation devices are used in your health-care setting? (check all that apply)

- _____ Laboratory hoods
 _____ Booths for sputum induction
 _____ Tents or hoods for enclosing patient or procedure

- d. What general ventilation systems are used in your health-care setting? (check all that apply)

- _____ Single-pass system
 _____ Variable air volume
 _____ Constant air volume
 _____ Recirculation system
 _____ Other _____

- e. What air-cleaning methods are used in your health-care setting? (check all that apply)

<u>HEPA filtration</u>	<u>UVGI</u>
_____ Fixed room-air recirculation systems	_____ Duct irradiation
_____ Portable room-air recirculation systems	_____ Upper-air irradiation
	_____ Portable room-air cleaners

Appendix B. (Continued) Tuberculosis (TB) risk assessment worksheet

f. How many All rooms are in the health-care setting? _____

Quantity _____

g. What ventilation methods are used for All rooms? (check all that apply)

Primary (general ventilation):

___ Single-pass heating, ventilating, and air conditioning (HVAC)

___ Recirculating HVAC systems

Secondary (methods to increase equivalent ACH):

___ Fixed room recirculating units

___ HEPA filtration

___ UVGI

___ Other (specify) _____

h. Does your health-care setting employ, have access to, or collaborate with an environmental engineer (e.g., professional engineer) or other professional with appropriate expertise (e.g., certified industrial hygienist) for consultation on design specifications, installation, maintenance, and evaluation of environmental controls?

i. Are environmental controls regularly checked and maintained with results recorded in maintenance logs?

j. Is the directional airflow in All rooms checked daily when in use with smoke tubes or visual checks?

k. Are these results readily available?

l. What procedures are in place if the All room pressure is not negative?

m. Do All rooms meet the recommended pressure differential of 0.01-inch water column negative to surrounding structures?

8. Respiratory-Protection Program

a. Does your health-care setting have a written respiratory-protection program?

b. Which HCWs are included in the respiratory-protection program? (check all that apply)

___ Physicians

___ Mid-level practitioners (NPs and PAs)

___ Nurses

___ Administrators

___ Laboratory personnel

___ Contract staff

___ Construction or renovation staff

___ Service personnel

___ Janitorial staff

___ Maintenance or engineering staff

___ Transportation staff

___ Dietary staff

___ Students

___ Others (specify) _____

c. Are respirators used in this setting for HCWs working with TB patients? If yes, include manufacturer, model, and specific application (e.g., ABC model 1234 for bronchoscopy and DEF model 5678 for routine contact with infectious TB patients).

Manufacturer

Model

Specific application

d. Is annual respiratory-protection training for HCWs performed by a person with advanced training in respiratory protection?

e. Does your health-care setting provide initial fit testing for HCWs? If yes, when is it conducted?

Date _____

f. Does your health-care setting provide periodic fit testing for HCWs? If yes, when and how frequently is it conducted?

Date _____

Frequency _____

g. What method of fit testing is used?

Method _____

h. Is qualitative fit testing used?

i. Is quantitative fit testing used?

Appendix B. (Continued) Tuberculosis (TB) risk assessment worksheet

9. Reassessment of TB Risk

a. How frequently is the TB risk assessment conducted or updated in the health-care setting?

Frequency _____

b. When was the last TB risk assessment conducted?

Date _____

c. What problems were identified during the previous TB risk assessment?

- 1) _____
- 2) _____
- 3) _____
- 4) _____
- 5) _____

d. What actions were taken to address the problems identified during the previous TB risk assessment?

- 1) _____
- 2) _____
- 3) _____
- 4) _____
- 5) _____

e. Did the risk classification need to be revised as a result of the last TB risk assessment?

* If the population served by the health-care facility is not representative of the community in which the facility is located, an alternate comparison population might be appropriate.

† Test conversion rate is calculated by dividing the number of conversions among HCWs by the number of HCWs who were tested and had previous negative results during a certain period (see Supplement, Surveillance and Detection of *M. tuberculosis* Infections in Health-Care Settings).

Appendix C. Risk classifications for various health-care settings and recommended frequency of screening for *Mycobacterium tuberculosis* infection among health-care workers (HCWs)*

Risk classification[†]

Setting	Low risk	Medium risk	Potential ongoing transmission [§]
Inpatient <200 beds	<3 TB patients/year	≥3 TB patients/year	Evidence of ongoing <i>M. tuberculosis</i> transmission, regardless of setting
Inpatient ≥200 beds	<6 TB patients/year	≥6 TB patients/year	
Outpatient; and nontraditional facility-based	<3 TB patients/year	≥3 TB patients/year	
TB treatment facilities	Settings in which • persons who will be treated have been demonstrated to have latent TB infection (LTBI) and not TB disease • a system is in place to promptly detect and triage persons who have signs or symptoms of TB disease to a setting in which persons with TB disease are treated • no cough-inducing or aerosol-generating procedures are performed	Settings in which • persons with TB disease are encountered • criteria for low risk are not otherwise met	
Laboratories	Laboratories in which clinical specimens that might contain <i>M. tuberculosis</i> are not manipulated	Laboratories in which clinical specimens that might contain <i>M. tuberculosis</i> might be manipulated	

Recommendations for Screening Frequency

Baseline two-step TST or one BAMT [¶]	Yes, for all HCWs upon hire	Yes, for all HCWs upon hire	Yes, for all HCWs upon hire
Serial TST or BAMT screening of HCWs	No ^{**}	At least every 12 months ^{††}	As needed in the investigation of potential ongoing transmission ^{§§}
TST or BAMT for HCWs upon unprotected exposure to <i>M. tuberculosis</i>	Perform a contact investigation (i.e., administer one TST or BAMT as soon as possible at the time of exposure, and, if the result is negative, give a second test [TST or BAMT, whichever was used for the first test] 8–10 weeks after the end of exposure to <i>M. tuberculosis</i>) ^{¶¶}		

* The term Health-care workers (HCWs) refers to all paid and unpaid persons working in health-care settings who have the potential for exposure to *M. tuberculosis* through air space shared with persons with TB disease.

† Settings that serve communities with a high incidence of TB disease or that treat populations at high risk (e.g., those with human immunodeficiency virus infection or other immunocompromising conditions) or that treat patients with drug-resistant TB disease might need to be classified as medium risk, even if they meet the low-risk criteria.

§ A classification of potential ongoing transmission should be applied to a specific group of HCWs or to a specific area of the health-care setting in which evidence of ongoing transmission is apparent, if such a group or area can be identified. Otherwise, a classification of potential ongoing transmission should be applied to the entire setting. This classification should be temporary and warrants immediate investigation and corrective steps after a determination has been made that ongoing transmission has ceased. The setting should be reclassified as medium risk, and the recommended timeframe for this medium risk classification is at least 1 year.

¶ All HCWs upon hire should have a documented baseline two-step tuberculin skin test (TST) or one blood assay for *M. tuberculosis* (BAMT) result at each new health-care setting, even if the setting is determined to be low risk. In certain settings, a choice might be made to not perform baseline TB screening or serial TB screening for HCWs who 1) will never be in contact with or have shared air space with patients who have TB disease (e.g., telephone operators who work in a separate building from patients) or 2) will never be in contact with clinical specimens that might contain *M. tuberculosis*. Establishment of a reliable baseline result can be beneficial if subsequent screening is needed after an unexpected exposure to *M. tuberculosis*.

** HCWs in settings classified as low risk do not need to be included in the serial TB screening program.

†† The frequency of screening for infection with *M. tuberculosis* will be determined by the risk assessment for the setting and determined by the Infection Control team.

§§ During an investigation of potential ongoing transmission of *M. tuberculosis*, testing for *M. tuberculosis* infection should be performed every 8–10 weeks until a determination has been made that ongoing transmission has ceased. Then the setting should be reclassified as medium risk for at least 1 year.

¶¶ Procedures for contact investigations should not be confused with two-step TSTs, which are used for baseline TST results for newly hired HCWs.

Appendix D. Environmental controls record and evaluation*

Type of environmental control [†]	No. [§]	Location in the health-care setting [‡]	How often maintained ^{**}	How often evaluated ^{**}	Last evaluation date	Next evaluation due date

* Some settings will not be able to complete all parts of the table. List environmental controls in order of effectiveness.

† For example, ultraviolet germicidal irradiation (UVGI), high-efficiency particulate air (HEPA) filters, or airborne infection isolation (AII) room.

§ Number of UVGI units, HEPA filters, and AII rooms in each location of the health-care setting.

‡ For example, inpatient rooms, emergency departments, bronchoscopy suites, sputum induction rooms, outpatient areas, and waiting areas.

** Daily, weekly, monthly, annually, or other frequency (describe).

Appendix E. Tuberculosis (TB) Internet addresses

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CDC Websites

CDC	http://www.cdc.gov
Division of Tuberculosis Elimination (DTBE)	http://www.cdc.gov/tb
Major TB Guidelines	http://www.cdc.gov/nchstp/tb/pubs/mmwrhtml/maj_guide.htm
State TB Program Contact Information	http://www.cdc.gov/nchstp/tb/pubs/tboffices.htm
TB Education and Training Resources	http://www.findtbresources.org
TB Program	http://www.cdc.gov/nchstp/tb/tbwebsites.htm
Division of AIDS, STD, and TB Laboratory Research	http://www.cdc.gov/ncidod/dastlr/TB/default.htm
National Center for Infectious Diseases (NCID)	http://www.cdc.gov/ncid
National Institute for Occupational Safety and Health (NIOSH)	http://www.cdc.gov/niosh/homepage.html
Respirator Information	http://www.cdc.gov/niosh/nppt/topics/respirators
CDC/NIOSH Certified Equipment List (CEL)	http://www.cdc.gov/niosh/nppt/topics/respirators/cel
CDC/NIOSH-Approved Disposable Particulate Respirators (Filtering Facepieces)	http://www.cdc.gov/niosh/nppt/respirators/disp_part/particlist.html
Division of Healthcare Quality Promotion	http://www.cdc.gov/ncidod/hip/enviro/guide.htm
Emergency Preparedness and Response	http://www.bt.cdc.gov

Other U.S. Federal Government Agencies

National Institutes of Health (NIH)	http://www.nih.gov
National Heart, Lung, and Blood Institute	http://www.nhlbi.nih.gov/funding/training/tbaa/index.htm
National Institute of Allergy and Infectious Diseases (NIAID)	http://www.niaid.nih.gov/dmid/tuberculosis
AIDSinfo	http://www.aidsinfo.nih.gov/guidelines
Occupational Safety and Health Administration (OSHA)	http://www.osha.gov ; www.osha.gov/qna.pdf
Tuberculosis (OSHA)	http://www.osha.gov/SLTC/tuberculosis/index.html
Recordkeeping (OSHA)	http://www.osha.gov/SLTC/respiratoryprotection/index.html
Respiratory Protection (OSHA)	http://www.osha.gov/recordkeeping
Ryan White Care Act/Wisconsin HIV/AIDS Program	http://www.dhfs.state.wi.us/AIDS-HIV/Resources/Overviews/AIDS_HIV.htm
Food and Drug Administration (FDA)	http://www.fda.gov
Safety Information and Adverse Event Reporting System (FDA-AERS)	http://www.fda.gov/medwatch
FDA and CDC Public Health Advisory: Infections from Endoscopes Inadequately Reprocessed by an Automated Endoscope Reprocessing System	http://www.fda.gov/cdrh/safety/endoreprocess.html

Regional Training and Medical Consultation Centers

Francis J. Curry National Tuberculosis Center, San Francisco, California	http://www.nationaltbcenter.edu
Heartland Regional Training Center, San Antonio, Texas	http://www.dshs.state.tx.us/tcid/educationctr.shtml
New Jersey Medical School National Tuberculosis Center Newark, New Jersey	http://www.umdnj.edu/ntbweb
Southeast Regional Training Center, Gainesville, Florida	http://snlc.medicine.ufl.edu/index.htm

Domestic Organizations

American Lung Association (ALA)	http://www.lungusa.org/diseases/lungtb.html
American Thoracic Society (ATS)	http://www.thoracic.org
Association for Professionals in Infection Control and Epidemiology, Inc. (APIC)	http://www.apic.org
HIV Drug Interactions Organization	http://www.hiv-druginteractions.org
Infectious Disease Society of America/Bioterrorism and Information Resources (IDSA)	http://www.idsociety.org/tb/toc.htm
National Prevention Information Network (NPIN)	http://www.cdcnpin.org/scripts/index.asp
National Tuberculosis Controllers Association (NTCA)	http://www.ntca-tb.org
PharmWeb: Rapid Screening of Tuberculosis Pharmaceuticals	http://www.pharmweb.net/pwmirror/library/pharmwebvlib.html

International Organizations

International Union Against Tuberculosis and Lung Disease (IUATLD)	http://www.iuatld.org/full_picture/en/frameset/frameset.phtml
Stop TB Initiative	http://www.stoptb.org
Tuberculosis Research Center, India	http://www.trc-chennai.org
World Health Organization (WHO) Global TB Program	http://www.who.int/tb

Appendix E. (Continued) Tuberculosis (TB) Internet addresses

State/Area TB and HIV Websites

Alabama	http://www.adph.org
Arizona	http://www.hs.state.az.us/phs/oids/tuberculosis/index.htm
Arkansas	http://www.epi.alaska.gov
California	http://www.dhs.ca.gov/ps/dcdc/TBCB/tubindex.htm
Colorado	http://www.cdphe.state.co.us/dc/tb/tbhome.asp
Connecticut	http://www.dph.state.ct.us
Delaware	http://www.state.de.us/dhss/dph/dpc/tuberculosis.html
Florida	http://www.doh.state.fl.us/disease_ctrl/tb/WorldTBDay/2004/WT2004main.html
Georgia	http://www.health.state.ga.us/epi
Hawaii	http://www.hawaii.gov/doh/resource/comm_dis/tb/index.htm
Indiana	http://www.in.gov/isdh/programs/tb
Iowa	http://www.idph.state.ia.us/ch/tb_control.asp
Kansas	http://www.kdhe.state.ks.us/tb/index.html
Kentucky	http://www.chs.state.ky.us/publichealth/TB.htm
Louisiana	http://www.opd.dhh.state.la.us/tuberculosis/index.html
Maine	http://www.maine.gov/dhs/boh/ddc/tuberculosis.htm
Maryland	http://www.edcp.org/tb/index.html
Massachusetts	http://www.state.ma.us/dph/cdc/tb
Michigan	http://www.michigantb.org
Minnesota	http://www.health.state.mn.us/tb
Montana	http://www.dphhs.state.mt.us
Nebraska	http://www.hhs.state.ne.us/cod/Tuberculosis/tbindex.htm
Nevada	http://www.health2k.state.nv.us
New Hampshire	http://www.dhhs.state.nh.us/DHHS/DHHS_SITE/default.htm
New York City	http://www.nyc.gov/html/doh/html/tb/tb.html
North Carolina	http://www.schs.state.nc.us/epi/tb
North Dakota	http://www.ndmtb.com
Ohio	http://www.odh.state.oh.us
Oklahoma	http://www.health.state.ok.us
Oregon	http://www.dhs.state.or.us/publichealth/tb
Pennsylvania	http://www.dst.health.state.pa.us
Puerto Rico	http://www.salud.gov.pr
Rhode Island	http://www.health.ri.gov/disease/communicable/tb_data.htm
South Carolina	http://www.scdhec.net/hs/diseasecont/tb/html
South Dakota	http://www.state.sd.us/doh/tb
Tennessee	http://www2.state.tn.us/health/CEDS/index.htm
Texas	http://www.dshs.state.tx.us/dcu/disease/tb
Utah	http://health.utah.gov/eis/hiv/aids/tb/tbrefugee.html
Virginia	http://www.vdh.virginia.gov/epi/tb
Washington	http://www.doh.wa.gov/cfh/tb
Wisconsin	http://dhfs.wisconsin.gov/tb
Wyoming	http://www.wdh.state.wy.us/tb

Appendix F. Quality control (QC) procedural observation checklists

Quality Control (QC) Procedural Observation Checklist for Placing Tuberculin Skin Tests (TSTs) — Mantoux Method

Date _____	Trainer (QC by) _____	Trainee (TST placed by) _____
------------	-----------------------	-------------------------------

Scoring: ✓ or Y = Yes X or N = No NA = Not Applicable

1. Preliminary ____ Uses appropriate hand hygiene methods before starting. ____ Screens patient for contraindications (severe adverse reactions to previous TST).[*] ____ Uses well-lit area. 2. Syringe[†] filled with exactly 0.1 mL of 5 tuberculin units (TU) purified protein derivative (PPD) antigen[‡] ____ Removes antigen vial from refrigeration and confirms that it is 5 TU PPD antigen.[§] ____ Checks label and expiration date on vial. ____ Marks opening date on multidose vial. ____ Fills immediately after vial removed from refrigeration. ____ Cleans vial stopper with antiseptic swab. ____ Twists needle onto syringe to ensure tight fit. ____ Removes needle guard. ____ Inserts needle into the vial. ____ Draws slightly over 0.1 mL of 5 TU PPD into syringe. ____ Removes excess volume or air bubbles to exactly 0.1 mL of 5 TU PPD while needle remains in vial to avoid wasting of antigen. ____ Removes needle from vial. ____ Returns antigen vial to the refrigerator immediately after filling. 3. TST administration site selected and cleaned ____ Selects upper third of forearm with palm up ≥2 inches from elbow, wrist, or other injection site.^{**} ____ Selects site free from veins, lesions, heavy hair, bruises, scars, and muscle ridge. ____ Cleans the site with antiseptic swab using circular motion from center to outside. ____ Allows site to dry thoroughly before administering antigen. 4. Needle inserted properly to administer antigen ____ Rests arm on firm, well-lit surface. ____ Stretches skin slightly.^{††}	____ Holds needle bevel-up and tip at 5°–15° angle to skin. ____ Inserts needle in first layer of skin with tip visible beneath skin. ____ Advances needle until entire bevel is under the first layer of skin. ____ Releases stretched skin. ____ Injects entire dose slowly. ____ Forms wheal, as liquid is injected. ____ Removes needle without pressing area. ____ Activates safety feature of device per manufacturer's recommendations, if applicable. ____ Places used needle and syringe immediately in puncture-resistant container without recapping needle. ____ Immediately measures wheal to ensure 6–10 mm in diameter (Actual wheal measurement _____ mm). ____ If blood or fluid is present, blots site lightly with gauze or cotton ball. ____ Discards used gauze or cotton ball according to local standard precautions. ____ If the TST is administered incorrectly (too deeply or too shallow) and the wheal is inadequate (<6 mm), a new TST should be placed immediately. Applying the second TST on the other arm or in a different area of the same arm (at least 2 inches from the first site) is preferable so that the TST result will be easier to read. ____ Documents all information required by the setting (e.g., date and time of TST placement, person who placed TST, location of injection site and lot number of tuberculin). ____ Uses appropriate hand hygiene methods after placing TST. 5. Explanation to the client regarding care instructions for the injection site ____ The wheal (bump) is normal and will remain about 10 minutes. ____ Do not touch wheal; avoid scratching. ____ Avoid pressure or bandage on injection site. ____ Rare local discomfort and irritation does not require treatment. ____ May wash with soap and water (without pressure) after 1 hour. ____ No lotions or liquids on site, except for light washing, as above. ____ Keep appointment for reading.
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^{*} Severe adverse reactions to the TST are rare but include ulceration, necrosis, vesiculation, or bullae at the test site, or anaphylactic shock, which is substantially rare. These reactions are the only contraindications to having a TST administered.

[†] Use a 1/4–1/2-inch 27-gauge needle or finer, disposable tuberculin (preferably a safety-type) syringe.

[‡] Prefilling syringes is not recommended. Tuberculin is absorbed in varying amounts by glass and plastics. To minimize reduction in potency, tuberculin should be administered as soon after the syringe has been filled as possible. Following these procedures will also help avoid contamination. Test doses should always be removed from the vial under strictly aseptic conditions, and the remaining solution should remain refrigerated (not frozen). Tuberculin should be stored in the dark as much as possible and exposure to strong light should be avoided. **SOURCE:** American Thoracic Society, CDC, Infectious Disease Society of America. Diagnostic standards and classification of tuberculosis in adults and children. *Am J Respir Crit Care Med* 2000;161:1376–95.

[§] Preventing tuberculin antigen and vaccine (e.g., Td toxoid) misadministration is important. Measures should include physical separation of refrigerated products, careful visual inspection and reading of labels, preparation of PPD for patient use only at time of testing, and improved record keeping of lot numbers of antigens, vaccines, and other injectable products. **SOURCE:** CDC. Inadvertent intradermal administration of tetanus toxoid-containing vaccines instead of tuberculosis skin tests. *MMWR* 2004;53:662–4.

^{**} If neither arm is available or acceptable for testing, the back of the shoulder is a good alternate TST administration site. **SOURCE:** National Tuberculosis Controllers Association, National Tuberculosis Nurse Consultant Coalition. *Tuberculosis nursing: a comprehensive guide to patient care*. Smyrna, GA: National Tuberculosis Controllers Association; 1997.

^{††} Stretch skin by placing nondominant hand of health-care worker (HCW) on patient's forearm below the needle insertion point and then applying traction in the opposite direction of the needle insertion. Be careful not to place the nondominant hand of the HCW opposite the administration needle if the patient is likely to move during the procedure, which might cause an accidental needle-stick injury to the HCWs. In children and others who are likely to move during the procedure, certain trainers prefer stretching the skin in the opposite direction of the needle insertion by placing the nondominant hand of the HCW under the patient's forearm. This method should not be used for persons with poor skin turgor.

Appendix F. (Continued) Quality control (QC) procedural observation checklists

Quality Control (QC) Procedural Observation Checklist for Reading Tuberculin Skin Test (TST) Results — Palpation Method		
Date _____	Trainer (QC by) _____	Trainee (TST placed by) _____
Scoring: ✓ or Y = Yes X or N = No NA = Not Applicable		
1. Preliminary _____ Uses appropriate hand hygiene methods before starting. _____ Keeps fingernails shorter than fingertips to avoid misreading TST result. _____ Keeps TST reading materials at hand (eyeliner pencil or ballpoint pen,* and ruler). _____ Uses well-lit area. _____ Inspects for the site of the injection.	_____ Marks dots transverse (perpendicular) to long axis of forearm.	4. Placing and reading ruler _____ Places the "0" ruler line inside the edge of the left dot. Reads the ruler line inside right dot edge (uses lower measurement if between two gradations on millimeter scale) (Figure 1). _____ Uses appropriate hand hygiene methods after reading TST result.
2. Palpate — finding margin ridges (if any) _____ Palpates with arm bent at elbow at a 90° angle. _____ Lightly sweeps 2-inch diameter from injection site in four directions. _____ Uses zigzag featherlike touch. _____ Repeats palpation with arm bent at elbow at a 45° angle to determine presence or absence of induration.	5. Documenting results _____ Records all TST results in millimeters, even those classified as negative. Does not record only as "positive" or "negative." Records the absence of induration as "0 mm." _____ Correctly records results in mm; only a single measured induration in mm should be recorded. Trainee's measurement _____ mm. Trainer's (gold standard) measurement _____ mm. Trainee's result within 2 mm of gold standard reading? [§] Yes _____ No _____	NOTE: In rare instances, the reaction might be severe (vesiculation, ulceration, or necrosis of the skin). Report severe adverse events to the FDA MedWatch Adverse Events Reporting System (AERS), telephone: 800-FDA-1088; fax: 800-FDA-0178; http://www.fda.gov/medwatch report form 3500, Physicians' Desk Reference.
If induration is present, continue with these steps[†]:		
3. Placing marks _____ Holds palm over injection site. _____ Cleanse site with antiseptic swab using circular motion from center to outside. _____ Uses fingertips to find margins of the induration. _____ Marks the induration by placing small dots on both sides of the induration. _____ Inspects dots, repeats finger movements toward indurated margin, and adjusts dots if needed.	NOTE: In rare instances, the reaction might be severe (vesiculation, ulceration, or necrosis of the skin). Report severe adverse events to the FDA MedWatch Adverse Events Reporting System (AERS), telephone: 800-FDA-1088; fax: 800-FDA-0178; http://www.fda.gov/medwatch report form 3500, Physicians' Desk Reference.	
* A fine-tipped eyeliner pencil or ballpoint pen can be used as a marker. An eyeliner pencil is useful for TST training and for blinded independent duplicate readings (BIDRs) because the dots are easy to remove with a dot of lubricant (e.g., baby oil). Alternative TST result reading methods have been described, including the pen method.		
† If induration is not present, record the TST result as 0 mm and go to the end of this form (Documenting results).		
§ For example, if the TST trainer reads the TST result (the gold standard reading) as 11 mm, the trainee's TST reading should be between 9–13 mm to be considered correct.		

Appendix G. Model framework for medical evaluation request and questionnaire for users of N95 disposable respirators

Medical Evaluation Request		Yes	No
1. Today's date _____		_____	_____
2. Your name _____		_____	_____
3. Your age (to nearest year) _____		_____	_____
4. Sex _____ Male _____ Female _____		_____	_____
5. Your height _____ feet _____ inches _____		_____	_____
6. Your weight _____ pounds _____		_____	_____
7. Your job title _____		_____	_____
8. A phone number where you can be reached by the health-care professional who reviews this questionnaire (include area code) _____		_____	_____
9. The best time to phone you at this number _____		_____	_____
10. Has your employer told you how to contact the health-care professional who will review this questionnaire? _____ Yes _____ No _____		_____	_____
11. Check the type of respirator you will use (check all that apply)			
_____ N-, R-, or P-disposable respirator (filter-mask, noncartridge type only)		_____	_____
_____ Half-facepiece type		_____	_____
_____ Full-facepiece type		_____	_____
_____ Powered air-purifying respirator (PAPR) – tight-fitting		_____	_____
_____ PAPR – loose-fitting		_____	_____
_____ Other type (supplied-air or self-contained breathing apparatus)		_____	_____
12. Have you worn a respirator? _____ Yes _____ No _____		_____	_____
If "yes," what types? _____		_____	_____
Yes No	Questionnaire for Users of N95 Respirators		
_____	1. Do you currently or have you smoked tobacco during the previous month? If "yes"	_____	_____
_____	a. At what age did you start smoking? _____	_____	_____
_____	b. How long ago did you quit smoking? _____	_____	_____
_____	c. How many packs per day did or do you smoke? _____	_____	_____
_____	2. Have you ever had any of the following conditions?		
_____	a. Seizures (fits)	_____	_____
_____	b. Diabetes (sugar disease)	_____	_____
_____	c. Allergic reactions that interfere with your breathing	_____	_____
_____	d. Claustrophobia (fear of closed-in places)	_____	_____
_____	e. Trouble smelling odors	_____	_____
_____	3. Have you ever had any of the following pulmonary or lung problems?		
_____	a. Asbestosis	_____	_____
_____	b. Asthma	_____	_____
_____	c. Chronic bronchitis	_____	_____
_____	d. Emphysema	_____	_____
_____	e. Pneumonia	_____	_____
_____	f. Tuberculosis	_____	_____
_____	g. Silicosis	_____	_____
_____	h. Pneumothorax (collapsed lung)	_____	_____
_____	i. Lung cancer	_____	_____
_____	j. Broken ribs	_____	_____
_____	k. Any chest injuries or surgeries	_____	_____
_____	l. Any other lung problem that you have been told about	_____	_____
_____	4. Do you currently have any of the following symptoms of pulmonary or lung illness?		
_____	a. Shortness of breath	_____	_____
_____	b. Shortness of breath when walking quickly on level ground or walking up a slight hill or incline	_____	_____
_____	c. Shortness of breath when walking with other people at an ordinary pace on level ground	_____	_____
_____	d. Have to stop for breath when walking at your own pace on level ground	_____	_____
_____	e. Shortness of breath when washing or dressing yourself	_____	_____
	4. (Continued)		
	i. Shortness of breath that interferes with your job	_____	_____
	g. Coughing that produces phlegm (thick sputum)	_____	_____
	h. Coughing that wakes you early in the morning	_____	_____
	i. Coughing that occurs primarily when you are lying down	_____	_____
	j. Coughing up blood in the last month	_____	_____
	k. Wheezing	_____	_____
	l. Wheezing that interferes with your job	_____	_____
	m. Chest pain when you breathe deeply	_____	_____
	n. Any other symptoms that you think might be related to lung problems	_____	_____
	5. Have you ever had any of the following cardiovascular or heart problems?		
	a. Heart attack	_____	_____
	b. Stroke	_____	_____
	c. Angina	_____	_____
	d. Heart failure	_____	_____
	e. Swelling in your legs or feet (not caused by walking)	_____	_____
	f. Heart arrhythmia (heart beating irregularly)	_____	_____
	g. High blood pressure	_____	_____
	h. Any other heart problem that you have been told about	_____	_____
	6. Have you ever had any of the following cardiovascular or heart symptoms?		
	a. Frequent pain or tightness in your chest	_____	_____
	b. Pain or tightness in your chest during physical activity	_____	_____
	c. Pain or tightness in your chest that interferes with your job	_____	_____
	d. In the previous 2 years, have you noticed your heart skipping or missing a beat?	_____	_____
	e. Heartburn or indigestion that is not related to eating	_____	_____
	f. Any other symptoms that you think might be related to heart or circulation problems	_____	_____
	7. Do you currently take medication for any of the following problems?		
	a. Breathing or lung problems	_____	_____
	b. Heart trouble	_____	_____
	c. Blood pressure	_____	_____
	d. Seizures (fits)	_____	_____
	8. If you have used a respirator, have you ever had any of the following problems? (If you have never used a respirator, check here _____ and go to question 9.)		
	a. Eye irritation	_____	_____
	b. Skin allergies or rashes	_____	_____
	c. Anxiety	_____	_____
	d. General weakness or fatigue	_____	_____
	e. Any other problem that interferes with your use of a respirator	_____	_____
	9. Are you currently taking any medications? If yes, list here _____		
	10. Would you like to talk with the health-care professional who will review this questionnaire about your answers to this questionnaire?	_____	_____
	Please explain "yes" answers (use back of form if necessary)	_____	_____

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Narrative review

Safe design and maintenance of bone marrow transplant units: a narrative review

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ABSTRACT

Background: Patients undergoing bone marrow transplantation or chemotherapy for cancer are profoundly immunosuppressed. They are at risk for both endogenous and exogenous infections and require enhanced protection from infection while in hospital.

Objectives: The aim of this narrative review was to determine the optimal design features of bone marrow transplant (BMT) units for reducing infection risk in these vulnerable patients.

Sources: A literature search was performed on PubMed and other databases for documents published between January 2000 and October 2021. Keywords were: bone marrow transplant unit OR hematopoietic stem cell transplant unit OR haematology unit OR haemato-oncology unit AND design OR design guidelines OR design criteria OR ventilation specification OR HEPA filtration OR water outbreaks OR water system design.

Content: Guidelines and other papers pertaining to BMT unit design are discussed. Key design features identified from the literature to reduce infection risks include high efficiency particulate air filtration, positive-pressure ventilation, sufficient air changes and sealed rooms. The evidence for each of these parameters and other findings are discussed. We found no guidelines specific to water quality and control in BMT units.

Implications: Guidelines on the various components of design were found, but no comprehensive guidance documents addressing all relevant aspects, such as ventilation, water, and other design features, were found. Literary publications and policy documents were combined and summarised to highlight key design features aimed at reducing infection risk in this vulnerable patient group. We propose the development of international guidance for the design of BMT units encompassing all components. **T. Inkster, Clin Microbiol Infect 2022;28:1091**

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Introduction

Patients undergoing bone marrow transplantation (BMT) or intensive chemotherapy regimens for blood cancers are profoundly immunosuppressed and have multiple risk factors for infection [1,2]. Damage to mucosal surfaces, impaired barrier defences, pancytopenia, and impaired cell-mediated and humoral immunity occur as a result of treatment [1]. Patients are at risk for endogenous infection as well as pathogens from the surrounding environment, especially those from air, water, equipment, and surfaces [1,3]. Environmental organisms of little consequence to healthy

humans can pose a significant threat to transplant recipients [4–16]. Safe design of the patients' environment with expert input is therefore crucial to minimize exposure to ubiquitous pathogens from environmental sources. This paper aims to summarize existing recommendations using specifications developed from amalgamating related documents, supported by design criteria from international and literary sources.

Existing guidelines for bone marrow transplant units

Search strategy

A narrative review was performed using relevant search terms: bone marrow transplant unit OR hematopoietic stem cell transplant unit OR haematology unit OR haemato-oncology unit AND

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design OR design guidelines OR design criteria OR ventilation specification OR HEPA filtration OR water outbreaks OR water system design. The databases employed were PubMed, CINAHL, CDSR, DARE and EMBASE from “Jan 2000 to Oct 2021” for guidelines, reviews, and original articles detailing recommendations for BMT facilities and/or outbreaks linked with transplant (and other immunosuppressed) patients. Relevant documents were scanned before exclusion, along with non-English papers, posters, and conference reports. Hospital types, study ward/unit, study length and size, outbreak pathogen, environmental involvement, infection control interventions, and other variables that might have an impact on the results were noted. Published data were checked for additional references and duplicate publication.

Findings

There are no bespoke guidelines for the design of BMT units incorporating all of ventilation, water, layout, and other key aspects of design of the built environment. Relevant guidance may be extracted from various technical and building documents.

International guidelines for preventing infections in BMT patients were published in 2009 by multiple agencies [17]. This multiagency publication delineates 10 global recommendations relevant to hospital design and ventilation for BMT patients [17]. A subsequent survey in 2018 revealed that the majority of respondents were unable to demonstrate that these recommendations had been implemented, with only one centre meeting all requirements [18]. In 2017, Crysandt et al. also highlighted the lack of standards for BMT unit infrastructure and commented on the variation of facilities [19]. They observed that local aspects dominated the decisions with regards to the technical specification of such units [19]. Throughout all documents reviewed, the key design features specified for a BMT unit are sealed rooms with high efficiency particulate air (HEPA) filtration, high air changes, and positive-pressure ventilation [1,17,20–26]. Anterooms are optional features but are required when BMT patients are isolated for airborne infections [23]. Given the lack of detail on BMT unit design, we propose additional recommendations for protective ventilation as follows, including risk management of water sources and a number of other relevant design features highlighted during this review.

Ventilation

HEPA filtration

Guidance documents from various countries recommend HEPA filtration [1,17,20–26]. The purpose of HEPA filtration is primarily to remove airborne particles from the room air supply. This is because it may include fungal spores as well as other contaminants from external air sources. The HEPA filtration stage can be incorporated into the air handling unit, such that all the air supplied to the BMT unit is filtered or at points of discharge into specific rooms. HEPA filters are tested at each filter's most penetrating particle size, normally around 0.2–0.4 microns because fungal spores are around 10 times larger. Each HEPA filter should also be tested on installation to verify that there are no gaps around the mounting through which air can bypass filtration. According to the European standard, there are various HEPA filter classifications, with effectiveness stated as between 99.95% and 99.999% for 0.3 micron particles [27]. Although some bodies have recommended specific grades of HEPA filter, there is probably little practical difference, even though the choice of HEPA has an impact on the performance and energy demands of an air handling unit.

Several studies support the use of HEPA filtration to protect BMT and leukaemic patients [28–32]. One paper reports the risk of hospital acquired aspergillosis as being tenfold greater in BMT

patients when not accommodated in a HEPA-filtered environment [28]. No cases were identified among 39 BMT patients accommodated in a HEPA-filtered room versus 14 cases in 74 BMT patients who were housed elsewhere [28]. Despite a range of control measures implemented in one haematology unit, cases of *Aspergillus* continued to occur. Introduction of HEPA filtration reduced the number of cases to zero with a subsequent reduction in diagnostic procedures and use of amphotericin B [29].

In another outbreak, 10 haematology patients developed invasive aspergillosis over a 6-month period [30]. After high counts of *Aspergillus* spores were detected in the air, HEPA filters were installed. Subsequently, only two patients developed invasive fungal infection – in the two years following the outbreak [30]. In the United States, HEPA filtration was installed in a newly constructed hospital in response to an increase in the number of patients with immunosuppression. Efficacy of the filtration system was demonstrated with air sampling markedly reducing *Aspergillus* spore counts to 0–0.7 cfu/m³ [31].

Ideally, a BMT suite should be supplied using HEPA-filtered air, including the corridor and supporting service areas such as prep and treatment rooms. In one study, invasive fungal infection cases were thought to be due to patients leaving their HEPA-filtered rooms for short periods; this exposed them to ingress of spores due to personnel entering the room from a non-HEPA-filtered corridor [32]. HEPA filtration in the BMT suite allows for patient movement outside the room and gives added protection to the patient when the room doors are opened.

Positive pressure (protective isolation)

Guidance documents reviewed recommend positive pressure but to varying degrees. Some documents stipulate a positive pressure of ten pascals [1,17,20–26]. Others do not specify the degree of positive pressure required [25,26]. BMT infection guidelines from the United States also highlight the importance of airflow direction, continuous pressure monitoring, and self-closing doors to maintain constant pressure differentials [22]. Positive pressure without HEPA-filtered air is unlikely to provide sufficient protection from fungal spores. The protective ventilation strategy aims to supply an excess of HEPA-filtered air into a room, and surplus air should leak outward through the inevitable gaps in the room's integrity (such as around and under door/windows and via cable conduits and integrated plumbing system panels). This outward airflow prevents unfiltered air in adjacent spaces from travelling into the room. Some guidance documents recommend a positive pressure of 10 Pa, which may help to reduce the risk of invasive fungal infection in the absence of corridor HEPA filtration [33]. The importance of positive air pressure may be seen from outbreak reports, particularly those with an identified source of fungal spores. While investigating 21 confirmed cases of invasive fungal infection among leukaemia and BMT patients, it was found that the pressure in the unit was negative relative to an adjacent building site. The assumption is that construction work led to dispersal of *Aspergillus* spp. spores, which entered the unit due to this pressure differential [4].

Air changes

Air changes per hour (ACHs) are a measure of how many times the air within the patient's room is replaced each hour. Air change rates serve three main functions (a) thermal comfort for the patient (b) odour control, and (c) dilution of infectious particles. The air change rate for BMT patient rooms and other rooms within the unit should therefore provide both comfort and safety. Vulnerable patients are protected from dilution of any airborne pathogens as well as aerosolised medication. Sufficient air change rates, specifically

for bathrooms, facilitate drying and aid the removal of excess humidity that might otherwise encourage fungal growth [34].

Computational fluid dynamic analysis concludes that six ACHs are the minimal rates required for patient comfort [35,36]. This is particularly important in the BMT setting because patients are isolated in rooms for a prolonged period. Applying the Wells-Riley equation means that increasing the volume of clean air in a patient room will expose the patient to fewer infectious particles [37]. There is a relationship between air changes and pathogen transmission with respect to airborne infections. At the present time, however, there are few studies and insufficient data to support minimal air change requirements [36]. The purpose of air changes in the protective isolation setting should be dilution and removal of infectious particles within the room. As such, recommended air change rates vary between guidance documents, with 10, greater or equal to 12, and 15 ACHs all being cited [1,17,20–26].

Sealing of rooms and corridor air

Bedrooms and en-suite walls, ceilings, and any maintenance access panels should be sealed. Adequate sealing ensures pressure differentials can be maintained and avoids ingress of unfiltered air into the room [17,20,21]. This includes sealing of all room services, such as electrical points, ceiling hatches, and sink panels. Permeability testing is recommended on initial validation and following any subsequent breach in integrity [38].

Not all documents recommend HEPA filtration of the ward corridor. To mitigate risk from the corridor, staff could potentially operate a door closing policy. This ensures that a drop in positive pressure when opening a door does not fall sufficiently to allow ingress of contaminated air from the corridor. Automatic door closures with a visual digital readout of pressure and an alarm at the nurses' station would be desirable.

Although an air lock entrance to the ward is not specified for neutropaenic wards, it functions as an additional measure to prevent ingress of air into the unit [17,20]. This is particularly important if a corridor has no HEPA-filtered air supply (apart from air spilling from the rooms themselves) and there are no patient anterooms.

Traditionally, anterooms are for donning and doffing of personal protective equipment and are not a requirement for protective isolation purposes. They are, however, likely to offer extra protection when accommodating immunosuppressed patients with airborne infections. This area is currently omitted from some guidance documents, but it features in those from the United States, with a recommendation for patients to be placed in a positive-pressure bedroom with a negative-pressure anteroom [23]. Patients with airborne infections in a positive-pressure room represent a serious risk to corridor traffic, which might include recovering patients, staff, and visitors.

BMT patients are known to be at increased risk for COVID-19 infection. It is unclear at this stage what role the ward environment has in prevention of COVID-19 infection in this vulnerable group. It is possible that, despite rigorous environmental control measures, patients may acquire infections from staff or visitors who are asymptomatic. Units that are designed with negative pressure anterooms may afford more protection. Table 1 summarises the ventilation requirements for a bone marrow transplant unit.

Monitoring of air quality

There is a lack of consensus in the literature regarding fungal air counts in BMT units along with variation in sampling methods [39]. Air sampling is performed on a monthly basis in the authors' own unit as a quality assurance check. If implementing a routine air

sampling policy, the pitfalls of air sampling and the factors that can influence results should be considered [40–46].

Water

Water control and monitoring

Immunosuppressed patients are at risk for waterborne pathogens such as *Ps. aeruginosa*, *Legionella* spp., other gram-negative bacteria, fungi, and atypical mycobacteria [5,9,47–52]. For this reason, control measures for water should be considered at the time of planning the unit. Outlets should be selected carefully. Tap components linked to *Pseudomonas* outbreaks have been reported since 1966, and flow straighteners have been linked with subsequent outbreaks [53,54]. Sinks should be designed with minimal splash in mind, and it has been suggested that sinks be located at least two metres from patients to minimise splash risk [55]. Little used outlets should be regularly surveyed and removed [54]. Flushing regimens should be incorporated into daily ward procedures to prevent stagnation, with regular maintenance programmes implemented for taps, tap filters, and other outlets.

Water testing for *Legionella* spp., *Ps. aeruginosa* and atypical mycobacteria is recommended before patients enter the unit and at regular intervals thereafter to demonstrate control. Should outbreaks of waterborne pathogens occur, accounts from published outbreaks contain detail on successful control measures. These include (a) avoidance of tap/shower water, (b) application of point-of-use filters, (c) replacement programme for showerheads and regular cleaning/disinfection, (d) cleaning and disinfection of storage tanks, (e) treatment of water system with biocides, (e) cleaning and thorough drying of infusion trays, and (f) protection of CVCs during showering/bathing [49,52,54,56–60].

Patient bathrooms

Patient bathrooms and associated plumbing represent a potential source of mould [34]. Surface finishes should be of a high standard with use of water-resistant products. Ongoing staff education is required for timely reporting of damage to en-suite flooring, shower areas, etc. to enable rapid repair and prevent buildup of mould. After 72 hours, the likelihood of fungal growth increases. In such high-risk units' disposable components such as showerheads may be desirable.

Other water sources

Other water sources, such as ice machines and water coolers, should not be installed in a BMT unit because they have frequently been associated with microbial contamination [61,62]. Air conditioning units have been linked to fungal contamination and should be avoided. If these are present, they should be regularly serviced, tested, and maintained [62,63]. Dishwashers have been shown to harbour pathogenic fungi such as *Aspergillus*, *Fusarium*, and *Exophiala* spp [64].

Energy efficiency

New technologies that promote energy efficiency are becoming a feature of new hospitals. Guidance recommends that energy efficiency methods, such as chilled beams for ventilation purposes, should not be installed in high-risk units [21]. Desired air changes for a BMT unit are unlikely to be achievable using this technology. Chilled beams involve a water source and can be prone to condensation, which along with potential accumulation of dust both poses a risk to immunosuppressed patients [65].

Table 1
Ventilation criteria for a bone marrow transplant unit

Recommendation	Rationale	References
All air entering the bedrooms must be HEPA filtered (minimum H13 [E12]) and located within the supply air diffuser (i.e., corridor and room air should be HEPA filtered).	External air carries fungal spores, and ducting may also become a source of fungus if not maintained or if there is any breach in the ducting or condensation/water ingress creating conditions for mould growth. Point-of-supply filtration ensures air entry into breathing space is in the cleanest state when supplied. Corridor air will ingress even into positive-pressured rooms when the door opens; increased filtration into the corridor space ensures a further level of protection. Patients will often need to travel along corridors and HEPA filtration ensures a degree of freedom during recovery phases.	[17,20–22,25,26,29]
Rooms should be positively pressurized to 10 pascals.	This robustly prevents ingress of unfiltered air into the patient room through all of the tiny gaps in the integrity of the room through which air can move depending on pressure differentials across the building, which can change with external factors such as wind direction and temperatures.	[17,20–22]
The minimum number of air changes at 10 ACHs should be achieved.	This ensures rapid dilution and removal of within room contamination (e.g., for airborne respiratory virus such as COVID; airborne bacteria such as those from water outlet aerosolisation, as well as any fungal spore ingress). Higher ACH can risk drafts and thermal discomfort.	[17,20–22,25,26]
Bedrooms and en-suite walls, ceilings, and any maintenance access panels should be sealed.	This ensures pressure differential can be maintained and avoids ingress of unfiltered air into the room.	[20–22,38]
All room services must be sealed (e.g., electrical points, ceiling hatches, sink panels).	As above.	[20–22,38]
Chilled beams should be avoided.	Condensation can occur on the chilled beam and promote damp conditions. Dirt can accumulate on the beam due to re-entrainment, and cleaning becomes a logistical issue when the beds are in use. Chilled beams involve a water source in the patient environment, so they introduce a potential biohazard in case of leaks (e.g., legionella and pseudomonas).	[65]
Avoid hatches placed in rooms that require regular access for maintenance of services.	Every breach in the seal of the room (such as ceiling voids and walls) requires the room to be resealed and tested to ensure that unfiltered air does not ingress into the room. Access to rooms for service work will mean the room needs to be emptied on a regular basis because work cannot take place when a high-risk patient is in the room due to risk of fungal spore ingress.	AR
A continuous pressure monitoring system with an automated alarm system should be installed for each room. Monitoring should be done with local digital readouts and central building management systems.	Alarms will give an early indication of a pressure drop and allow for risk assessment and moving of the patient, if required	[17,21,24,25]
Treatment, preparation rooms and supply stores should be HEPA filtered.	Reduction of bioburden in spaces where IVs are prepared is important for sterile field.	AR
Backup air handling unit should be fitted or detailed contingency plan if only a single AHU is present.	In the event of a failure and a patient <i>in situ</i> , there is usually no ability to reverse immune compromise and so the accommodation needs continuity of care ensured in event of failures.	AR
Ensure double-door entry system with a corridor airlock.	This provides additional protection from ingress of outside air.	AR
Ensure the whole system is commissioned and verified prior to being put into use. The results for the commissioning and verification should be signed off by all parties and all documentation recorded in the operating and maintenance manual.	When a unit is occupied, it is very difficult to rectify faults because the clinical needs are immediate.	[20,21]
Allowance should be made for annual verification of the system.	Service planning with careful coordination with the clinical teams is required to ensure access for verification is not denied. AHU failures in non-maintained systems will pose an immediate issue for high-risk patients.	[20,21,26]

HEPA, high efficiency particulate air; ACH, air changes/hour; AHU, air handling unit; AR, author recommendation.

Discussion

Given the vulnerabilities of the immunocompromised patient population, it seems that their accommodation in today's hospitals would benefit from more stringent guidance. Most documents reviewed recommended BMT units have HEPA-filtered patient rooms, with high air changes and positive pressure. However, not all recommend units have HEPA filtration in corridors.

With relation to water, there is no specific guidance document for water quality and control in BMT units. Outbreaks in BMT units have been described in the scientific literature in relation to *Legionella* spp., fungi, *Pseudomonas* spp., atypical mycobacteria and other Gram-negative bacteria such as *S. maltophilia* [9,10,47,50,51]. Evidence exists as to outlets, sinks, showers, and drains all being implicated in such outbreaks [9,10,66].

Guidance documents also omit detail in relation to other BMT ward areas such as treatment and preparation rooms. These BMT facilities might differ from the other wards in that, ideally, they should also be HEPA filtered. Patient bathrooms are frequently conducive to growth of mould [34], and guidance on how to mitigate the risks associated with this issue would be beneficial.

In conclusion, there is a notable absence of bespoke guidance for design and ventilation/water standards for BMT units. We combined findings from international guidance documents and published literature on outbreaks/incidents. We propose the development of international guidance for BMT units, which goes beyond ventilation specification to incorporate other environmental risks and provides overarching detail on ward design as a whole.

Authors' contributions

TI: conception, literature review, data analysis and interpretation, writing, revisions, approval; CP: data analysis and interpretation, writing, revisions, approval; SD: literature review, writing, revisions, editing, approval.

Transparency declaration

The authors declare that they have no conflicts of interest.

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References

- Guidelines for preventing opportunistic infections among haematopoietic stem cell transplant recipients. Recommendations of CDC, the infectious disease society of America and the American society of blood and bone marrow transplantation. *Biol Blood Marrow Transpl* 2000;6:7–83. [https://doi.org/10.1016/s1083-8791\(00\)70002-4](https://doi.org/10.1016/s1083-8791(00)70002-4).
- Schelenz S, Nwaka D, Hunter PR. Longitudinal surveillance of bacteraemia in haematology and oncology patients at a UK cancer centre and the impact of ciprofloxacin use on antimicrobial resistance. *J Antimicrob Chemother* 2013;68:1431–8. <https://doi.org/10.1093/jac/dkt002>.
- Gastmeier P. From one size fits all to personalized infection prevention. *J Hosp Infect* 2020;104:256–60. <https://doi.org/10.1016/j.jhin.2019.12.010>.
- Thio CL, Smith D, Merz WG, Streifel A. Refinements of environmental assessment during an outbreak investigation of invasive aspergillosis in a leukaemia and bone marrow transplant unit. *Infect Control Hosp Epidemiol* 2000;21:18–23. <https://doi.org/10.1086/501691>.
- Cervia JS, Barber F, Armellino D, Klocke J, Bayer RL. Point of use water filtration reduces hospital acquired infection in bone marrow transplant recipients. *Transpl Infect Dis* 2010;12:238–41. <https://doi.org/10.1111/j.1399-3062.2009.00459.x>.
- Guyot A, Turton JF, Garner D. Outbreak of *Stenotrophomonas maltophilia* on an intensive care unit. *J Hosp Infect* 2013;85:303–7. <https://doi.org/10.1016/j.jhin.2013.09.007>.
- Macesic N, Morrissey CO, Cheng AC, Spencer A, Peleg AY. Changing microbial epidemiology in hematopoietic stem cell transplant recipients: increasing resistance over a 9-year period. *Transpl Infect Dis* 2014;16:887–96. <https://doi.org/10.1111/tid.12298>.
- Kern WV, Roth JA, Bertz H, Gelting T, Dettenkofer M, Widmer AF, et al. Contribution of specific pathogens to blood stream infection mortality in neutropenic patients with haematologic malignancies: results from a multicentric surveillance cohort study. *Transpl Infect Dis* 2019;21:e13186. <https://doi.org/10.1111/tid.13186>.
- Garvey MI, Bradley CV, Holden E. Waterborne *Pseudomonas aeruginosa* transmission in a haematology unit? *Am J Infect Control* 2018;46:383–6. <https://doi.org/10.1016/j.ajic.2017.10.013>.
- Baranovsky S, Jumas-Bilak E, Lotthé A, Marchand H, Parer S, Hicheri Y, et al. Tracking the spread routes of opportunistic premise plumbing pathogens in a haematology unit with water points-of-use protected by antimicrobial filters. *J Hosp Infect* 2018;98:53–5. <https://doi.org/10.1016/j.jhin.2017.07.028>.
- Vonberg RP, Gastmeier P. Nosocomial aspergillosis in outbreak settings. *J Hosp Infect* 2006;63:246–54. <https://doi.org/10.1016/j.jhin.2006.02.014>.
- Arnold PM, Sadigh M, Costas C, Weil D, Chudy R. Endemic and epidemic aspergillosis associated with in-hospital replication of aspergillus organisms. *J Infect Dis* 1991;164:998–1002.
- Tablan OC, Anderson LJ, Besser R, Bridges C, Hajjeh RCDC. Guidelines for preventing healthcare associated pneumonia [Internet]. Centers Dis Control Prev 2003 [cited 2020 Aug 28]. Available from: <https://www.cdc.gov/infectioncontrol/pdf/guidelines/healthcare-associated-pneumonia-H.pdf>.
- Best E, Parnell P, Couturier J, Barbut F, Le-Bozec A, Arnoldo L, et al. Environmental contamination by bacteria in hospital washrooms according to hand drying method: a multicentre study. *J Hosp Infect* 2018;100:469–75. <https://doi.org/10.1016/j.jhin.2018.07.002>.
- Kramer A, Schwabke I, Kampf G. How long do nosocomial pathogens persist on inanimate surfaces? A systematic review. *BMC Infect Dis* 2006;6:130. <https://doi.org/10.1186/1471-2334-6-130>.
- Bonadonna L, Briancetto R, Coccia AM. Analysis of microorganisms in hospital environments and potential risks. In: Capolongo S, Settimo G, Gola M, editors. Indoor air quality in healthcare facilities. SpringerBriefs in public health. Cham: Springer; 2017. p. 53–62. https://doi.org/10.1007/978-3-319-49160-8_5.
- Tomblyn M, Chiller T, Einsele H, Gress R, Sepkowitz K, Storek J, et al. Guidelines for preventing infectious complications among haematopoietic cell transplantation recipients: a global perspective. *Biol Blood Marrow Transpl* 2009;15:1143–238. <https://doi.org/10.1016/j.bbmt.2009.06.019>.
- Styczynski J, Tridello G, Donnelly JP, Lacobelli S, Hoek J, Mikulska M, et al. Protective environment for haematopoietic cell transplant recipients: the Infectious Diseases Working party EBMT analysis of global recommendations on health care facilities. *Bone Marrow Transpl* 2018;53:1131–8. <https://doi.org/10.1038/s41409-018-0141-5>.
- Crysanndt M, Yakoub-Agha I, Reib P, Theisen S, Gilling G, Glatte P, et al. How to build an allogeneic hematopoietic cell transplant unit in 2016: proposal for a practical framework. *Curr Res Trans Med* 2017;65:149–54. <https://doi.org/10.1016/j.retram.2017.10.003>.
- Uk Department of Health. HTM 3–1. Specialised ventilation for healthcare premises. Part A: design and validation. UK Department of Health 2021 [cited 2020 Aug 27]. Available from: <https://www.england.nhs.uk/publication/specialised-ventilation-for-healthcare-buildings/>.
- Health Facilities Scotland. SHTM 3–1. Specialised ventilation for healthcare premises. Part A: design and validation [Internet]. Health Facilities Scotland 2022 [Cited 2020 Aug 28]. Available from: <https://www.nss.nhs.scot/publications/ventilation-for-healthcare-premises-shtm-03-01/>.
- Centers for Disease Control and Prevention. Guidelines for environmental infection control in health-care facilities [Internet]. Centers Dis Control Prev 2003 [cited 2020 Aug 25]. Available from: <https://www.cdc.gov/infectioncontrol/pdf/guidelines/environmental-guidelines-P.pdf>.
- Siegel JD, Rhinehart E, Jackson M, Chiarello L. The Healthcare Infection Control Practices Advisory Committee. Guideline for isolation precautions: preventing transmission of infectious agents in the healthcare setting. Centers Dis Control Prev 2007 [cited 2020 Aug 25]. Available from: <https://www.cdc.gov/infectioncontrol/pdf/guidelines/isolation-guidelines-H.pdf>.
- Yokoe D, Casper C, Dubberke E, Lee G, Munoz P, Palmore T, et al. Infection prevention and control in healthcare facilities in which haematopoietic cell transplant recipients are treated. *Bone Marrow Transpl* 2009;44:495–507. <https://doi.org/10.1038/bmt.2009.261>.
- Csa Z8000. Canadian health care facilities – planning, design and construction [Internet]. CSA Group 2020. Aug 25]. Available from: <https://www.csagroup.org/store/canadian-health-care-facilities-planning-design-and-construction/>.
- National Health and Medical Research Council. Australian guidelines for the prevention and control of infection in healthcare [Internet]. MAGIC. NHMRC; 2019 [31/8/21]. Available from: <https://app.magicapp.org/#/guideline/jn37kn>.
- Set EN. 1822 and EN ISO 29463 standards for high efficiency particulate air filters [Internet]. Eur Stand 2018–2019 2020. May 14]. Available from: <https://www.en-standard.eu/set-en-1822-and-en-iso-29463-standards-for-high-efficiency-air-filters-epa-hepa-and-ulpa/>.
- Sherertz RJ, Belani A, Kramer BS, Elfenbein GJ, Weiner RS, Sullivan ML, et al. Impact of air filtration on nosocomial aspergillus infections. Unique risk of bone marrow transplant recipients. *Am J Med* 1987;83:709–18. [https://doi.org/10.1016/0002-9343\(87\)90902-8](https://doi.org/10.1016/0002-9343(87)90902-8).
- Withington S, Chambers ST, Beard ME, Inder A, Allen JR. Invasive aspergillosis in severely neutropenic patients over 18 years: impact of intranasal amphotericin B and HEPA filtration. *J Hosp Infect* 1998;38:11–8.
- Hahn T, Cummings KM, Michalek AM, Lipman BJ, Segal BH, McCarthy PL. Efficacy of high efficiency particulate air filtration in preventing aspergillosis in immunocompromised patients with haematologic malignancies. *Infect Control Hosp Epidemiol* 2002;23:525–31. <https://doi.org/10.1086/502101>.
- Noskin GA, Peterson LR. Engineering infection control through facility design. *Emerg Infect Dis* 2001;7:354–7. <https://doi.org/10.3201/eid0702.010242>.
- Rhame FS, Streifel AJ, Kersey Jr JH, McGlave PB. Extrinsic risk factors for pneumonia in the patient at high risk of infection. *Am J Med* 1984;76:42–52.
- Humphreys H. Positive pressure isolation and the prevention of invasive aspergillosis. What is the evidence? *J Hosp Infect* 2004;56:93–100. <https://doi.org/10.1016/j.jhin.2003.10.011>.
- Picot-Guéraud R, Khouri C, Brenier-Pinchart M-P, Saviuc P, Fares A, Sellon T, et al. En-suite bathrooms in protected haematology wards: a source of filamentous fungal contamination? *J Hosp Infect* 2015;91:244–9. <https://doi.org/10.1016/j.jhin.2015.07.005>.
- Ninomura P, Bartley J. New ventilation guidelines for health-care facilities. *Ashrae J* 2001;43:29–33. Available from: https://www.mintie.com/assets/img/resources/ASHRAE_Article-on-VentilationChanges.pdf.
- Memaradeh F. Thermal comfort, uniformity and ventilation effectiveness in patient rooms: performance assessment using ventilation indices. *Ashrae Trans* 2000;106. 2.
- Memaradeh F. Literature review: room ventilation and airborne disease transmission [Internet]. American Society of Engineering 2013 [cited 2020 Aug 28]. Available from: https://www.orf.od.nih.gov/TechnicalResources/Bioenvironmental/Documents/MONOGRAPH-ROOM%20VENTILATION%20AND%20AIRBORNE%20DISEASE%20TRANSMISSION_508.pdf.
- Bsria. Air permeability testing of isolation facilities. BTS 3(2018) [Internet] BSRIA 2018 [cited 2022 March 25]. Available from: https://www.bsria.com/uk/product/BA8E4D/air_permeability_testing_of_isolation_facilities_bts_32018_a15d25e1/.
- Menegueti MG, Ferreira LR, Silva MFI, Silva ASD, Bellissimo-Rodrigues F. Assessment of microbiological air quality in haemato-oncology units and its

- relationship with the occurrence of invasive fungal infections: an integrative review. *Rev Soc Bras de Med Trop* 2013;46:391–6. <https://doi.org/10.1590/0037-8682-0022-2013>.
- [40] Falvey DG, Striefel A. Ten-year air sample analysis of *Aspergillus* prevalence in a university hospital. *J Hosp Infect* 2007;67:35–41. <https://doi.org/10.1016/j.jhin.2007.06.008>.
- [41] Shiomori T, Miyamoto H, Makishima K, Yoshida M, Fujiyoshi T, Uda T, et al. Evaluation of bedmaking-related airborne and surface methicillin-resistant *Staphylococcus aureus* contamination. *J Hosp Infect* 2002;50:30–5. <https://doi.org/10.1053/jhin.2001.1136>.
- [42] Montagna MT, de Giglio O, Napoli C, Lovero G, Caggiano G, Delia M, et al. Invasive fungal infection in patients with haematologic malignancies (Auora project), lights and shadows during 18 months surveillance. *Int J Mol Sci* 2012;13:774–87. <https://doi.org/10.3390/ijms13010774>.
- [43] Leenders AC, van Belkum A, Behrendt M, Luijendijk A, Verburgh HA. Density and molecular epidemiology of *Aspergillus* in air and relationship to outbreaks of *Aspergillus* infection. *J Clin Microbiol* 1999;37:1752–7.
- [44] Sautour M, Sixt N, Dalle F, L'Ollivier C, Fourquenot V, Calinon C, et al. Profiles and seasonal distribution of airborne fungi in indoor and outdoor environments at a French hospital. *Sci Total Environ* 2009;12:3766–71. <https://doi.org/10.1016/j.scitotenv.2009.02.024>.
- [45] Shajahan A, Culp CH, Williamson B. Effects of indoor environmental parameters related to building heating, ventilation and air conditioning systems on patients' medical outcomes: a review of scientific research on hospital buildings. *Indoor Air* 2019;29:161–76. <https://doi.org/10.1111/ina.12531>.
- [46] National guidelines for the prevention of nosocomial aspergillosis. A report of the *Aspergillus* subcommittee of the health protection surveillance centre scientific advisory committee [internet]. Health Protection Surveillance Centre 2018 [cited 2020 Oct 20]. Available from: <https://www.hpsc.ie/az/respiratory/aspergillosis/guidance/Aspergillus%20Guidelines%202018.pdf>.
- [47] Oren L, Zuckerman T, Avivi I, Finkelstein R, Yigla M, Rowe JM. Nosocomial outbreak of pneumonia caused by *Legionella Pneumophila* serogroup 3 in a new bone marrow transplant unit: evaluation, treatment and control. *Bone Marrow Transplant* 2002;30:175–9. <https://doi.org/10.1038/sj.bmt.1703628>.
- [48] Knirsch CA, Jakob K, Schoonmaker D, Kiehlbauch JA, Wong SJ, Della-Latta P, et al. An outbreak of *Legionella micdadei* pneumonia in transplant patients; evaluation, molecular epidemiology and control. *Am J Med* 2000;108:290–5. [https://doi.org/10.1016/s0002-9343\(99\)00459-3](https://doi.org/10.1016/s0002-9343(99)00459-3).
- [49] Litvinov N, da Silva MT, van der Herjden IM, Graca MG, Marques de Oliveria L, Fu L, et al. An outbreak of invasive fusariosis in a children's cancer hospital. *Clin Microbiol Infect* 2015;21:268e1. <https://doi.org/10.1016/j.cmi.2014.09.004>.
- [50] Kanamon H, Weber DJ, Rutala WA. Healthcare outbreaks associated with a water reservoir and infection prevention strategies. *Clin Infect Dis* 2016;62:1423–35. <https://doi.org/10.1093/cid/ciw122>.
- [51] Anaisse EJ, Costa SF. Nosocomial aspergillosis is waterborne. *Clin Infect Dis* 2001;33:1546–8. <https://doi.org/10.1086/322967>.
- [52] Kline S, Cameron S, Striefel A, Yakus MA, Kairis F, Peacock K, et al. An outbreak of bacteraemias associated with *Mycobacterium mucogenicum* in a hospital water supply. *Infect Control Hosp Epidemiol* 2004;25:1042–9. <https://doi.org/10.1086/502341>.
- [53] Cross DG, Benchimol A, Dimond EG. The faucet aerator – a source of *Pseudomonas* infection. *New Engl J Med* 1966;274:1430–1.
- [54] Walker JT, Jhutti A, Parks S, Willis C, Copley V, Turton JF, et al. Investigation of healthcare-acquired infections associated with *Pseudomonas aeruginosa* biofilms in taps in neonatal units in Northern Ireland. *J Hosp Infect* 2014;86:16–23. <https://doi.org/10.1016/j.jhin.2013.10.003>.
- [55] De Geyter D, Blommaert L, Verbraeken N, Sevenois M, Huyghens L, Martini H, et al. The sink as a potential source of transmission of carbapenemase-producing *Enterobacteriaceae* in the intensive care unit. *Antimicrob Resist Infect Control* 2017;6:24. <https://doi.org/10.1186/s13756-017-0182-3>.
- [56] Gavalda L, Garcia-Nunez M, Quero S, Gutierrez-Milla C, Sabria M. Role of hot water temperature and water system use on *Legionella* control in a tertiary hospital: an 8-year longitudinal study. *Water Res* 2019;149:460–6. <https://doi.org/10.1016/j.watres.2018.11.032>.
- [57] Anaissie EJ, Kuchar RT, Rex JH, Francesconi A, Kasai M, Müller FM, et al. Fusariosis associated with pathogenic fusarium species colonization of a hospital water system: a new paradigm for the epidemiology of opportunistic mold infections. *Clin Infect Dis* 2001;33:1871–8. <https://doi.org/10.1086/324501>.
- [58] Aumeran C, Paillard C, Robin F, Kanold J, Baud O, Bonnet R, et al. *Pseudomonas aeruginosa* and *Pseudomonas putida* outbreak associated with contaminated water outlets in an oncohaematology paediatric unit. *J Hosp Infect* 2007;65:47–53. <https://doi.org/10.1016/j.jhin.2006.08.009>.
- [59] Baird SF, Taori SK, Dave J, Willocks LJ, Roddie H, Hanson M. Cluster of nontuberculous mycobacteremia associated with water supply in a haematology unit. *J Hosp Infect* 2011;79:339–43. <https://doi.org/10.1016/j.jhin.2011.07.006>.
- [60] Tagashira Y, Kozai Y, Yamasa H, Sakurada M, Kashiwayama T, Honda H. A cluster of central line-associated bloodstream infections due to rapidly growing nontuberculous mycobacteria in patients with hematologic disorders at a Japanese tertiary care center: an outbreak investigation and review of the literature. *Infect Control Hosp Epidemiol* 2015;36:76–80. <https://doi.org/10.1017/ice.2014.14>.
- [61] Kanwar A, Cadnum JL, Xu D, Jenson AL, Donskey CJ. Hiding in plain sight: contaminated ice machines are a potential source for dissemination of Gram-negative bacteria and *Candida* species in healthcare facilities. *Infect Control Hosp Epidemiol* 2018;39:253–8. <https://doi.org/10.1017/ice.2017.321>.
- [62] Clark T, Huhn GD, Conover C, Cali S. Outbreak of blood stream infection with the mold *Phialemonium* among patients receiving dialysis at a haemodialysis unit. *Infect Control Hosp Epidemiol* 2006;27:1164–70. <https://doi.org/10.1086/508822>.
- [63] Horner WE. Managing building related *Aspergillus* exposure. *Med Mycol* 2006;44:S33–8. <https://doi.org/10.1080/13693780600925194>.
- [64] Zalar P, Novak M, de Hoog GS, Gunde-Cimerman N. Dishwashers, a man-made ecological niche accommodating human opportunistic fungal pathogens. *Fungal Biol* 2011;115:997–1107. <https://doi.org/10.1016/j.funbio.2011.04.007>.
- [65] Inkster T, Peters C, Soulsby H. Potential infection control risks associated with chilled beam technology, experience from a UK hospital. *J Hosp Infect* 2020;106:613–6. <https://doi.org/10.1016/j.jhin.2020.08.011>.
- [66] Kossow A, Kompmeier S, William S, Berdwell WE, Groll AH, Burkhardt B, et al. Control of multidrug resistant *Pseudomonas aeruginosa* in allogeneic hematopoietic stem cell transplant recipients by a novel bundle including remodelling of sanitary and water supply systems. *Clin Infect Dis* 2017;15:935–42. <https://doi.org/10.1093/cid/cix465>.

AN EVALUATION OF HOSPITAL SPECIAL-VENTILATION-ROOM PRESSURES

Nancy Rice, MPH; Andrew Streifel, MPH; Donald Vesley, PhD

ABSTRACT

OBJECTIVE: To quantitate the magnitude and consistency of positive (airflow out) and negative (airflow in) hospital special-ventilation-room (SVR) airflow.

DESIGN: A room-pressure evaluation was conducted during two seasons on a total of 18 rooms: standard rooms, airborne infection isolation rooms, and protective environment rooms. The pressures were measured using a digital pressure gauge-piezoresistive pressure sensor that measured pressure differentials. With doors closed, the rooms were measured a minimum of 30 times each for a cooling season and a heating season.

RESULTS: The standard rooms showed the least amount of variability in pressure differential, with an average of -0.2 Pa (median, -0.2 Pa), and an interquartile range (IQR) of 0.4 Pa. Airborne infection isolation rooms showed more variability in

pressure, with an average of -0.3 Pa (median, -0.2 Pa) and an IQR of 0.5 Pa. Protective environment rooms had the greatest fluctuation in pressure, with an average of 8.3 Pa (median, 7.7 Pa) and an IQR of 8.8 Pa. Dramatic pressure changes were observed during this evaluation, which may have been influenced by room architectural differences (sealed vs unsealed); heating, ventilation, and air-conditioning zone interactions; and stack effect.

CONCLUSION: The pressure variations noted in this study, which potentially affect containment or exclusion of contaminants, support the need for standardization of pressure requirements for SVRs. To maintain consistent pressure levels, creating an airtight seal and continuous pressure monitoring may be necessary (*Infect Control Hosp Epidemiol* 2001;22:19-23).

Pressurization controls for hospital ventilation systems play an important part in protecting employees and patients from airborne infection hazards. When these systems fail, disease outbreaks can result. An example of this occurred in 1991 in a New York hospital, where a highly infectious patient with multiple drug-resistant tuberculosis was housed in hospital rooms equipped with improperly functioning ventilation controls. Three patients and one correctional officer who were in the hospital at the time developed active multiple drug-resistant tuberculosis; two patients and the correctional officer died.¹

Another study of airborne-infection (AI) rooms in seven midwestern hospitals showed that nearly one half of the isolation rooms had air flowing in the wrong direction.² Instances like these underscore the need to ensure that ventilation systems are working properly.

In this survey, three room types at the University of Minnesota Hospital were monitored for pressure stability from June to August and September to December 1996, which allowed room pressurization to be observed under a variety of weather conditions. One room type, the standard patient room, was not designed to be under any particular pressurization. These rooms were constructed according to 1981 Guidelines for Minimum Requirements for Construction and Equipment in Hospitals.³ The second room type, the AI isolation room, was designed to be under

negative pressure in order to contain infectious agents. The third room type, the protective-environment room (PR), was designed to be under positive pressure to prevent airborne contaminants from entering the room.⁴

Given the degree of ventilation control on each room type, it was expected that the PR and AI rooms included in this study would hold pressure at fairly constant levels for the duration of the observation periods, while the standard rooms would show frequent fluctuations in pressure. The objective of this project was to determine which, if any, of the rooms would fluctuate in pressure, and to attempt to identify possible reasons for any large fluctuations that did occur.

METHODS

Room-pressure measurements took place on the fourth, fifth, and sixth floors in the northeastern wing of the eight-story hospital building.

The studied floors of the northeastern wing of the hospital had a total of 12 rooms, with 4 rooms on each of three sides of the wing (Figure 1). The fourth, fifth, and sixth floors all had 2 AI rooms, which were located on the northwest and southeast corners of each floor.

On the fourth floor, all of the patient rooms in the northeastern wing functioned as PR for bone marrow transplant patients. Two rooms on this floor, PR 4a and PR 4f,

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The authors thank Dr. Dorothy Aeppli, Dr. Frank Rhame, Dr. Timothy Church, and John Marshall for their assistance with this project. 99-OA-163. Rice N, Streifel A, Vesley D. An evaluation of hospital special-ventilation-room pressures. *Infect Control Hosp Epidemiol* 2001;22:19-23.

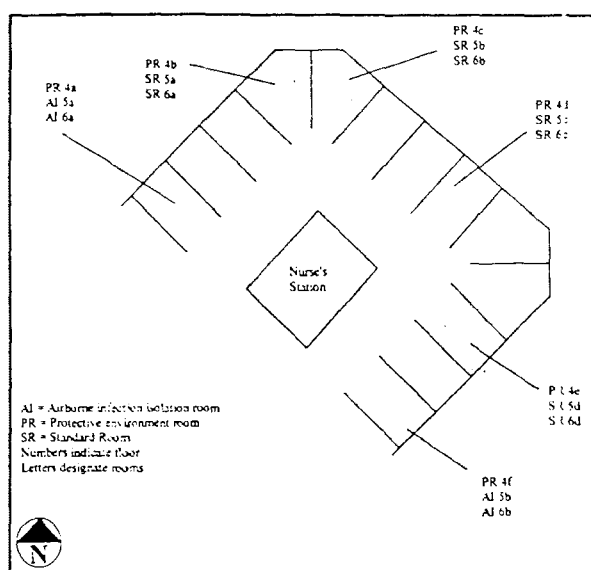


FIGURE 1. Location of the sampled rooms in the northwest wing of the hospital. The sampled rooms were located on the fourth, fifth, and sixth floors of the wing.

were intended to serve patients requiring both infectious and protective isolation. These two protective-infectious isolation rooms had anterooms, while the other PR did not have anterooms. The patient rooms on this floor were designed with constant air-volume ventilation systems, which provide a consistent airflow rate to an area, with temperatures being altered as needed for thermal control. The hallways were designed with a variable air-volume system, which maintains temperature at a constant level while altering the airflow rates to an area for thermal control.

On both the fifth and sixth floors of the northeastern wing, there were 10 standard rooms (with no special ventilation control) and 2 AI rooms with anterooms. As on the fourth floor, the patient rooms had a constant air-volume ventilation system, while the hallways were designed with a variable air-volume ventilation system.

A total of 18 rooms were sampled for this project, with 6 arbitrarily selected rooms sampled on each of the fourth, fifth, and sixth floors. The sampled rooms were selected so that they would be located directly above or below sampled rooms of another floor, in a column configuration (Figure 1). This helped to ensure that the rooms on different floors would be subjected to approximately the same environmental conditions occurring outside of the building, such as wind and temperature. The 2 AI rooms were included in the sample of each floor. The other 4 rooms on each floor were chosen to include 2 adjacent rooms in the northeast corner of the hospital wing, and 2 non-adjacent rooms located in each row of 4 rooms on the northeast and southeast side of the hospital wing.

Pressure readings were taken three times per week in the early afternoon to obtain representation of room pressures at approximately the same time each sampling day. Rooms were sampled in approximately the same order

each time, with alterations made when activities in a particular room prevented immediate sampling. Occasionally, it was necessary to omit a room for 1 sampling day, due to nurses' request or circumstances that prevented closing the door to the patient rooms.

The first group of readings was collected from June 5 to August 16, 1996, with 32 sets of measurements obtained. The second group was collected from September 25 to December 20, 1996, with 37 sets of measurements obtained during this time period.

Pressure differentials were measured in Pascals ([Pa] $0.25 \text{ Pa} = 0.001 \text{ in water gauge [wg]}$) with a Minneapolis Digital Pressure and Fan Flow Gauge (Energy Conservatory, Bloomington, MN). This self-calibrating instrument had a sensitivity to 0.1 Pa (0.0004 in wg). The probe to this instrument was positioned under the closed door for sampling. Samples for both the rooms and anterooms always were taken from the hallway side of the door. For consistency, the probe was placed under the closed door about 20 cm from the hinged side of the door, perpendicular to the plane of the door frame. In the event of an unplanned door opening, rooms were allowed time for pressure stabilization after the door was reclosed before data were recorded. Each sample consisted of 12 consecutive 5-second readings, which were averaged and recorded as the pressure differential for the room on that day.

Windows and bathroom-door positions were not considered variables in this project, as the windows were locked and sealed and the bathroom doors were underfoot to allow for unrestricted airflow.

Weather variables were analyzed using multiple linear regression, with room pressure as the dependent variable and weather values, centered around their means, as the independent variables. Dummy variables were used to indicate wind direction (N, NE, E, SE, S, SW, W, or NW), with "1" coded to signify wind from a particular direction and "0" if the wind was not from that direction.

RESULTS

The data collected for this project showed that the pressure stability of the rooms varied by room type (see Table).

Standard Rooms

Standard rooms (5a to 6d) were the most stable of the three room types, with an overall mean pressure of -0.2 Pa (median, -0.2 Pa) and an interquartile range (IQR) of 0.4 Pa (see Table; as a point of reference, $-0.25 \text{ Pa} = -0.001 \text{ in of water}$, which is the 1994 Centers for Disease Control and Prevention [CDC] recommendation for AI isolation room pressure⁵). There were small fluctuations in pressure in most of the standard rooms of about $\pm 0.4 \text{ Pa}$, but the standard rooms usually had consistently weak positive ($0 \leq x \leq 1.0 \text{ Pa}$) or weak negative ($0 \geq -x \geq -1.0 \text{ Pa}$) pressure differentials throughout the sampling period. This consistency in pressure of the standard rooms would result in consistency of direction of airflow in these rooms.

TABLE
SUMMARY STATISTICS FOR ALL ROOM TYPES

Room Type	Readings	Mean Pressure (Pa)*	Median Pressure (Pa)	Interquartile Range† (Pa)	Minimum Pressure (Pa)	Maximum Pressure (Pa)	Range (Pa)
Standard room	533	-0.2‡	-0.2	0.4	-1.4	0.8	2.2
Airborne infection isolation room	274	-0.3	-0.2	0.5	-1.3	0.7	2.0
Protective environment room	551	8.3	7.7	8.8	-1.1	21.7	22.8

Abbreviation: Pa, Pascal.

* 0.25 Pa = 0.1 in. of water.

† Interquartile range = Q1-Q3, where Q1 is the median of observations below the median and Q3 is the median of observations above the median.

‡ Negative numbers indicate negative pressure (airflow into the room).

Infectious Isolation Rooms

The four AI (AI 5a to AI 6b) rooms showed more pressure fluctuation than the standard rooms, with an average pressure of -0.3 Pa (median, -0.2 Pa) and an IQR of 0.5 Pa (see Table). Unlike the standard rooms, where some rooms had consistently positive pressure and some rooms had consistently negative pressure, most of the AI rooms and their accompanying anterooms had an overall negative pressure differential, as intended. Of the 274 total sample readings taken of AI rooms, there were only 10 readings (3.6%) where both the anteroom and the patient room of an AI room had slightly positive (0.1 Pa) or neutral (0 Pa) pressure differentials. However, the magnitude of the negative pressure differentials varied over time. Adequate negative pressure, as suggested by the CDC, is -0.25 Pa (-0.001 in wg).⁵ Of the 274 pressure readings for AI rooms, 186 (68%) of the readings showed compliance with the CDC recommendations.

Air-balance data obtained from maintenance and operation records for these rooms showed that the rooms all had appropriate numbers of air changes per hour (ACH). All sampled isolation rooms had greater than the minimum of 6 ACH required by the CDC, but less than the 12 ACH that the CDC recommends. Although only one room, AI 6a, met the CDC recommendations that air be exhausted from the room at a rate of 10%, or 50 cubic feet per minute (cfm), greater than air supplied, two rooms were within 5 cfm of this requirement and the other was within 15 cfm.

Protective Isolation Rooms

The pressure differentials of the six PR (PR 4a to PR 4f) were much stronger than the AI rooms or the standard rooms (see Table). The PR pressure differentials also fluctuated to a much greater degree than the other two types of rooms. The average pressure for the PR was 8.3 Pa (median, 7.7 Pa) with an IQR of 8.8 Pa. There currently are no required positive pressure levels established for protective environment rooms. While the other types of rooms were relatively stable in pressure over time, the PR showed a large number of fluctuations, with a few sudden, dramatic changes in pressure.

The pressure differential of room PR 4d, for example, located in the middle of a set of four rooms, suddenly

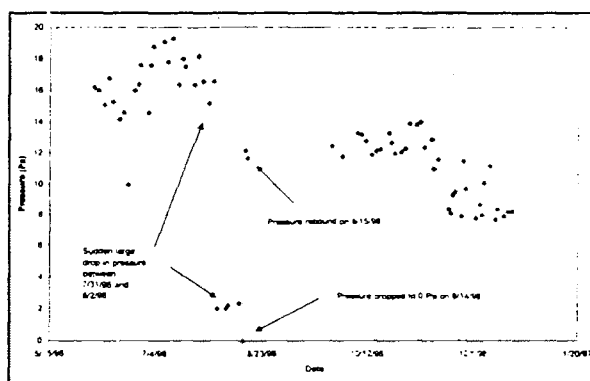


FIGURE 2. Pressure fluctuation in a protective isolation room (PR 4).

dropped from 16.6 Pa to 2.0 Pa between two sample readings, taken 2 days apart. Twelve days later, the pressure dropped further to 0.0 Pa for this room (Figure 2). The following day, after notification of hospital maintenance staff, the pressure in this room was restored to 12.0 Pa after the fan belt was tightened. Sudden pressure increases or decreases such as this occurred in five of the six sampled rooms, with an average pressure change of 10.1 Pa, and ranging from 3.7 Pa to 14.6 Pa. The two PR that did not experience sudden pressure changes, PR 1a-r and PR 3, showed gradual increase or decrease in pressure over the entire sampling time, with overall pressure changes in the magnitude of 10.8 Pa and 3.4 Pa, respectively.

In most rooms, the rate of air change in the PR was somewhat lower than the original design of 15 ACH.⁴ However, the differences between the supply and exhaust rates were found to be 125 cfm or greater, which would help to ensure the room maintained positive pressure.

Room Pressure and Weather Variables

Analysis of weather variables by multiple regression showed little correlation for all rooms between the atmospheric pressure ($P > .05$) and room pressure, relative humidity ($P > .05$) and room pressure, or wind direction and speed ($P > .05$) and room pressure. One influencing factor on room pressure, in terms of weather, appeared to be outdoor temperature, with a slight statistical correlation ($R^2 \leq 0.5$) for 11 of the 18 rooms. The effect was negligible in a practical

sense, with an increase in room pressure of less than 0.01 Pa for each 1 degree Fahrenheit increase in outdoor temperature. Physical explanations for this association are not clear, though they may involve air movement within the building associated with stack effect.

DISCUSSION

This study demonstrated room-pressure fluctuations for the three types of rooms sampled using a method that quantifies the pressure differential. Because most of the studies use a qualitative analysis method vis-a-vis smoke stick, the degree of pressure (airflow direction) has been subjective.

The standard rooms in this study, which were not under any special ventilation control, were expected to have the greatest degree of variation in pressure. The results show, however, that the mean standard room pressurization during the study period was similar to the mean AI pressurization. Likewise, the IQR also was similar for the two rooms, although only about 30% of the readings for standard rooms would have met the CDC's 0.001 in wg requirement for isolation rooms, whereas 68% of the AI rooms met this requirement.⁵ The similarity of the pressurization for the two room types, along with the inconsistency of pressure magnitude, gives evidence of a need for better pressurization control in isolation rooms.

Some authors have suggested the need for greater pressure differentials for isolation rooms than the 0.001 in wg (0.25 Pa) that is recommended by the CDC.⁵ These suggestions have ranged from 0.005 to 0.05 in wg (0.5 Pa to 12.5 Pa).^{6,9} The American Institute of Architects reportedly will recommend in its 2001 guidelines for hospital construction that isolation rooms be constructed to maintain pressures differentials of 0.01 in wg (2.5 Pa). Greater pressure differentials may help to establish and maintain better infection control, but rooms still will need to be monitored closely. This is evidenced by the sharp fluctuations in the PR in this study, which maintained large pressure differentials, but occasionally experienced sharp drops in pressure differential. Therefore, while magnitude of pressure differential is an important factor for the special ventilation room (SVR), other factors need to be considered as well, including air tightness (seal) of the room, careful maintenance, and continuous monitoring of rooms.

The level of pressure due to the offset of ventilation (supply vs exhaust or return) in an SVR may be obviated with a room designed with excessive leakage. In fact, the areas in hospitals are designed to include smoke-barrier status, which means smoke should not be able to penetrate such areas, according to code requirements.¹⁰ Such a basic consideration for making an area airtight already is incorporated into healthcare design; however, little attention is paid to the detail necessary to seal a room completely to prevent leakage of air. The leakage occurs naturally around windows, utility connections (plumbing, electrical, and gas connections), and basic construction detail. To control air leakage and better maintain consistent pressurization of SVR, considerations for an airtight

design should include solid ceilings, caulked connections, and sealed windows.

During construction of the hospital studied, considerations for an airtight design were followed for PR,⁴ but not for AI. When selected rooms of each type (PR and AI) were tested with a pressure test device (blower door) for routine maintenance, pressure was applied to 50 Pa. The airflow into the room at that pressure was monitored, with the AI room allowing for 1,500 cfm leakage while the PR allowed for 150 cfm (personal communication, Andrew Streifel, MPH, 1997). However, the leakage around the ceiling panels in the AI rooms proved excessive. Until such deficiencies are corrected, control remains inconsistent.

It must be recognized that maintenance procedures should be conducted on ventilation systems, including adjusting dampers, tightening fan belts, testing fire-management systems, and thermostat adjustments. However, all of these maintenance operations potentially can alter the ventilation intention of an SVR. For example, we detected large pressure changes in a PR due to change in the position of a room return damper. Such a change was a result of an employee inadvertently moving the damper while cleaning dust from the surface, which resulted in an increase of airflow out of the room. In another instance, a fluctuation in pressure for an AI room was thought to be the result of tightening a fan belt; hence, making the exhaust fan more efficient by moving more air. The rooms with minimal pressure gradients are prone to such changes, which can result in the change of room airflow direction.

Fire-management tests required by the Joint Commission on Accreditation of Healthcare Organizations also may result in altered SVR pressurization if dampers do not reset. The common use of variable air volume in corridors may also change airflow direction in AI rooms that have minimal pressure differentials (<0.25 Pa) due to thermal comfort adjustments brought on by the thermostat demand for change of temperature.

These potential factors for altering airflow indicate a need for close monitoring of pressure variation. Unfortunately, pressure-monitoring devices have additional problems associated with nuisance alarms, often due to low pressure differentials. The PR in this study were equipped with Velocitrol (Honeywell, Minneapolis, MN) pressure monitors that were available during the design and construction phase of the University of Minnesota Hospital and Clinic.⁴ These monitors would sound an audible alarm if the airflow to a PR became too low, although the monitors were not equipped to provide quantitative or logged data. The advantage of such continuous monitoring is that it identifies changes occurring in critical ventilation systems that may alter the intended SVR purpose. For example, in the hospital studied, when a fan belt would start to slip, the alarm for the room at the end of a duct run would sound, indicating a problem with the airflow. This alarm would help to dictate maintenance schedules.

The results of this study indicated changes in the room pressures that at times altered the SVR ventilation

intent, which potentially could result in an infectious event. With the tuberculosis ventilation regulation, the AI are required to be evaluated before admission of a potential tuberculosis patient. There is not a regulation for PR. Continuous monitoring of SVRs is necessary to assure consistent airflow direction in critical patient-care environments. Hospitals should be designed to identify special ventilation needs with specification for ventilation control parameters.¹¹ Without detailed SVR standards, especially for creating an airtight (sealed) room, ventilation control may be inconsistent.

REFERENCES

- Ikeda RM, Birkhead GS, DiFerdinando GT Jr, Bornstein DL, Dooley SW, Kubica GP, et al. Nosocomial tuberculosis: an outbreak of a strain resistant to seven drugs. *Infect Control Hosp Epidemiol* 1995;16:152-159.
- Fraser VJ, Johnson K, Primack J, Jones M, Medoff G, Dunagan WC. Evaluation of rooms with negative pressure ventilation used for respiratory isolation in seven midwestern hospitals. *Infect Control Hosp Epidemiol* 1993;14:623-628.
- American Institute of Architects Academy of Architecture for Health and USDHHS. Guidelines for minimum requirements for construction and equipment in hospitals. In: *Guidelines for Design and Construction of Hospital and Health Care Facilities, 1996-1997*. Washington, DC: AIA Press; 1996.
- Murray WA, Streifel AJ, O'Dea TJ, Rhame FS. Ventilation for protection of immune compromised patients. *ASHRAE Transactions* 1988;94:1185-1192.
- Guidelines for preventing the transmission of *Mycobacterium tuberculosis* in health-care facilities, 1994—CDC. Notice of final revisions to the "Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in health-care facilities, 1994." *Fed Regist* 1994;59:54242-54303.
- First MW. Ventilation for biomedical research, biotechnology, and diagnostic facilities. In: Liberman DF, Gordon JG, eds. *Biohazards Management Handbook*. New York, NY: Marcel Dekker, Inc; 1989:45-72.
- Nicas M, Sprinson JE, Royce SE, Harrison RJ, Macher JM. Isolation rooms for tuberculosis control. *Infect Control Hosp Epidemiol* 1993;14:619-622.
- Hitchings DT. Laboratory Space Pressurization Control Systems. *ASHRAE Journal* 1994;362:36-40.
- Rousseau CP, Rhodes WW. HVAC system provisions to minimize the spread of tuberculosis bacteria. *ASHRAE Transactions* 1993;99:1201-1204.
- National Fire Protection Association. Life Safety Code 101. Quincy, MA: NFPA; 1997.
- Streifel AJ, Marshall JW. Parameters for ventilation controlled environments in hospitals. In: *Design, Construction, and Operation of Healthy Buildings. LAQ 97*. Bethesda, MD: ASHRAE Press; 1998.

Chile Establishes Law to Control Antibiotic Use

Jaime Labarca

Antibiotics commonly are sold over the counter in Latin American countries. Bavestrello and colleagues from Hospital Dr. Gustavo Fricke, Viña del Mar, Chile, recently studied antimicrobial use and related costs in Chile and reported on how these data were used to implement a governmental policy mandated on prescriptions. Using antibiotic sales in Chile, per year, either in grams of antibiotics or in sale units, they reported a significant increase in the daily defined dose (DDD) per 1,000 person-days. From January 1997 to December 1998, they reported a 498% increase in amoxicillin, 309% increase in oral cephalosporin, and a 473% increase in oral fluoroquinolones. Chloramphenicol was the only antibiotic that decreased (18%) during this period.

A number of groups, including the Chilean Scientific Societies, Ministry of

Health, National Health Institute, and the Health Commission of Congress, met to review these data. It was agreed that a law requiring medical prescriptions for antibiotics was needed. Since it was anticipated that the law would be unpopular, a national educational campaign to rally public support was developed with assistance from the Chilean College of Physicians, the Chilean College Pharmacists, and the National Consumer Services.

One year after the intervention, a second study was done to evaluate the change in consumer behavior and trends in consumption of antibiotics. This second study compared the use of antibiotics in two trimesters, during the same calendar months, the first one before and the second one after the intervention. (October-December 1998 vs the same period in 1999). The consumption and sale of amoxicillin decreased 36%, ampicillin 56%, and

erythromycin 30%. This change resulted in a \$6.4 million (US) savings for the period of 1998 to 1999.

The studies show how scientific data can be used to influence governmental policy to optimize antibiotic use and to help prevent antimicrobial resistance. A collaborative effort among scientific societies and the government contributed to the success of this program. The researchers note that Chile is the first Latin American country to establish mandatory medical prescription for controlling antibiotic use in the outpatient setting.

FROM: Bavestrello L, Cabello A. (1) First evaluation of the impact of the regulatory measures on antibiotic use in the outpatient setting in Chile. (2) Trends of use of antibiotics in Chile in the last 10 years. Presented at the XVII Annual Conference of the Chilean Infectious Diseases Society. August 2000; Viña del Mar, Chile.

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ORIGINAL ARTICLE

Room-Based Assessment of Mobile Air Cleaning Devices Using a Bioaerosol Challenge

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Abstract

Introduction: The widespread transmission of the SARS-CoV-2 virus has increased scientific and societal interest in air cleaning technologies, and their potential to mitigate the airborne spread of microorganisms. Here we evaluate room scale use of five mobile air cleaning devices.

Methods: A selection of air cleaners, containing high efficiency filtration, was tested using an airborne bacteriophage challenge. Assessments of bioaerosol removal efficacy were undertaken using a decay measurement approach over 3 h, with air cleaner performance compared with bioaerosol decay rate without an air cleaner in the sealed test room. Evidence of chemical by-product emission was also checked, as were total particle counts.

Results: Bioaerosol reduction, exceeding natural decay, was observed for all air cleaners. Reductions ranged between devices from <2-log per m³ room air for the least effective, to a >5-log reduction for the most efficacious systems. One system generated detectable ozone within the sealed test room, but ozone was undetectable when the system was run in a normally ventilated room. Total particulate air removal trends aligned with measured airborne bacteriophage decline.

Discussion: Air cleaner performance differed, and this could relate to individual air cleaner flow specifications as well as test room conditions, such as air mixing during testing. However, measurable reductions in bioaerosols, beyond natural airborne decay rate, were observed.

Conclusion: Under the described test conditions, air cleaners containing high efficiency filtration significantly reduced bioaerosol levels. The best performing air cleaners could be investigated further with improved assay sensitivity, to enable measurement of lower residual levels of bioaerosols.

Keywords: air cleaner, purification, HEPA, UV-C, bioaerosol, bacteriophage

Introduction

Air cleaning devices are intended to remove particulate material from the air, generally doing so in the background while the treated area is occupied. They differ in design and not all contain scientifically proven technology or provide relevant test data to support manu-

facturer claimed performance.¹ The claims made for the benefits of air cleaners have become so widely publicized, especially in the context of the COVID-19 pandemic, that a rapid evidence review was commissioned by United Kingdom (UK) Government in late 2020, to consider the efficacy of various systems.²

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The information from Scientific Advisory Group for Emergencies-Environment and Modelling Group (Sage-EMG) and Chartered Institution of Building Services Engineers^{1,2} emphasizes that air cleaners are most appropriate for spaces where there is insufficient ventilation and/or where existing ventilation cannot be improved. The Sage-EMG also concluded that air cleaning devices using germicidal UV and/or high efficiency air filtration are most likely to achieve safe and effective bioaerosol removal, but that other air cleaning systems, such as those emitting free radicals or ionizing effects, are not excluded from consideration. These other particulate removal methods are, however, deemed less likely to have the impact required to influence airborne disease transmission, based on data available at the time of that review.²

Air cleaners are typically left running for long periods in treated spaces and as such, they should not produce harmful chemical by-products.³ One way to assess their performance is by measuring their clean air delivery rate (CADR). This indicates how rapidly an air cleaner can remove airborne particles from the air of a room and the higher the CADR, the more particles the air cleaner will remove and the larger the room volume it can serve.⁴⁻⁶ Some available systems are scalable, and others can be inserted into existing ventilation ductwork.¹ For the purposes of this study, only floor-standing or wall-mounted units were tested.

Most published air cleaner studies are small-scale assessments of one or two devices, with test conditions often differing greatly between studies, making comparisons of performance difficult. Some published reports are based on first principles, rather than scientific evidence.⁷ Others relate to non-biological air quality tests, rather than bioaerosols.^{8,9} In terms of expressing measured efficacy, some authors have used disease incidence or frequency of disease symptoms in a setting as a measurement method.^{10,11}

Other reports present environmental contamination levels measured before and after air cleaner intervention.^{9,12,13} However, precise data about the ability of a device to reduce bioaerosol levels remain limited and there is little consistency across the design of investigative tests. At the time of writing, no internationally accepted test standard exists for evaluating air cleaning devices performance against bioaerosol challenge, even at the most basic level. Straightforward side-by-side comparisons of multiple systems are also rare.

Safety in use is an important consideration for these devices but despite their widespread marketing, relatively little safety information exists. A published guidance note to health care premises does describe conditions for safe operation.¹⁴ This includes the recommended use of respiratory protective equipment and/or personal protective equipment when filters are changed and the importance of following the manufacturer's instructions

in relation to high efficiency particle arrestance (HEPA) filter/UV lamp replacement and any periodic cleaning of the air cleaner's interior surfaces.

Some reports have suggested ozone as a possible by-product, though this is dependent on the air cleaning mechanism used. Electrostatic particle precipitators are reported as those most likely to cause this by-product due to their use of corona discharge mechanisms.¹⁵ For other types of air cleaner the published information for ozone by-product is limited.¹⁶ Some air treatment devices do produce localized ozone by design, utilizing its biocidal effect, but these systems are generally based on the use of UV and ozone, have no HEPA filtration, and are outside the scope of this study.

The main aim of this study was to test and compare the performance of five air cleaning devices of standalone floor or wall-mounted design, incorporating either HEPA filtration only or HEPA filtration in combination with germicidal UV. The assessments were made using bacteriophage MS2 (hereafter known as MS2), as a bioaerosol challenge, with viable MS2 recovery assessed, alongside parallel total particle count data. MS2 is a single-stranded RNA virus that has been widely used as a mammalian virus surrogate and is known to survive well during aerosolization.¹⁷⁻¹⁹

The five tested devices were all monitored for ozone and hydrogen peroxide (H₂O₂) by-product generation using calibrated measurement sensors capable of parts per million (PPM) level detection or better.

Methods

Air Cleaner Systems Tested

For the purposes of this publication, we refer to the test equipment based on specification and design principles, rather than by brand name. The systems on test are described in Table 1 and all were run on their maximum flow rate during testing, if this feature was adjustable.

Test Room Facility

All testing was carried out in a fully gas sealable exposure chamber of brushed stainless steel construction, with a 34 m³ room volume and temperature and humidity control stabilized at 22°C and 40% relative humidity (RH) respectively, before each test. A stationary air mixing fan, 0.8 m high, was used to ensure the uniform mixing of particles inside the chamber for the duration of each test. On completion of each test, the room was purged with clean air for 30 min, before staff re-entering the room to recover equipment and materials.

Bioaerosol Generation

Bacteriophage MS2 (ATCC 15597-B1) was used as a bioaerosol test challenge for this work. Fresh cultures of MS2 were prepared from frozen bacteriophage stocks and propagated in *Escherichia coli* using nutrient broth

Table 1. Air cleaning equipment tested

Device ID reference	Mode of operation	Additional comments	Claimed air flow rate (if known)
#1	Combined high efficiency filtration and cold atmospheric pressure plasma unit	Small, portable unit. Floor or table top mounted. Brushed steel outer casing. Manual control. Dimensions: $0.19 \times 0.35 \times 0.28$ m. Max. claimed noise level: 55 dB	Claimed max. $150 \text{ m}^3/\text{h}$ with the specification tested. Scalable, depending on application.
#2	Circular HEPA filter unit with radially dispersed clean air delivery.	Wall mounted. Combined powder-coated steel/plastic outer casing. Manual control. Dimensions: $0.2 \times 0.5 \times 0.5$ m. Max. claimed noise level: 72.5 dB	Claimed max. $600 \text{ m}^3/\text{h}$
#3	HEPA EN 1822 H14 level air filtration unit with activated carbon filter.	Wall mounted with heavy duty powder-coated steel outer case. Remote control. Dimensions: $0.59 \times 0.39 \times 0.42$ m. Max. claimed noise level: 58 dB.	Claimed max. $1440 \text{ m}^3/\text{h}$ with cyclonic air circulation, designed to mix room air. Scalable, depending on application.
#4	HEPA EN 1822 H13 with activated carbon filter and UV lamp emitting at 253.7 nm.	Floor-standing unit with lightweight metal case. Remote control. Dimensions: $0.43 \times 0.13 \times 0.72$ m. Max. claimed noise level: 55 dB.	Claimed max. $380 \text{ m}^3/\text{h}$
#5	PM20 grade cotton prefilter, HEPA filter with activated carbon filter. UV lamp emitting at 253.7 nm.	Small portable unit. Floor or tabletop standing. Remote control. Dimensions: $0.30 \times 0.33 \times 0.13$ m. Noise level: not given.	Total air flow rate not provided but claimed CADR: $62 \text{ m}^3/\text{h}$

CADR, clean air delivery rate; HEPA, high efficiency particle arrestance.

(Oxoid) without supplements. Briefly, the preliminary *E. coli* culture (*E. coli* ATCC[®] 15597) was prepared by adding 1 mL *E. coli* stock to 100 mL nutrient broth (1.3% w/v) and maintained at 37°C for 3–4 h in a shaking incubator at 70 rpm. A 100 μL volume of MS2 stock was added to the *E. coli* host culture and maintained overnight at 35°C in a shaking incubator at 70 rpm.

After incubation, the MS2 suspension was centrifuged at 3000 rpm (1690 g) for 10 min to remove host cell debris. The supernatant was filtered consecutively through 0.45 and 0.2 μm filters (Millipore, United Kingdom). To quantify the stock MS2 as plaque forming units per mL (PFU/mL), the freshly filtered stock was diluted using a 10-fold serial dilution in phosphate-buffered saline (PBS). One hundred microliters of each dilution was mixed with 300 μL *E. coli* (3–6 h culture). The MS2:*E. coli* mix was then added to 3 mL nutrient agar overlay and poured onto 1.5% Oxoid nutrient agar plates without supplements and incubated overnight at 35°C. PFU/mL of the MS2 stock was then back calculated. Forty milliliters volumes of MS2 were added to the Collison nebulizer before each test run.

A bioaerosol of MS2 was generated in the exposure chamber using a Collison 6-jet nebulizer,²⁰ operated from breathing quality compressed air delivered at 25 psi for 30 min. This provides a nebulizer flow delivery rate of 12 L/min. The liquid bacteriophage suspension was prepared so as to sit at a starting level exactly 1 cm above the lower tip of the Collison inlet tube, as recom-

mended by the supplier. An assessment of particle sizes generated by the Collison nebulizer, based on Optical Particle Sizer (OPS) measurement, confirmed that the majority of nebulized particles fell within 0.1–1.4 μm size range (data not shown).

This is consistent with the findings of others^{21,22} and is within the respirable particle size fraction, that is, if inhaled, a particle of this size may penetrate deep into the lungs, rather than depositing in the upper airways. It is known that the diameter of droplets generated by sneezing, coughing or speech may vary from <1 to 100 μm , but also recognized that those particles in the medium to large size range may either fall out of the airborne state, or else reduce in diameter due to rapid drying effects while in the airborne state.^{23–25} Based on these earlier reports, the particle sizes produced by the Collison nebulizer were deemed appropriate for this air cleaning challenge study.

Bioaerosol Testing Procedure

Before bioaerosol generation, with the test chamber stabilized at a target temperature of 22°C and 40% RH, the stationary, oscillating air mixing fan was turned on to ensure uniform distribution of aerosols inside the chamber.

Twelve all glass impingers (AGI-30²⁶), each containing the recommended volume of sterile PBS, were placed in the chamber at one collective location. These were used to sample the air sequentially at 12.5 L/min over

four time points across a 3 h test period. The impingers were secured to their stands at worktop height. Vacuum pumps, positioned outside the test chamber, were connected to these via Teflon tubing running through a sealed port in the wall of the test room, allowing pump control from outside the test room. Three impingers were run simultaneously for 15 min at each time point as follows: immediately after aerosol generation ($T=0$); after $T=1$ h; $T=2$ h and $T=3$ h.

Using the earlier cited test conditions and sampling time points, three identical “baseline” control runs were undertaken, to assess the natural decay of the bio-aerosol over 3 h with no air cleaner in the room. A fourth control run was later completed as a final check of sampling equipment performance. This was done before air cleaner testing and the baseline testing was therefore the only test sequence to include four test runs, rather than three. This was then followed by three repeat test runs for each of the five air cleaner devices.

A pre-calibrated optical particle scanner TSI OPS (TSI, Buckinghamshire, UK) was used to log particle measurements over the test period, commencing at background levels just before activating the nebulizer, through to each run completion point. Particle count measurements were made for all control and test sampling runs.

Sample Processing and Quantification

A fresh *E. coli* culture was prepared for each test run by adding 1 mL *E. coli* stock suspension (10^{10} to 10^{11} CFU/mL) to 100 mL nutrient broth and incubating at 37°C for 4 h at 70 rpm in a shaking incubator. Impinger PBS sample volumes were removed by pipetting, and the recovered volume was noted. Sample losses during impinger use were calculated, and fresh sterile PBS was added to replenish the original total volume for each impinger. The air sample suspensions and MS2 stock (as used in the Collison nebulizer) were each prepared as 10-fold serial dilutions. Each dilution of MS2 sample was added in 100 μ L volumes to 300 μ L of the 4 h *E. coli* culture.

The MS2/*E. coli* was then mixed with 3 mL of nutrient semi-solid overlay (maintained at 55°C until used) and immediately poured onto nutrient agar plates. Samples were left to cool and solidify for 20 min and incubated at 35°C for overnight. After incubation, plates were examined visually for PFU, were counted and log reduction was calculated.

Ozone and H₂O₂ by-Product Measurement Close to Air Cleaners

Ozone levels were measured using a 2B Technologies Model 205 Dual Beam Ozone Monitor, accurate to within 1 part per billion (ppb). The pre-calibrated monitor was located outside of the test room, and appropriate diameter Teflon™ tubing was run in to the test area via an access port, with the tip of the tubing placed within

10 cm of the outlet of the air cleaner. Ozone levels were logged constantly, for the duration of each test. H₂O₂ levels were measured with an ATI Portasens III D16 portable gas detector fitted with a newly calibrated low level H₂O₂ sensor, capable of detecting to 0.1 ppm. The whole monitor was placed with its sampler tip within 10 cm of each device during air cleaner operation. The UK workplace exposure limit for both chemicals falls within the low ppm range.²²

Statistical Analysis

The microorganism concentration used for analysis was the mean of the air samples taken at each time point ($T=0$ h, $T=1$ h, $T=2$ h, $T=3$ h) across the multiple test runs. The bacteriophage impinger-based sampling method had a lower limit of detection (LOD) of 200 PFU/m³ of sampled room air. Therefore, an observed value of zero PFU of air might not represent a true zero. To account for this, a $\frac{1}{2}$ LOD value was used in place of a zero reading at sample level, before taking the mean of the three samples at each sampling time point.

Reduction in microorganism levels after 3 h of air cleaning treatment was measured using log reduction analysis over the test period, which was calculated as $\log_{10}$ (untreated air concentration) minus $\log_{10}$ (treated air concentration). As there were three runs for each air cleaning system, there are three log reduction figures and $\log_{10}$ (untreated air concentration) figures for each system. These data are best summarized by showing the range of the values obtained.

The variation in log reduction and log concentration with time was also determined for each system and plotted on graphs to allow a comparison of the systems. These figures were obtained by calculating the mean concentration at each time point across all samples and all runs for each system and then taking the log value. Thus, each point plotted is a log of the mean, rather than a mean of the logs.

The CADR combines the effects of filtration efficiency and the effectiveness of the air cleaner to draw the test chamber's air through it.^{4,5} CADR, therefore, provides an indication of comparable performance between different air cleaning systems. Foarde^{4,5} refers to CADR as CARm when it is applied to microbiological (bio)aerosols, and provides a formula for calculating CARm, which has been applied here in a slightly amended form to derive a metric (rather than imperial) measure:

$$\text{CARm} = 60V(k_e - k_n)$$

where: V is the volume of the test chamber in m³; k_e is the measured particulate decay rate (min⁻¹) for the bioaerosol; k_n is the natural decay rate (min⁻¹) for the bioaerosol; The expression is multiplied by 60 so that CARm is measured in units of m³/h.

The particulate decay rate is defined as the decrease in particles while the air cleaner is operating, whereas the natural decay rate is the decrease when an air cleaner is not used. The work of Foarde^{4,5} provides the formula that is used to calculate decay rate.

The CARM calculations were performed twice; first using the culture-based PFU data, and second using OPS particle counts, which were total counts of all particles within the test room air. In calculating CARM, the concentration of bioaerosols at all available time points was used. As the PFU concentration was measured at $T=0$ h and subsequently every hour for 3 h, the PFU dataset comprises four time points in each run that were used to calculate CARM. This was in contrast to the calculation of log reduction, where only the initial and final time points were used.

The OPS particle counts covering a wide range of particle sizes were logged, reflecting the range of particles present in the test room after bioaerosol generation. The Collison nebulizer produces particles mainly within the 1–10 μm range, and where particles of $<1 \mu\text{m}$ are present, these are counted less reliably by the OPS. For this reason, particles of $<1 \mu\text{m}$ were excluded from the OPS data analysis. The OPS allocates counted particles in to “bins” based on their size, and the closest bin to 1 μm had a minimum threshold of 1.117 μm , so all particles of this size or larger were included. These particles were summed at each time point.

For the purposes of calculating CARM, OPS data were used from the point at which aerosol generation was at its peak (immediately after the aerosol generator was stopped), until completion of the $T=3$ h triplicate air samples. Any values before or after these periods were excluded as they did not relate to the monitored bioaerosol decay period.

For both CARM calculations (using PFU and OPS counts), the decay rate was calculated for each run, and the mean rate obtained for each system, before calculating CARM and its standard error. The formula for the standard error of the CARM was derived here from the standard errors of the decay rates and the formula for CARM above. For example, for air cleaner #4:

Standard error of mean baseline decay rate, SE_B

$$= \sqrt{\frac{\text{Variance of baseline decay rate}}{\text{Number of baseline runs (4)}}}$$

Standard error of mean air cleaner #4 decay rate, SE_N

$$= \sqrt{\frac{\text{Variance of air cleaner #4 decay rate}}{\text{Number of air cleaner #4 runs (3)}}}$$

Standard error of CARM estimate for #4

$$= 60V \sqrt{(SE_B^2 + SE_N^2)},$$

where V is the air volume of the test chamber in m^3 .

Results

Log Reduction

The range of log reduction results obtained after a 3 h test period and $\log_{10}$ (untreated air concentration) for each system across the experimental runs are shown in Table 2.

The untreated concentration of bioaerosol in the room at the start of each test represents the maximum theoretically achievable log reduction, that is, bioaerosol levels present in the room air just as bioaerosol generation was stopped and air cleaning commenced. Bioaerosol reduction exceeding natural decay was observed for all air cleaners. Reductions varied between devices from <2 -log for the least effective, to a >5 -log reduction for the three most efficacious systems (Table 2).

In Table 2, performance differences can be seen for systems 1 and 4. For a well-performing air cleaner, a greater potential for bioaerosol reduction is best demonstrated when the bioaerosol challenge concentrations are higher. Table 2 shows that the starting concentrations for system 1 were lower at the top and bottom of the indicated range compared with systems 2, 3, and 4, despite efforts to maintain bioaerosol challenge consistency across tests.

This may have limited the demonstrable performance of system 1 compared with other air cleaners. Conversely, systems 2 and 5 had very similar bioaerosol starting concentrations, but showed quite different overall log reductions, and here it is clear that system 5 performed less effectively than system 2.

Full bioaerosol removal was never achieved for any of the test systems (Table 2). For some systems, this was where a zero PFU observation was observed after treatment, but where the assay LOD adjustment meant that a PFU figure above zero was substituted instead. This may have underestimated the actual removal efficiency of some air cleaning systems.

Table 2. Range of log reduction values and the range of log(untreated air concentration) values

System identifier	Log reduction range		Log(untreated air concentration) range ^a	
	Minimum	Maximum	Minimum	Maximum
Baseline ^b	0.12	1.55	7.59	9.90
#1	3.14	3.37	5.99	7.30
#2	4.03	5.41	8.14	8.64
#3	3.13	5.39	7.24	8.54
#4	4.71	5.31	7.44	8.86
#5	1.91	2.37	7.89	8.61

Log(untreated air concentration) varies for each system and each run and represents a “ceiling” for maximum log reduction that could be achieved.

^aThis range represents the bioaerosol concentrations immediately after the generation of the bioaerosol atmosphere but before air cleaner was switched on for systems #1 to #5.

^bNatural bioaerosol decay range observed over 3 h and based on four control runs, with no air cleaner in room.

Also in Table 2, the untreated bioaerosol baseline value represents a worst-case scenario in terms of bioaerosol decline as this is where no air cleaner is used and only the natural airborne decay of the MS2 challenge was recorded. Table 2 shows that test system 5 was the least effective of the systems tested, as it gave low levels of log reduction that were substantially below the other systems on test. From Table 2, systems 2, 3, and 4 all gave higher log reductions than system 1, but they also had higher untreated (starting) concentrations.

System 4 performance appeared better than the other systems. However, three data points were recorded for each test system, and at each time point a substantial spread of bioaerosol reduction values was observed despite the consistently applied test approach. This was especially true for system 3, and more data would be needed to unequivocally confirm which system (2, 3 or 4) offered the best levels of log reduction overall, based on PFU counts.

The change in log reduction over time, after the activation of each air cleaner, is shown in Figure 1. The data were derived from the log of the mean of the three test run concentrations obtained at each time point. Each system is represented by a different color and a different line type. As would be expected, the baseline data (no air cleaner) display the lowest rate of log reduction. The worst performing air cleaner system was system 5.

Of systems 1 to 4, three gave substantially higher log reductions (of around 4 logs) during the first hour, whereas the fourth system (system 1) was less effective, with a log reduction of only 1.1 logs after the first hour. However, system 1's log reduction performance continued to increase in a linear manner throughout the test period, reaching 3.3 logs after 3 h. The performance of systems 2 and 3 leveled off after the first hour, so that

their log reductions were 4.4 and 4.0 logs respectively after 3 h. System 4 performance leveled off only after 2 h, achieving a bioaerosol reduction of 5.3 logs after 3 h. Based on Figure 1, system 4 was the best performing air cleaner of those tested.

Table 3 shows the log reduction achieved for each system after 3 h alongside values for the untreated concentration. These data also show the log reduction as a percentage of the "ceiling," another indication of overall system performance, with system 4 again giving the greatest impact by this measure, system 5 the least. Figure 1 presents these data visually, showing the progressive log reduction for each system over time, with Figure 2 providing a further comparison of system performances, showing variation in log concentration over time.

Despite a number of zero PFU counts being recorded over the course of all testing (17 zero counts from a total of 45 mean PFU counts obtained during air cleaners use; data not shown), Table 3 confirms that the adjustment of zero counts using $\frac{1}{2}$ LOD values had only a small effect on calculated log reduction. Data obtained with or without a zero count adjustment demonstrated the same trends and very similar measurement values for each tested air cleaner.

Clean Air Delivery Rate

The calculations of CARM based on PFU concentrations are shown in Table 4 in descending order of efficacy and show that system 5 was the least effective system tested. This was consistent with calculations based on bioaerosol log reduction data, with system 1 the next worst performer. Data in Table 4 show that system 4 had the highest CARM based on PFU concentrations. However, the relatively high standard errors for the three units

Figure 1. Observed log reduction after 3 h and log (untreated air concentration) values by system and run. The log reduction at each time point after the air cleaner is activated is shown. The log reduction here is derived from the log of the mean of the MS2 bacteriophage concentrations across the three runs for each system (four runs for untreated baseline air).

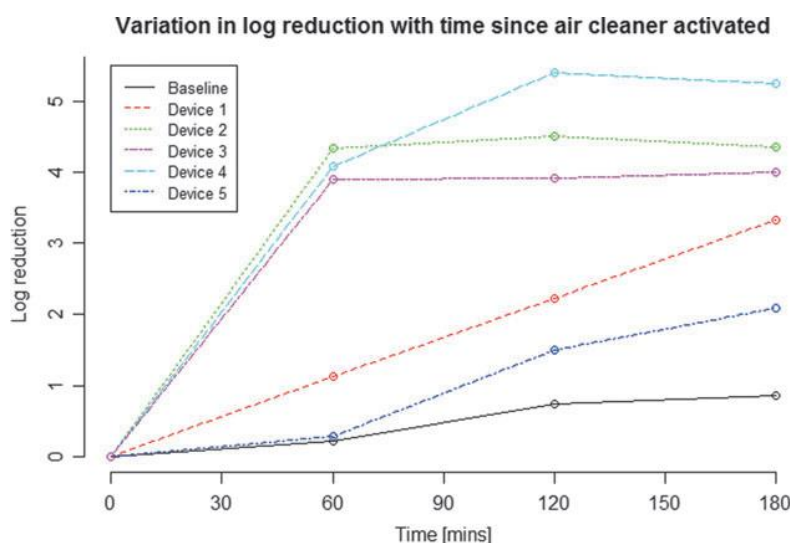


Table 3. Log reduction value after 3 h and showing the “ceiling” log reduction

System	Log reduction after 3 h			Log reduction (as percentage of “ceiling”)	
	Zeroes replaced with $\frac{1}{2}$ LOD value	Include zero counts	“Ceiling” log reduction	Zeroes replaced with $\frac{1}{2}$ LOD value (%)	Include zero counts (%)
Baseline	0.85	0.85	9.38	9	9
1	3.32	3.36	6.99	48	48
2	4.36	4.36	8.48	51	51
3	4.00	4.00	8.15	49	49
4	5.25	5.34	8.46	62	63
5	2.09	2.09	8.45	25	25

The log reduction is derived from the log of the mean of the concentrations across the three runs for each system (four runs for baseline). Two scenarios are included: the first where recorded zero PFU counts are substituted with $\frac{1}{2}$ LOD values; the second where the zero counts are included and not replaced. LOD, limit of detection; PFU, plaque forming units.

with the highest CARM values mean it is not possible to conclude from these data which was the best performing system. System 3 had a particularly high standard error, and this was consistent with the observations in Table 2, as influenced by its performance during test run 1, which was better than its second and third test runs.

An Analysis of Variance test found that there was a highly significant difference in the system decay rates underlying these CARM values (p -value=0.006). A Tukey multiple comparison of means (with a 95% family-wise confidence level) showed that none of the system decay rates were found to be significantly different from each other (adjusted p -value >0.05), with the following exceptions: systems 5 and 2 were significantly different (adjusted p -value=0.021) as were systems 5 and 4 (adjusted p -value=0.006). Importantly, when comparing the decay rates of the best two performers (4 and 2), the adjusted p -value was 0.89.

The calculation of CARM based on OPS counts (Table 5) found that system 1 gave a low CARM value. This was surprising, given the system’s better perfor-

mance based on PFU concentrations, and implies that the OPS data for system 1 may have been skewed. It was noted that the raw OPS particle data for system 1 contained a high number of coincidence error readings (data not shown). This occurs when bioaerosol levels exceed the upper accurate detection range for the OPS and would have influenced OPS particle detection accuracy. Of the remaining systems, system 5 had the next lowest CARM, with a similar value to that obtained using PFU concentrations.

The CARM values calculated for the three remaining systems (system 2, 3, and 4) were all more than double those based on PFU concentrations (Table 4) and the order of performance was reversed, so that system 3 gave the highest CARM and system 4 the lowest CARM of these three systems.

Ozone and H₂O₂ Measurement

Only one system (#1) generated detectable airborne ozone emission during sealed room chamber testing, with a maximum 550 ppbv (0.55 ppmv) detected. This

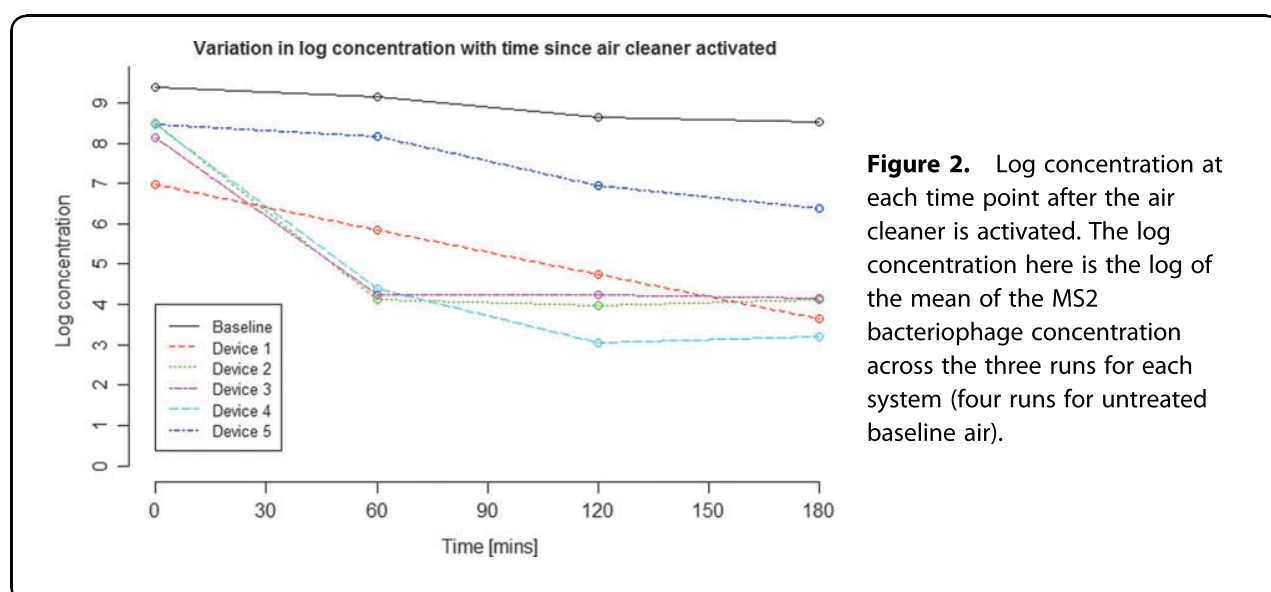


Table 4. Clean air delivery rate based on plaque forming units concentrations—shown in descending order of performance

System	CADR (m^3/h)	Standard error
4	98.0	10.2
2	86.0	11.1
3	77.3	17.7
1	57.4	6.7
5	34.6	6.9

A decay rate was obtained for each run. The CARm for each system (and its standard error) is derived from these figures.

exceeds the UK workplace exposure limit for ozone gas.²⁷ However, it was recognized that a sealed 34 m³ test environment was not representative of how the unit would be used in the real world. Its residual ozone production was, therefore, tested again in a similarly sized laboratory space with a mechanical ventilation rate confirmed at 8 air changes per hour. Under these conditions, no ozone was detectable. Similarly, there was no detectable evidence of H₂O₂ residue in the air within the test environment for any of the five air cleaners, even with the room sealed for experimental purposes.

Discussion

All systems tested here met the criteria for an air cleaner system that included high efficiency filtration and could treat the air of a room of dimensions used (34 m³). All five test systems demonstrated the ability to remove MS2 bioaerosols successfully from the test room environment, exceeding losses by natural decay alone, though considerable performance variation was observed across the equipment tested. It was always likely that such differences would be observed, since the test systems covered a range of claimed flow rates and system designs.

System 5 consistently gave the weakest performance, in terms of both log reduction (compared with maximum potential) and CADR. This coincided with the lowest claimed flow rate of the five systems so it was not surprising. System 4 gave the best log reduction profile with time. It was one of three systems giving a log reduction of around 4 logs after the first hour of operation. However, unlike systems 2 and 3, there was a further substan-

Table 5. Clean air delivery rate based on total optical particle sizer particle counts (across all bins of size $\geq 1.117 \mu\text{m}$)—shown in descending order of performance

System	CADR (m^3/h)	Standard error
3	435	16.6
2	334	3.8
4	281	11.2
5	29.1	4.1
1	4.0	4.0

A decay rate was obtained for each run. The CARm for each system (and its standard error) is derived from these figures.

tial improvement in log reduction during the second hour of operation for system 4, which was still providing the best log reduction value of all the systems tested during the later stages of the tests.

Even when the maximum achievable log reduction (based on starting concentration) was taken into account by calculating log reduction percentage, system 4 was the best performer. System 4 is a combined HEPA/UV-C treatment system and despite its overall performance, it did not have the highest claimed flow rate of the five systems, based on supplier information.

Four of the five test systems yielded some zero detectable PFU counts during testing. The LOD of the bacteriophage assay meant that this did not necessarily indicate that all MS2 bacteriophage had been removed from the test room air. The effect of adjusting the zero value using a 1/2 LOD value had little effect on log reduction results, with each system's performance trends unchanged.

Although three systems provided higher log reduction performances than system 1 over the 3 h test period, system 1 performance did not level off in the manner of systems 2, 3, and 4. Bioaerosol log reduction using system 1 increased at a constant rate, and thus we might speculate that if the test period had been longer, system 1's performance might have exceeded that of the other systems. Only a longer test period could confirm this, and this was beyond the scope of the current study.

When CADR was calculated using PFU concentrations, there was a highly significant difference in the system decay rates underlying these CARm values. System 4 gave the best performance, but there was not a statistically significant difference between this and the next best performer, system 2 or any of the other systems, apart from system 5.

The calculation of CARm based on OPS counts found that system 1 gave an unexpectedly poor CARm value. This is surprising given the system's performance based on PFU concentrations, and it implied that OPS data for system 1 were in some way inaccurate. This may have occurred because the OPS data for system 1 were found to have numerous "coincidence errors," which reflect the OPS trying to measure aerosol levels beyond its calibrated range.

If particle concentration is increased sufficiently, more than one particle occupies the same space in the OPS sensing volume and "coincidence" occurs, resulting in a drop in counting efficiency and particle sizing inaccuracy.²⁸ This can cause inconsistencies in OPS performance and may explain why the OPS CARm value was not as high as expected for system 1. Of the remaining systems, system 5 gave the next lowest CARm, with a similar value to that obtained using PFU concentrations.

However, the CARm values calculated for the three remaining systems (2, 3, and 4) were all more than double

those based on their PFU CARm performance. Based on OPS particle counts, the order of performance was therefore reversed, so that system 3 gave the highest CARm and system 4 the lowest value of these three systems.

The OPS counts and associated CARm values clearly indicate that system 3 was the best performing machine, despite the high standard error of its estimated CADR. The authors are aware of a specific recommendation for system 3 operation that may have influenced its performance. In operating this device, the manufacturer recommends it be allowed to run and acclimatize for ~30 min before testing as opposed to turning the device on immediately after bioaerosol chamber release.

To keep test conditions consistent with other systems and to allow bioaerosol delivery into the chamber immediately before air cleaner activation, this device acclimatization was not possible. This may explain some inconsistencies in the performance of system 3.

The PFU log reduction figures conclusively show system 4 as the best performing system. However, the relative performance of the different systems based on CARm varies substantially according to the type of count data used, so it is not possible to conclude which is the best system tested overall, based on PFU and OPS counts. What is clear is that systems 2, 3, and 4 are consistently the strongest performers and these devices are based on HEPA, HEPA, and HEPA/UV-C respectively.

Airflow is clearly important to the performance of air cleaners, but the results from air cleaner 4, which did not have the highest claimed airflow value (Table 1), demonstrate that airflow rate alone is not the whole story. Other factors may come in to play, such as the internal design of the air cleaner systems, including the size and quality of the installed HEPA filter(s) and related filter fit/sealing within the machine.

Also, the presence/absence of additional elements such as coarse filters/germicidal UV lamps/physical baffling to slow air flow down over UV emitters. During this study, we used the air cleaners as received and did not open them up to see how well they were put together internally, so such influences were outside the scope of our investigation.

Conclusion

To date, there is little information and a lack of consistent research regarding the ability of air cleaning technologies to remove bioaerosols in a side-by-side comparison study. This work reports a comparison study using a selection of air cleaning devices, which were either portable/floor standing or wall mounted, to determine their efficiency against a biological challenge in combination with CARm assessment. Under the described conditions, all the selected air cleaners provided some reduction in the bioaerosol concentration.

These devices were evaluated using high bioaerosol challenge concentrations, probably far higher than most real-world situations would create. Some devices performed well under these challenging conditions, reducing the concentration below the experimental detection threshold. To determine more definitive CARm, the best performing air cleaners could be investigated further with improved assay sensitivity, to enable measurement of lower residual levels of bioaerosols.

Overall, when considering the high level of biological challenge, the worst performing device still demonstrated a measurable reduction in bioaerosol concentration. This suggests that in real-world scenarios, even the worst performing device could potentially help to mitigate bioaerosol spread and may offer benefits for reducing the airborne spread of viruses such as SARS-CoV-2.

Authors' Contributions

A.B.: conceptualization, methodology, validation, investigation, writing (original draft, review, and editing); J.B.: methodology, validation, investigation, writing (original draft, review, and editing); I.R., C. Bailey., and C. Beynon: validation, investigation; S.S.: investigation; N.B.: formal analysis.

Disclaimer

Its contents, including any opinions and/or conclusions expressed, are those of the authors alone and do not necessarily reflect Government or HSE Policy.

Authors' Disclosure Statement

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References

1. Chartered Institute of Building Services Engineers (CIBSE). COVID-19: Air Cleaning Technologies (v1). 2021. Available from: <https://www.cibse.org/knowledge-research/knowledge-portal/covid-19-air-cleaning-technologies-v1> [Last accessed: June 27, 2022].
2. The Scientific Advisory Group for Emergencies (Sage)—Environment and Modelling Group. Rapid Review of Air Cleaning Devices; 2020. Available from: <https://www.gov.uk/government/publications/emg-potential-application-of-air-cleaning-devices-and-personal-decontamination-to-manage-transmission-of-covid-19-4-november-2020> [Last accessed: June 27, 2022].
3. Collins DB, Farmer DK. Unintended consequences of air cleaning chemistry. *Environ Sci Technol* 2021;55(18):12172–12179
4. Foarde KK. Methodology to perform clean air delivery rate type determinations with microbiological aerosols. *Aer Sci Technol* 1999;30(2):235–245. <https://www.tandfonline.com/doi/abs/10.1080/713834074>

5. Foarde KK. Development of a method for measuring single-pass bioaerosol removal efficiencies of a room air cleaner. *Aer Sci Technol* 1999;30(2):223–234; doi: 10.1080/027868299304804
6. US-Environmental Protection Agency. Guide to Air Cleaners in the Home, 2nd edition; 2018. Available from: https://www.epa.gov/sites/default/files/2018-07/documents/guide_to_air_cleaners_in_the_home_2nd_edition.pdf [Last accessed: June 27, 2022].
7. Elias B, Bar-Yam Y. Could Air Filtration Reduce COVID-19 Severity and Spread. *New England Complex Systems Institute*. 2020;9. Available from: <https://necsi.edu/could-air-filtration-reduce-covid19-severity-and-spread>. [Last accessed: June 27, 2022].
8. Offermann FJ, Sextro RG, Fisk WJ, et al. Control of respirable particles in indoor air with portable air cleaners. *Atmosph Environ* 1985;19(11):1761–1771; doi: 10.1016/0004-6981(85)90003-4
9. Du L, Batterman S, Parker E, et al. Particle concentrations and effectiveness of free-standing air filters in bedrooms of children with asthma in Detroit, Michigan. *Build Environ* 2011;46(11):2303–2313; doi: 10.1016/j.buildenv.2011.05.012
10. Verhougstraete M, Reynolds K. Use of a portable air disinfecting system to remove seeded coliphage in hospital rooms. *Am J Inf Control* 2016;44(6):714–715; doi: 10.1016/j.ajic.2015.12.025
11. Rao NG, Kumar A, Colon C, Goswami DY. Impact of a new portable air purification technology device in the pediatric hospital setting—A pre-post assessment study. *Cureus* 2020;12(3); doi: 10.7759/cureus.7440
12. Boswell TC, Fox PC. Reduction in MRSA environmental contamination with a portable HEPA-filtration unit. *J Hosp Inf* 2006;63(1):47–54; doi: 10.1016/j.jhin.2005.11.011
13. Brągoszewska E, Bogacka M, Pikoń K. Efficiency and eco-costs of air purifiers in terms of improving microbiological indoor air quality in dwellings—A case study. *Atmosphere* 2019;10(12):742; doi: 10.3390/atmos10120742
14. Scott J, Zaroni PG. Michigan Department of Licensing & Regulatory Affairs (LARA)—Guidelines for use of Portable Air Filtration Systems in Health Care Facilities; 2002. Available from: https://www.michigan.gov/documents/mdch/bhs_hepa_337337_7.pdf [Last accessed: June 27, 2022].
15. Lee Y, Kim YS, Han B, et al. Minimizing the size and ozone emission of electrostatic precipitators using dielectric and rolled carbon film coatings. *IEEE Trans Ind Appl* 2021;58(1):753–759; doi: 10.1109/TIA.2021.3122402
16. Sublett JL. Effectiveness of air filters and air cleaners in allergic respiratory diseases: A review of the recent literature. *Curr Allergy Asthma Rep* 2011;11(5):395–402; doi: 10.1007/s11882-011-0208-5
17. Walls HJ, Ensor DS, Harvey LA, et al. Generation and sampling of nanoscale infectious viral aerosols. *Aerosol Sci Technol* 2016;50(8):802–811; doi: 10.1080/02786826.2016.1191617
18. Dietrich WL, Bennett JS, Jones BW, et al. Laboratory modeling of SARS-CoV-2 exposure reduction through physically distanced seating in aircraft cabins using bacteriophage aerosol—November 2020. *Morb Mortal Wkly Rep* 2021;70(16):595; doi: 10.15585/mmwr.mm7016e1
19. Luo H, Zhong L. Ultraviolet germicidal irradiation (UVGI) for in-duct airborne bioaerosol disinfection: Review and analysis of design factors. *Build Environ* 2021;197:107852; doi: 10.1016/j.buildenv.2021.107852
20. CH Technologies. Collision Nebulizer—Instructions: MRE 1, 3, 6 and 24 Jet; 2016. Available from: http://chtechusa.com/Manuals/MRE_Collision_Manual.pdf [Last accessed: June 27, 2022].
21. Paton S, Clark S, Spencer A, et al. Characterisation of particle size and viability of SARS-CoV-2 aerosols from a range of nebuliser types using a novel sampling technique. *Viruses* 2022;14(3):639; doi: 10.3390/v14030639
22. Crosswy FL. Particle Size Distributions of Several Commonly Used Seeding Aerosols. NASA. Langley Research Center Wind Tunnel Seeding Systems for Laser Velocimeters; 1985. Available from: <https://ntrs.nasa.gov/citations/19860001974> [Last accessed: June 27, 2022].
23. Han ZY, Weng WG, Huang QY. Characterizations of particle size distribution of the droplets exhaled by sneeze. *J Royal Soc Interface* 2013;10(88):20130560; doi: 10.1098/rsif.2013.0560
24. Gorbunov B. Aerosol particles generated by coughing and sneezing of a SARS-CoV-2 (COVID-19) host travel over 30 m distance. *Aerosol Air Qual Res* 2021;21(3):200468; doi: 10.4209/aaqr.200468
25. Stadnytskyi V, Anfinrud P, Bax A. Breathing, speaking, coughing or sneezing: What drives transmission of SARS-CoV-2? *J Int Med* 2021;290(5):1010–1027; doi: 10.1111/joim.13326
26. May KR, Harper GJ. The efficiency of various liquid impinger samplers in bacterial aerosols. *Br J Ind Med* 1957;14(4):287; doi: 10.1136/bj.14.4.287
27. Health and Safety Executive (GB). EH40/2005 Workplace Exposure Limits Containing the List of Workplace Exposure Limits for Use with the Control of Substances Hazardous to Health Regulations 2002 (as amended); 2020. Available from: <https://www.hse.gov.uk/pubns/books/eh40.htm> [Last accessed: June 27, 2022].
28. TSI. Optical Particle Sizer Spectrometer 3330—Operation and Service Manual. P/N 6004403, Revision F; 2013. Available from: https://www.kenelec.com.au/wp-content/uploads/2016/06/TSI_3330_Opticle_Particle_Sizer_Manual.pdf [Last accessed: June 27, 2022].



Establishment and application of test methodology demonstrating the functionality of air purification systems in reducing virus-loaded aerosol in indoor air

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SUMMARY

Background: The global COVID-19 pandemic has resulted in a greater interest in improving the ventilation of indoor environments in order to remove aerosolized virus and thus reduce transmission. Air purification systems have been proposed as a solution to improve aerosol removal.

Aim: The aim was to determine the efficacy of air purification systems in reducing the viral load in the environmental air of a room.

Methods: A containment room equipped with HEPA filter on air intake and exhaust was constructed. It was connected via an inlet with the BSL-2 facility. From the BSL-2, Feline Coronavirus (FCoV)-loaded aerosols were released into the containment room. After nebulization, air sampling was performed to determine the viral load in air prior to assessing the clean air delivery rate of the air purification systems. The infectivity of the captured viruses was also examined.

Findings: The air purification systems realized a 97–99% reduction in viral load in air in 1 h.

Captured infectious FCoV was reduced by 99.9%–99.99% by use of an ESP technology.

Conclusions: The air purification systems, using ESP technology or HEPA filter, reduce the viral load in air. The ESP purifiers inactivate captured FCoV viruses. Therefore, air purification systems can be used as an adjunctive infection control measure.

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Introduction

The global COVID-19 pandemic caused a dramatic change in our socio-economic life. Social distancing, self-isolation and travel restrictions caused a reduced workforce across all economic sectors resulting in a loss of jobs [1]. Lockdown and

school closures have placed a substantial mental health burden on children and college students [2].

According to current knowledge about transmission, SARS-CoV-2 transmission primarily occurs between people when an infected person is in close contact with another person. The extent to which the virus will transmit between individuals

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depends on the amount of infectious virus being shed and expelled by a person, the type of contact that person has with other individuals, the setting where exposure occurs, and what preventative measures are in place [3]. In laboratory studies, after an initial 90% loss of viability [4], SARS-CoV-2 remained infectious in aerosols for at least 3 h with a reduction in infectious titre from $10^{3.5}$ to $10^{2.7}$ TCID₅₀ per litre of air [5]. In normal circumstances, particles will also be lost by gravitational deposition. Micro-organisms including viruses migrate as droplet nuclei in indoor air. These can be removed by processes such as ventilation, filtration, electrostatic precipitation, and combinations thereof [6,7].

Electrostatic filtration by electrostatic precipitator (ESP) uses an electrostatic charge to generate air ions. This technology is commonly used in industry to charge particulate matter such as dust, smoke and fungal spores and filter them by deposition on oppositely charged plates [8]. Particles with sizes $<0.03 \mu\text{m}$ are not charged and the efficiency of the filter decreases for particle sizes $<0.05 \mu\text{m}$ [9,10]. HEPA filters consist of fibrous media made with multiple layers of randomly arranged fibres that trap airborne particles via three mechanisms, inertial impaction, interception and diffusion. Their combined action dictates the efficiency of the filter. Although there are no recommendations by the CDC for application of HEPA purifiers for air decontamination of airborne SARS-CoV-2, HEPA purifiers should be considered an adjunctive infection control measure [11].

This study aimed to establish and apply a method for determining the efficacy of air purification systems in reducing virus-loaded aerosols in a room. Four air purification systems were included in the study representing ESP and HEPA filtration. These were tested for their efficacy in removing viral aerosol, bacteriophage MS2 [12] and Feline Coronavirus (FCoV) [13] from air. FCoV was used as a surrogate for SARS-CoV-2 because it represents an enveloped virus highly similar to SARS-CoV-2. It has a similar envelope structure with spike-protein, virus size of about 120 nm and ssRNA type of genome [13], but has fewer biosafety implications despite the impact on feline health [14].

Material and methods

Biological material

The biological agents used in the project are described in Table I.

Table I
Biological materials used in the study

Biological species	Description	Source/number	Characteristics
<i>Escherichia coli</i>	<i>E. coli</i>	DSM 5695	Host for MS2 bacteriophage
MS2 bacteriophage	MS2	DSM 13767	RNA-virus (single strand RNA) in protein coat, diameter about 25 nm (1)
Crandell-Rees Feline Kidney cells	CRFK cells	Faculty Veterinary Medicine Utrecht	Host for FCoV
Feline Coronavirus	FCoV	Faculty Veterinary Medicine Utrecht	RNA-virus (single strand RNA approximately 30 kb) enveloped with lipid layer with S-protein, diameter about 120 nm (2)

Containment room for air purification experiments

A containment room was constructed for performing the air purification experiments. The room had a volume of approximately 50 m^3 (width $4.5 \text{ m} \times$ depth $4.3 \text{ m} \times$ height 2.6 m) and was physically closed from the external environment by a door with rubber seals and door-lock for controlled entrance. For sampling, the containment room was connected to a BSL-2 laboratory via a double door lock equipped with a UVC and chemical disinfection system that enabled the workers to manage the processes in the containment room and to collect samples in a controlled way without risk of spreading viral particles outside the containment room. The intake and exhaust air of the containment room were both HEPA filtered. The room was cleared of biological material after every experiment by UVC disinfection (Signify, Eindhoven, The Netherlands) and by air refreshment of 300 m^3 air per hour via HEPA filtering. Shaded places are treated by chemical disinfection. Air sampling was performed by using a Coriolis air sampler (Bertin Technologies, Montigny-le-Bretonneux, France).

Air purification systems

The air purification systems used in the study were supplied by the partners of the PPP Room disinfection project. The air purification systems applied ESP or HEPA technology with an airflow of $400\text{--}500 \text{ m}^3/\text{h}$.

Virus nebulization and sampling

The viruses, MS2 bacteriophages and FCoV viruses, were aerosolized using an eFlow® rapid nebulizer (PARI GmbH, Germany). This nebulizer applies a vibrating plate and appears to be more gentle on viral particles compared with jet nebulizers and is used for nebulization of high counts of bacteriophages against tuberculosis [15]. The system released 0.28 mL virus suspension per minute. The aerosol particle size released by the eFlow is up to $5 \mu\text{m}$ [16]. These particles were transported and released into the containment room via a tube with an airflow of 1 bar pre-pressure. To prevent accidental release of virus from the nebulizer system to the environmental air, it was placed in a closed plastic box in the BSL-2 laboratory from which the nebulized virus containing mist was transported via a tube of 50 cm directly into the containment room.

Air sampling was performed by the Coriolis sampler (Bertin Instruments, France) that samples 300 L of air per minute. This

sampler demonstrated good biological sampling efficiencies and physical sampling efficiencies for viruses in a comparative test [17]. The samples were collected in a small beaker containing 15 mL of sampling liquid, which was placed in a UVC-closed transport box after sampling to prevent UVC illumination. Sampling liquid was sterile saline solution for MS2 bacteriophage and DMEM cell culture medium including 0.45% glucose, 2 mM L-glutamine and 100 U/mL penicillin and 100 U/mL streptomycin without 2% fetal calf serum for FCoV. Air samples taken by the Coriolis sampler in the containment room were transported into the BSL-2 laboratory via the inlet equipped with a double door. Application of UVC and chemical disinfection with VirkonS (Biosecurity BV, The Netherlands) prevents environmental release of virus upon transportation of the contained material in the transport box via the inlet into the BSL-2 laboratory. The samples were processed in the biosafety cabinet of the BSL-2 laboratory.

Sample analysis

Samples were analysed using two different approaches. Firstly, by detection of biological activity, implying infection of target cells and subsequent lysis of the cells. For MS2 bacteriophage samples, these samples were serially diluted and spread on Luria-Bertani Agar (LBA) (Oxoid Limited, USA) plates in overlay with confluent seeded *Escherichia coli* in LBA 0.5% w/v top agar. The plates were incubated at 37 °C for 24 h, after which the plaques of lysed *E. coli* cells were counted. For FCoV-containing samples, an infectivity assay was performed [18] whereby serial dilutions were seeded on cell cultures of CRFK cells on DMEM including 0.45% glucose, 2 mM L-glutamine and 100 U/mL penicillin and 100 U/mL streptomycin supplemented with 2% fetal calf serum in 96-well microtitre plates. After two days of incubation at 37 °C in a CO₂ incubator, the wells of the plate were inspected for the cytopathic effect of the virus on the monolayer of CRFK cells and scored for TCID₅₀.

Secondly, samples were analysed by detection and quantification of the viral genomes using reverse transcriptase quantitative PCR (RT-qPCR). Prior to PCR, RNA was extracted and purified from the FCoV samples by using the QIAamp Viral RNA Mini Kit (Qiagen, Netherlands) according to the supplier's protocol. A one-step RT-qPCR was performed on a mixture of 5 µL purified viral RNA, 0.4 µM Fel-CoV-F forward primer, 5'-TGCCACAGGATGGGCTTAC-3', 0.5 µM Fel-CoV-R reverse primer, 5'-TTGTCACTACGTGCTTCT GTTGAG-3', 0.25 µM Fel-CoV-P-FAM/MGB probe, FAM-5'-ACGTAAAATCTAAAGCTGGTG-3'-MGB, and TaqMan Fast virus 1-step Master mix (Applied Biosystems, USA) in a total reaction volume of 25 µL. The thermocycler programme was 5 min at 50 °C, 20 s at 95 °C, 40 cycles alternating 15 s at 95 °C and 60 s at 60 °C. The RT-qPCR assay yields information on the quantity of the amount of target FCoV RNA based on a standard curve. It reflects the number of viruses both infectious and non-infectious that were sampled and thereby the basis to calculate the number of FCoV genome equivalents; the size of the FCoV RNA genome is about 30 kb [13], which equals 0.016 fg.

Decay of MS2 loaded aerosol in the containment room

MS2 phage suspension of about 1×10^{10} pfu/mL was prepared by culturing the phage on *E. coli* on LBA plate, scraping the top agar layer from the plate and resuspending in 5 mL

phage buffer according to DSMZ protocol (DSMZ, Germany). After subsequent centrifugation at 4000 g and filtration of the supernatant through a 0.45-µm filter, the filtrate was nebulized at 0.28 mL/min for 5 min into the containment room of 50 m³ using the e-Flow vibrating mesh nebulizer (Pari GmbH, Germany) while the air mixing was constantly achieved by four fan units. One minute after nebulization, the $t = 0$ sample was collected by the Coriolis sampler at 300 L/min for 3 min, which resulted in 900 L of sampled air. Subsequent samples were taken at $t = 15$ min, $t = 30$ min, $t = 45$ min and $t = 60$ min. These phage recovery data indicate the natural decay of MS2 phage in the containment room. Following the same nebulization and sampling conditions, the air purification systems' effect was explored on additional removal of MS2 phage loaded aerosol in the containment room. The decay realized by the air purification system was calculated by total decay with purifier action minus natural room decay without purifier action based on triplicate tests.

Decay of FCoV loaded aerosol in the containment room

The FCoV suspension was prepared by virus culturing on CRFK cells on DMEM including 0.45% glucose, 2 mM L-glutamine and 100 U/mL penicillin and 100 U/mL streptomycin supplemented with 2% foetal calf serum. After centrifugation at 4000 g, the FCoV suspension was nebulized. The decay of FCoV loaded aerosol was measured upon the action of the air purification systems. In the experiments with FCoV, a TCID₅₀ load of FCoV in the suspension was about 2.5×10^5 /mL. Because infectious virus could hardly be retrieved from the containment room at $t = 0$, the virus was detected using the FCoV specific RT-qPCR. All tests were performed in triplicate.

Calculation of clean air delivery rate, single pass efficiency and log and percentage reduction

The effectiveness of an air purification system in reducing the viral load in air was assessed while the aerosol load was constantly homogenized in the room. Based on the ANSI/AHAM AC-1-2006 test method [19], air cleaning for smoke, fine dust and pollen can be expressed as Clean Air Delivery Rate (CADR). In line with this, the CADR was calculated for virus-loaded aerosols. The following two formulae were used:

$C_{tx} = C_{t0} e^{-\kappa tx}$, where C is concentration at time point tx or $t0$ and κ is decay constant.

$CADR (m^3/h) = V(\kappa_t - \kappa_n)$, where V is volume test chamber, κ_t is test decay constant and κ_n is natural decay constant.

Percentage reduction was calculated based on log reduction by the formula:

$P = (1 - 10^{-L}) \times 100$, where P is percentage reduction and L is log₁₀ reduction.

Determination of virus inactivation upon capturing in purifier system

The air purification system using ESP technology contains a collector tube for capturing the particles. The captured virus particles were analysed for remaining infectivity. This was performed by examining the ratio of the TCID₅₀ per quantity of virus RNA determined by RT-qPCR on the FCoV virus particles collected on the collector inside the purifier system. For this,

nebulized FCoV was directly released from 50 cm distance into the inlet of the active air purification system for 5 min. After virus nebulization, the fan units in the containment room were switched on and the virus containing air in the room was exchanged with fresh air by 1 h ventilation of 300 m³ of air through the HEPA filter in the exhaust of the room and additional UVC treatment for virus inactivation of environmental virus in the containment room. Then, three areas of 10 × 10 cm of the internal collector tube in the air purification system were sampled individually by wet swab to collect virus material. The swabs were each directly submerged into 3 mL of DMEM medium with 50% v/v glass beads to resuspend the viruses into the medium by vortexing for 1 min. These virus suspensions were examined for TCID₅₀ and viral RNA content by RT-qPCR after RNA isolation. For reference, the natural stability of the virus on the collector surface was explored by nebulizing the virus on top of stainless-steel surfaces. The plates were dried in the biosafety cabinet for 15 min and then swab samples were taken after 1 h. The recovered viruses from the surface were analysed for TCID₅₀ and total viral RNA by RT-qPCR. The difference between TCID₅₀/fg of viral RNA ratio of the control and the collector surface of the purifier system allowed calculation of the reduction of viral infectivity.

Results

Decay of MS2 loaded aerosol in the containment room

MS2 phage decay in the containment room was measured with and without an active air purification system. Natural decay of phage presence and decay by the action of the air purification systems are shown in Table II. The natural phage MS2 decay in the room without an active air purification system appeared to be about 0.3 log units in 1 h. In the presence of each of the four types of air purification systems, A, B, C and D, we observed greater phage MS2 decay compared with the natural decay, ranging from about 1.7 to 2.3 log units or 98%–99.5% reduction in a period of 1 h.

Decay of FCoV loaded aerosol in the containment room

FCoV loaded aerosol decay in the containment room was measured with and without an active air purification system. In the absence of an active air purification system, infectious viruses were hardly detected. Only 0.8 log TCID₅₀ per mL sample was obtained at $t = 0$. A decline of infectious properties of the airborne viruses at low relative humidity was previously also observed by Oswin *et al.* [4]. Based on quantity

determination of FCoV virus in sampled air using the FCoV specific RT-qPCR, the number of genome equivalents of the virus could be detected in the room. At $t = 0$, the number of FCoV genome equivalents is about 9.1 log/m³ and in the absence of an active air purification system, the number reduced to about 8.7 log/m³ of air in 1 h (Figure 1). In the presence of an active air purification system, the FCoV reduction in air proceeded faster compared with the natural reduction of FCoV particles in the containment room (Figure 1, Table III). The natural reduction in the containment room is about 0.4 log units per hour. The decay attributable to the air purification systems ranges from about 1.5 to 2.3 log units or 96.8%–99.5% reduction in 1 h (Table III).

Calculation of clean air delivery rate and virus inactivation

The CADR of the different air purification systems was calculated for both MS2 bacteriophage clearance (based on plaque forming units) and for FCoV particle clearance (based on qPCR quantified viral RNA). The CADR values obtained with the air purification systems for both types of particles, e.g., aerosol containing MS2 and aerosol containing FCoV, were in a range of about 169–290 m³/h (Table IV).

Apart from the CADR, it was also relevant to conclude on the fate of the captured FCoV particles. Because the aerosolized FCoV loses its infectivity at low relative humidity, the FCoV-loaded aerosol was directly inhaled by the active air purifier systems. The subsequently sampled viral material from the inner metal collector surfaces of the ESP systems showed at least a factor 1000 to 10,000 less TCID₅₀ per fg viral RNA compared with FCoV containing aerosol sedimented on steel plates. This experiment indicated a reduction of viral infectivity of at least 3 log or 99.9% of captured viral particles by the ESP-based air purification systems (Table IV). Attempts to retrieve viral material from HEPA by grinding and vigorous shaking in DMEM appeared unsuccessful.

Discussion

The configuration of the containment room with four ventilators in the corners realizes a constant homogeneous distribution of virus loaded aerosol in the room. This was visually confirmed by releasing smoke from the point of virus release at one side of the room. By the action of the air purification systems, a constant intake of aerosol is realized and a concomitant output of purified air. The collected data shows therefore a decay of the viral load in the air as captured by the sampler over time. By correcting the natural decay of viral load in the room, the contribution of the air purification system to the decay could be determined as shown in Tables II and III, which show the reduction of virus in 1 h. Irrespective of the type of virus, MS2 phage or FCoV, the purifiers realize a decay of about 96.8–99.5% in 1 h. Beswick *et al.* [20] showed similar MS2 decay data for air cleaning systems in a comparable room setting.

The decay of bacteriophage MS2 could be analysed by quantifying the number of infectious particles in the samples of air. The numbers of this virus in the air were in the range of about 10⁸ plaque forming units per cubic metre; thus, there was enough virus to show plaque formation when seeding the particles collected from 900 L of air in 15 mL of sampling liquid

Table II

MS2 decay averaged data and data corrected for natural decay in the room in the absence of a purifier system for 60 min

System	MS2 decay in log units	Corrected MS2 decay in log units	Corrected MS2 decay percentage
Natural	0.3 ± 0.5	0	0.0
System A	2.5 ± 0.4	2.2	99.4
System B	2.6 ± 0.3	2.3	99.5
System C	2.0 ± 0.3	1.7	98.0
System D	2.6 ± 0.2	2.3	99.5

Decay data is provided as Log and percentage reduction in 60 min.

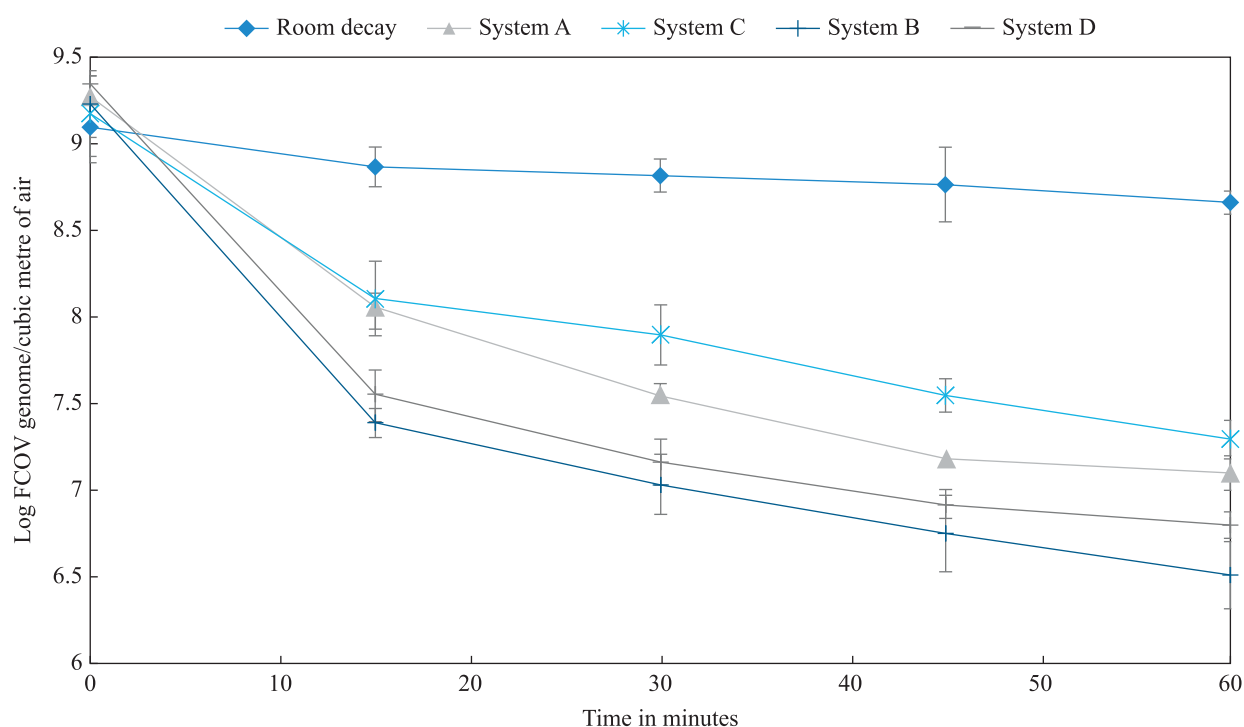


Figure 1. Feline Coronavirus (FCoV) genome equivalent decay in containment room per cubic metre. Natural decay is indicated in the upper blue line with diamonds and the decay with additional action of four air purification systems A, B, C and D are given in green line, dark blue line, light blue line and dark green line, respectively.

with the Coriolis sampler. This results in about 10^8 infectious viruses in 15 mL if all viruses are collected. Despite some sampling efficiency loss, MS2 virus always showed a plaque count on plates with *E. coli* target bacterium. Unfortunately, infectious particles of FCoV could only be found in the samples at low TCID₅₀ counts; the reason for this was that the number of FCoV that can be captured in 15 mL sampling liquid is about TCID₅₀ of 100. This is close to the limit of detection with additional inactivation of FCoV because of low relative humidity of the air. Oswin *et al.* [4] showed that the low humidity does severely affect infectivity to about 10% of the starting value for SARS-CoV-2 over 20 min. Because FCoV has an identical structure and size [13], the fate of the virus is anticipated to be similar. An alternative method to detect and quantify the virus particles was by targeting the RNA genome of the virus by RT-qPCR. This seemed successful and yielded

Table III

Feline Coronavirus (FCoV) genome equivalent decay based on RT-qPCR averaged data and data corrected for natural decay in the room in absence of a purifier system for 60 min expressed as log and percentage reduction in 60 min

System	FCoV genome decay in log units	Corrected FCoV genome decay in log units	Corrected FCoV decay percentage
Natural	0.4 ± 0.1	0	0.0
System A	2.2 ± 0.1	1.8	98.4
System B	2.7 ± 0.1	2.3	99.5
System C	1.9 ± 0.2	1.5	96.8
System D	2.6 ± 0.1	2.2	99.4

insight into the numbers of viral genomes sampled regardless of the virus' infectiousness. The decay of FCoV in the containment room as a result of the action of the air purification systems show a similar trend of about 2 log reduction in 1 h as roughly also observed for the decay of MS2. This trend is likely the result of the similar type of aerosols released by the MESH nebulizer that releases similar volumes of aerosols, which may be influenced by the different nature of the virus and the medium. Importantly, it provides confidence in the applied methodology and demonstrates a similar result of particle capturing of the purifier systems. However, typical differences in virus capturing were observed when having a more detailed look at the log reduction data and calculated CADR. The trend based on the CADR data in Table IV suggests a slightly better CADR for MS2 compared with FCoV-loaded particles. This may suggest a slightly different type of aerosol for the two different viruses. None the less, the ESP- and HEPA-based purifiers show a CADR range that has been previously described for medium-sized particles in the range of 0.5–3.0 μm [21] and for ultra-fine particles by HEPA-based purifiers [22]. The CADR was shown to depend on the nature of airborne particles [21]. Despite the minor differences in CADR observed when challenging the systems with two distinct types of virus-loaded aerosol, these differences show a similar trend depending on the air purification system. This is in line with the statement that the CADR permits an intercomparison of performance among various air cleaners [21].

The publication by Feng *et al.* [23] expressed the fear of re-aerosolization of infectious SARS-CoV-2 from HEPA and ESP air purification systems. They proposed in their simulated filtration performance study that UVC treatment should be added as technology to air purification systems to eradicate virus

Table IV

Clean Air Delivery Rate (CADR) of purifier systems based on exposure of nebulized MS2 bacteriophage and nebulized Feline Coronavirus (FCoV) particles in separate experiments in a 50-m³ containment room

System	CADR (m ³ /h) MS2 aerosol	CADR (m ³ /h) FCoV aerosol	Log reduction of infectivity captured FCoV	Percentage reduction of infectivity captured FCoV
System A	268	200	4.1	99.99
System B	290	263	3.1	99.92
System C	229	167	3.7	99.98
System D	281	243	ND ^a	ND ^a

CADR is calculated based on experimental data shown in previous paragraphs. Infectivity reduction of captured FCoV virus is shown in the latter two columns.

^a Virus could not be retrieved from HEPA matrix; no TCID₅₀ nor qPCR amplifiable RNA was detected.

infectivity. Moreover, they stated that the biological disinfection effect on SARS-CoV-2 aerosols exposure to ions and electric field should be investigated. The latter has been carried out in this study using the surrogate virus FCoV that has identical structural and physical characteristics to SARS-CoV-2 but only has a different host range. The outcome of our study demonstrates that ESP inactivates the captured FCoV by 3–4 log units that equals a reduction of infectiousness of about 99.9% to 99.99%. Similar inactivating effects on captured bacteriophages by an ESP-based system has been reported by Kettleson *et al.* [24].

Our findings indicate that the HEPA- and ESP-based air purification systems evaluated in this study reduced the viral load in air. The captured viruses were inactivated by a percentage of 99.9–99.99% in the ESP systems that apply a strong electric field for capturing airborne particles. From this study it can be concluded that the evaluated air purification systems can be used as adjunctive infection control measure.

Conflict of interest statement

The authors declare the research was conducted to find out whether air purification systems could be used as additional infection control measure. Although the project was also financially supported by the partners Genano, Euromate, Formula Air and VFA Solutions, their support did not pose any conflict of interest as TNO executed the work as an independent research organization. The protocol and work were designed and carried out without any input from the manufacturers.

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References

- [1] Nicola M, Alsafi Z, Sohrabi C, Kerwan A, Al-Jabir A, Iosifidis C. The socio-economic implications of the coronavirus pandemic (COVID-19): a review. *Int J Surg* 2020;78:185–93.
- [2] Elharake JA, Akbar F, Malik AA, Gilliam W, Omer SB. Mental health impact of COVID-19 among children and college students: a systematic review. *Child Psychiatry Hum Dev* 2022;11:1–13.
- [3] Anonymous. Preventing and mitigating COVID-19 at work: policy brief, 19 May 2021. WHO/2019-nCoV/Workplace_actions/Policy_brief/2021.1. Available at: Preventing and mitigating COVID-19 at work: policy brief, 19 May 2021 (who.int) [last accessed 11 2022].
- [4] Oswin HP, Haddrell AE, Otero-Fernandez M, Mann JFS, Cogan TA, Hilditch TG. The dynamics of SARS-CoV-2 infectivity with changes in aerosol microenvironment. *Proc Natl Acad Sci U S A* 2022 Jul 5;119(27):e2200109119.
- [5] Van Doremalen N, Bushmaker T, Morris DH, Holbrook MG, Gamble A, Williamson BN. Aerosol and surface stability of SARS-CoV-2 as compared with SARS-CoV-1. *N Engl J Med* 2020 Apr 16;382(16):1564–7.
- [6] Zeng Y, Xie R, Cao J, Chen Z, Fan Q, Liu B. Simultaneous removal of multiple indoor-air pollutants using a combined process of electrostatic precipitation and catalytic decomposition. *Chem. Eng. J.* 2020;388:124219.
- [7] Day DB, Xiang J, Mo J, Clyde MA, Weschler CJ, Li F. Combined use of an electrostatic precipitator and a high-efficiency particulate air filter in building ventilation systems: effects on cardiorespiratory health indicators in healthy adults. *Indoor Air* 2018;28:360–72.
- [8] González-Martín J, Kraakman NJR, Pérez C, Lebrero R, Muñoz R. A state-of-the-art review on indoor air pollution and strategies for indoor air pollution control. *Chemosphere* 2021;262:128376.
- [9] Brincat JP, Sardella D, Muscat A, Decelis S, Grima JN, Validramidis V. A review of the state-of-the-art in air filtration technologies as may be applied to cold storage warehouses. *Trends Food Sci Technol* 2016;50:175–85.
- [10] Yoo KH, Lee JS, Oh M. Charging and collection of submicron particles in two-stage parallel-plate electrostatic precipitators. *Aerosol Sci Technol* 1997;27(3):308–23.
- [11] Christopherson DA, Yao WC, Lu M, Vijayakumar R, Sedaghat AR. High-efficiency particulate air filters in the era of COVID-19: function and efficacy. *Otolaryngol Head Neck Surg* 2020;163(6):1153–5.
- [12] Kuzmanovic DA, Elashvili I, Wick C, O'Connell C, Krueger S. Bacteriophage MS2: molecular weight and spatial distribution of the protein and RNA components by small-angle neutron scattering and virus counting. *Structure* 2003;11:1339–48.
- [13] de Barros BCV, de Castro CMO, Pereira D, Ribeiro LG, Júnior JWBD, Casseb SMM, Holanda GM, Cruz ACR, Júnior ECS, Mascarenhas JDP. First Complete Genome Sequence of a Feline Alphacoronavirus 1 Strain from Brazil. *Microbiol Resour Announc.* 2019 Mar 7;8(10):e01535-18. <https://doi.org/10.1128/MRA.01535-18>. PMID: 30863824; PMCID: PMC6406114.
- [14] Chang HW, de Groot RJ, Egberink HF, Rottier PJ. Feline infectious peritonitis: insights into feline coronavirus pathobiogenesis and epidemiology based on genetic analysis of the viral 3c gene. *J Gen Virol* 2010 Feb;91(Pt 2):415–20.
- [15] Carrigy NB, Chang RY, Leung SSY, Harrison M, Petrova Z, Pope WH. Anti-tuberculosis bacteriophage D29 delivery with a vibrating mesh nebulizer, jet nebulizer, and soft mist inhaler. *Pharm. Res.* 2017;34:2084–96.
- [16] Vecellio L. The mesh nebuliser: a recent technical innovation for aerosol delivery. *Breathe* 2006;2:252–60.
- [17] Dybwad M, Skogan G, Blatny JM. Comparative testing and evaluation of nine different air samplers: end-to-end sampling efficiencies as specific performance measurements for bioaerosol applications. *Aerosol Sci Technol* 2014;48(3):282–95.

- [18] McDonagh P, Sheehy PA, Norris JM. In vitro inhibition of feline coronavirus replication by small interfering RNAs. *Vet Microbiol* 2011;150(3–4):220–9.
- [19] Anonymous. Association of Home Appliance Manufacturers Method for Measuring Performance of Portable Household Electric Room Air Cleaners. ANSI/AHAM AC-1-2006. Approved American National Standard. Available at: ANSI/AHAM AC-1-2006 - Method for Measuring Performance of Portable Household Electric Room Air Cleaners [last accessed 11 2022].
- [20] Beswick A, Brookes J, Rosa I, Bailey C, Beynon C, Stagg S. Room-Based Assessment of Mobile Air Cleaning Devices Using a Bio-aerosol Challenge. *Appl Biosaf* 2023;28:1–10.
- [21] Shaughnessy RJ, Sextro RG. What is an effective portable air cleaning device? A review. *J Occup Environ Hyg* 2006;3(4):169–81.
- [22] Waring MS, Siegel JA, Corsi RL. Ultrafine particle removal and generation by portable air cleaning devices. *Atmos Environ* 2008;42:5003–14.
- [23] Feng Z, Cao SJ, Haghighat F. Removal of SARS-CoV-2 using UV+Filter in built environment. *Sustain Cities Soc* 2021;74:103226.
- [24] Kettleson EM, Ramaswami B, Hogan Jr CJ, Lee M-H, Statyukha GA, Biswas P. Airborne virus capture and inactivation by an electrostatic particle collector. *Environ Sci Technol* 2009;43(15):5940–6.

The Removal of Airborne Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) and Other Microbial Bioaerosols by Air Filtration on Coronavirus Disease 2019 (COVID-19) Surge Units

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Airborne severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) was detected in a coronavirus disease 19 (COVID-19) ward before activation of HEPA-air filtration but not during filter operation; SARS-CoV-2 was again detected following filter deactivation. Airborne SARS-CoV-2 was infrequently detected in a COVID-19 intensive care unit. Bioaerosol was also effectively filtered.

Keywords. SARS-CoV-2; air filtration; COVID-19; nosocomial infection; airborne pathogens.

Airborne dissemination is likely an important transmission route for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) [1], with SARS-CoV-2 RNA detected in air samples from coronavirus disease 2019 (COVID-19) wards [1, 2].

Despite the use of personal protective equipment (PPE), there are multiple reports of patient-to-healthcare worker transmission of SARS-CoV-2 [3], potentially through the inhalation of viral particles [4]. There is a need to improve the safety for healthcare workers and patients by decreasing airborne transmission of SARS-CoV-2 [4]. Portable air filtration systems, which combine high efficiency particulate filtration and ultraviolet (UV) light sterilization, may be a scalable solution for removing respirable SARS-CoV-2 [5]. A recent review by the UK Scientific Advisory Group for Emergencies modeling group found limited data regarding the effectiveness of such devices [6]. Here we present the first data providing evidence for the removal of SARS-CoV-2 and microbial bioaerosols from the air using portable air filters with UV sterilization on a COVID-19 ward.

METHODS

The study was conducted in 2 repurposed COVID-19 units in Addenbrooke's Hospital, Cambridge, United Kingdom. One area was a "surge ward" (ward) managing patients requiring simple oxygen therapy or no respiratory support, the second was a "surge intensive care unit" (ICU) managing patients requiring invasive and noninvasive (noninvasive ventilation, high flow nasal oxygen) respiratory support. The ward was a fully occupied 4-bedded bay (Figure 1A top left panel). The ICU was fully occupied 5-bedded bay, with a supra-capacity sixth occupied bed used in week 2 (Figure 1B top left panel). Both units were passively ventilated, with 2–4 air-changes per hour at baseline.

In the ward we installed an AC1500 HEPA14/UV sterilizer (Filtrex, Harlow, UK); in the ICU we installed a Medi 10 HEPA13/UV sterilizer (Max Vac, Zurich, Switzerland). The air filters were placed in fixed positions before the initiation of the three-week study period (Figure 1A and 1B), switched on at the beginning of week 2 and run continuously from Sunday to Sunday for 24 hours per day, providing approximately 5–10 room-volume filtrations per hour.

We performed a crossover evaluation, with the primary outcome being detection of SARS-CoV-2 RNA in the various size fractions of air samples. Air sampling was conducted using National Institute for Occupational Safety and Health (NIOSH) BC 251 2-stage cyclone aerosol samplers [7] (B Lindsley, Centers for Disease Control and Prevention [CDC]), operated in accordance with previous studies [7, 8]. Air samplers were assembled daily with a control sampler left in a sealed bag. Samplers were placed adjacent to the air filter inlet and the other at approximately 4 meters from the filter and no closer than 2 meters to patients. In ICU 2 distant samplers were used: 1 mounted at head height and 1 at bed height. Samplers were operated on

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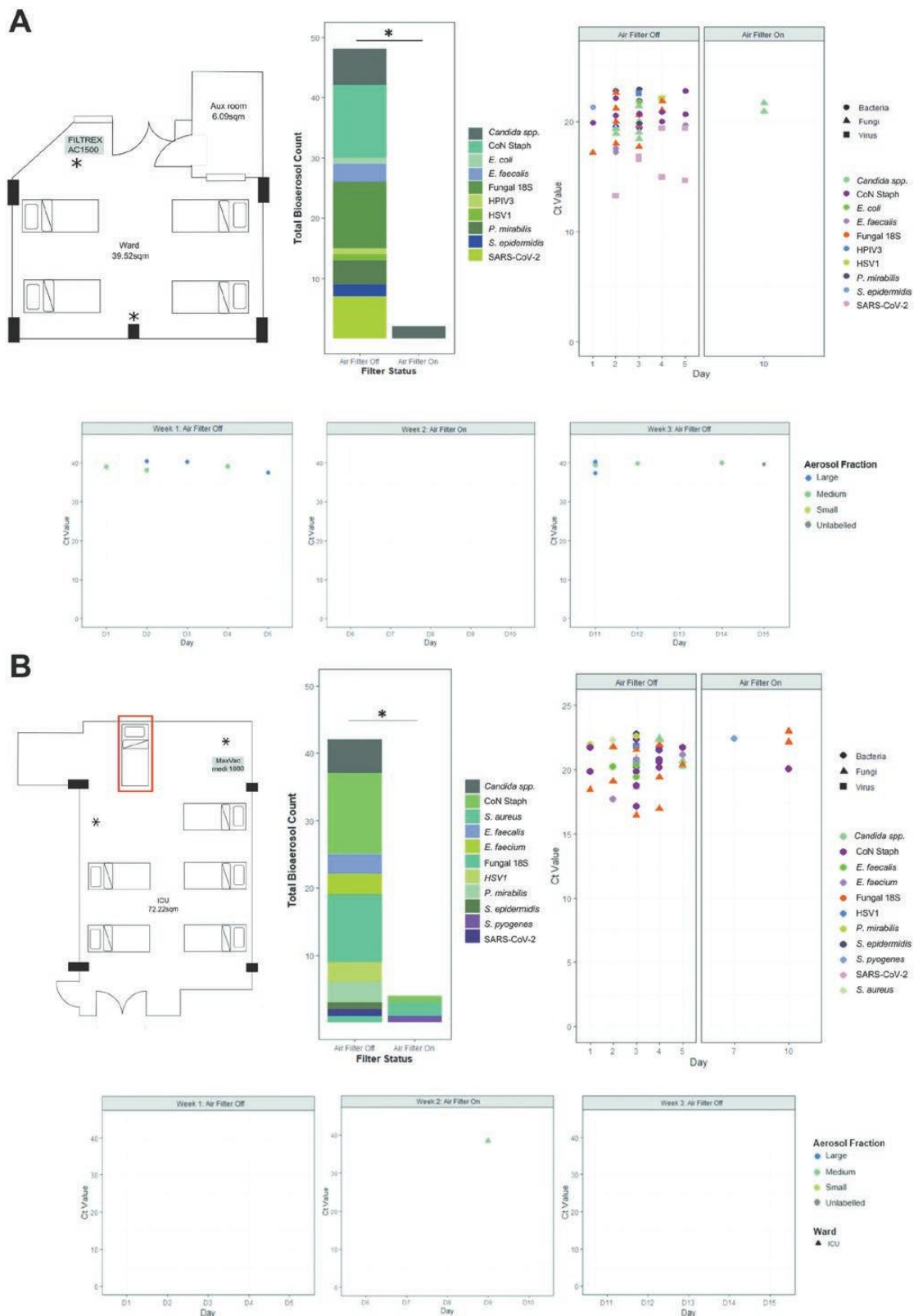
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weekdays (from 08:15 to 14:15) for 3 consecutive weeks. After sampling, samplers were disassembled using sterile technique. The samples were processed and then stored at -80°C until analysis

Nucleic acids were extracted from each NIOSH sampler component (tubes containing large aerosols, medium aerosols, and filter). Methodological details including extractions, reverse transcription quantitative polymerase chain reaction (RT-qPCR) for SARS-CoV-2 and high throughput qPCR assays for a range of bacterial, viral, and fungal pathogens are in the [Supplementary Methods](#) (organisms listed in [Supplementary Table 1](#)). Differences in numbers of pathogens detected with filters on and off were compared by Mann-Whitney *U* test, and $P \leq .05$ was considered significant.

RESULTS

From 18 January to 5 February beds in the ward and ICU were at 100% occupancy; 15 patients were admitted to the ward, and 14 were admitted to the ICU over the sampling period. All patients were symptomatic and tested positive for SARS-CoV-2 RNA.

In the ward, during the first week while the air filter was inactive, we were able to detect SARS-CoV-2 on all sampling days; RNA was detected in both the medium (1–4 μM) and the large ($>4 \mu\text{M}$) particulate fractions ([Figure 1A](#) lower panel). SARS-CoV-2 RNA was not detected in the small ($<1 \mu\text{M}$) particulate filter. The air filter was run continuously in week 2; we were unable to detect SARS-CoV-2 RNA in any of the sampling fractions on any of the 5 testing days. We completed the study by repeating the sampling with an inactive air filter. As in week 1, we were able to detect SARS-CoV-2 RNA in the medium and the large particulate fractions on 3/5 days of sampling (a sample without tube size indicated tested positive on day 5) ([Figure 1A](#) lower panel). SARS-CoV-2 RNA was not detected from the control sampler.

We subjected the extracted nucleic acid preparations to high-throughput qPCR to detect a range of viral, bacterial, and fungal targets. In week 1, we detected nucleic acid from multiple viral, bacterial, and fungal pathogens on all sampling days ([Figure 1A](#) top, middle, and right panels). In contrast, when the air filter was switched on, we detected yeast targets only on a single day, with a significant reduction ($P = .05$) in microbial bioaerosols when the air filter was operational ([Figure 1A](#)). Using this high-throughput approach, SARS-CoV-2 RNA was detected on 4/5 days tested in week 1 but was again absent in week 2. We were unable to generate multiplex

data for week 3 due to sample degradation following SARS-CoV-2 RNA amplification.

In contrast to the ward, we found limited evidence of airborne SARS-CoV-2 in ICU in weeks 1 and 3 (filter off) but detected SARS-CoV-2 RNA in a single sample in the medium (1–4 μM) particulates on week 2 (filter on) ([Figure 1B](#) lower panel). This contrary result did not reflect a general lack of bioaerosols in the ICU, which demonstrated a comparable quantity and array of pathogen associated nucleic acids to that seen in the unfiltered ward air on week 1 ([Figure 1B](#) top, middle, and right panels). Again, the use of the air filtration device significantly ($P = .05$) reduced the microbial bioaerosols ([Figure 1B](#)); with only 3 organism types detected on 2 of the sampling days. SARS-CoV-2 RNA was only detected once during week 1 on the high throughput qPCR assay.

DISCUSSION

Our study represents the first report to our knowledge of removal of airborne SARS-CoV-2 in a hospital environment using combined air filtration and UV sterilization technology. Specifically, we provide evidence for the circulation of SARS-CoV-2 in a ward within airborne droplets of $>1 \mu\text{M}$. Droplets of 1–4 μM are likely a key vehicle for SARS-CoV-2 transmission [9], as they remain airborne for a prolonged period and can deposit in the distal airways. Recent data have shown that exertional respiratory activity, such as that seen in patients with COVID-19, increases the release of 1–4 μM respiratory aerosols, relative to conventionally defined “aerosol generating procedures” such as noninvasive respiratory support [10]. Patients in ICU are commonly at a later stage of disease and may shed less virus as a result. These data are consistent with our observations, suggesting that aerosol precautions may be more important in conventional wards than in well-defined “aerosol risk areas.”

The sampling and detection of airborne viruses poses several technological challenges, and there remains no agreed standard for their use or interpretation [11]. However, the detection of SARS-CoV-2 RNA by RT-qPCR (albeit at a high cycle threshold [CT] value), and the lack of detection during use of an air sterilization system, adds to a growing body of evidence implicating the airborne transmission of SARS-CoV-2 [1]. The detection of SARS-CoV-2 RNA in the air of a ward managing patients with COVID-19 intimates that this is a key mechanism by which healthcare professionals could become infected. The removal of airborne viral particles and other pathogens may help reduce the likelihood of hospital-acquired respiratory infections.

bar chart showing collated total number of bioaerosol detections during weeks 1 (filter off) and 2 (filter on) * $P = .05$ by Mann-Whitney *U* test. Top right: CT values of detected pathogens by high-throughput qPCR when filter switch on and off. Bottom: CT values for the single qPCR SARS-CoV-2 detection when filter switched on and off. NB: variation in CT values is a function of the microfluidics technology and do not reflect higher bioaerosol burdens. Abbreviations: CT, cycle threshold; ICU, intensive care unit; qPCR, quantitative polymerase chain reaction; SARS-CoV-2, severe acute respiratory syndrome coronavirus 2.

This reduction may be by both decreasing the load of respirable particles and by removal of larger droplets that can facilitate fomite-associated spread [11]. The clearance of bioaerosol was not restricted to SARS-CoV-2. Although the impact of air filtration on nosocomial infection is uncertain [5, 12], the broad range of pathogens removed in this study suggests potential for benefit beyond SARS-CoV-2.

This study has limitations. The evaluation was conducted in 2 rooms, and there are no data defining the optimal air changes required to remove detectable pathogens with the specified devices, nor their impact in better ventilated facilities. Given the large volume of air within the room and the stability of viruses in the sampling fluid, it was predictable that the amount of SARS-CoV-2 detected would be minimal. However, negative results from the control sampler—and the striking but reversible effect of the air filtration devices—suggest these are not false positive detections, and we cannot exclude the risk of airborne infection. Future studies should examine whether air filtration devices have an impact on healthcare professional and patient focused outcomes, including measuring infection/exposure as an endpoint, as well as assessing potential harm, such as noise, reduced ambient humidity, or impact on delivery of care.

We were able to detect airborne SARS-CoV-2 RNA in a repurposed COVID-19 “surge ward” and found that air filtration can remove SARS-CoV-2 RNA below the limit of qPCR detection. SARS-CoV-2 was infrequently detected in the air of a “surge ICU”; however, the device retained its ability to reduce microbial bioaerosols. Portable air filtration devices may mitigate the reduced availability of airborne infection isolation facilities when surges of COVID-19 patients overwhelm healthcare resources and improve safety of those at risk of exposure to respiratory pathogens such as SARS-CoV-2.

Supplementary Data

Supplementary materials are available at *Clinical Infectious Diseases* online. Consisting of data provided by the authors to benefit the reader, the posted materials are not copyedited and are the sole responsibility of the authors, so questions or comments should be addressed to the corresponding author.

Notes

Author contributions.

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R. B.: Investigation, supervision, writing review, and editing.

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Data sharing statement.

Data for organisms detected by single plex PCR (SARS-CoV-2) and high throughput PCR (bioaerosol) are included as supplementary data files.

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Potential conflicts of interest. V. N. is the founder, director, and shareholder of Cambridge Infection Diagnostics Ltd. A. C. M., P. W., G. D., and S. B. are members of the Scientific Advisory Board of Cambridge Infection Diagnostics Ltd. T. G. has received a research grant from Shionogi in materials for antimicrobial susceptibility testing in 2021 unrelated to this study and collaborated with Inivos in a PPE decontamination project (materials provided by the company unrelated to this study). R. A. F. has received research grants and/or consultancy payments from UK Cystic Fibrosis Trust during and outside of the submitted work, Wellcome Trust, Medical Research Council, Foundation Botnar, GlaxoSmithKline, AstraZeneca, Chiesi, Shionogi, Inmed, Thirty Technology, and received NIOSH air samplers provided by B. Lindsey (US CDC). E. G.-K. has received a National Institute of Health Research Green Shoots Award and is a NIHR Clinical Research Network Lead; fees for ECCMID meeting registration from ESCMID; unpaid roles for the European Society of Clinical Infectious Diseases and Microbiology COVID 19 guidelines writing group member and guidelines committee member. G. D. received financial or nonfinancial interests from Microbiotica Ltd and had a leadership or fiduciary role in other board, society, committee, or advocacy group, paid or unpaid for Wellcome. All other authors report no potential conflicts. All authors have submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest. Conflicts that the editors consider relevant to the content of the manuscript have been disclosed. This work is licensed under a Creative Commons Attribution 4.0 International License.

References

- Greenhalgh T, Jimenez JL, Prather KA, Tufekci Z, Fisman D, Schooley R. Ten scientific reasons in support of airborne transmission of SARS-CoV-2. *Lancet* **2021**; 397:1603–5.
- Zhou J, Otter JA, Price JR, et al. Investigating SARS-CoV-2 surface and air contamination in an acute healthcare setting during the peak of the COVID-19 pandemic in London. *Clin Infect Dis* **2021**;73:e1870–7.
- Illingworth CJ, Hamilton WL, Warne B, et al. Superspreaders drive the largest outbreaks of hospital onset COVID-19 infections. *Elife* **2021**; 10:e67308.
- Fennelly KP. Particle sizes of infectious aerosols: implications for infection control. *Lancet Respir Med* **2020**; 8:914–24.

5. Morawska L, Allen J, Bahnfleth W, et al. A paradigm shift to combat indoor respiratory infection. *Science* **2021**; 372:689–91.
6. UK scientific advisory group for emergencies. Potential application of air cleaning devices and personal decontamination to manage transmission of COVID-19, 4 November 2020. Available at: <https://www.gov.uk/government/publications/emg-potential-application-of-air-cleaning-devices-and-personal-decontamination-to-manage-transmission-of-covid-19-4-november-2020>. Accessed 18 September 2021.
7. Lindsley WG, Schmechel D, Chen BT. A two-stage cyclone using microcentrifuge tubes for personal bioaerosol sampling. *J Environ Monit* **2006**; 8:1136–42.
8. Killingley B, Greatorex J, Digard P, et al. The environmental deposition of influenza virus from patients infected with influenza A(H1N1)pdm09: implications for infection prevention and control. *J Infect Public Health* **2016**; 9:278–88.
9. Fears AC, Klimstra WB, Duprex P, et al. Persistence of severe acute respiratory syndrome coronavirus 2 in aerosol suspensions. *Emerg Infect Dis* **2001**; 26:2168–2171.
10. Wilson NM, Marks GB, Eckhardt A, et al. The effect of respiratory activity, non-invasive respiratory support and facemasks on aerosol generation and its relevance to COVID-19. *Anaesthesia* **2021**; 76:1465–74.
11. Stockwell RE, Ballard EL, O'Rourke P, Knibbs LD, Morawska L, Bell SC. Indoor hospital air and the impact of ventilation on bioaerosols: a systematic review. *J Hosp Infect* **2019**; 103:175–84.
12. Mousavi ES, Kananizadeh N, Martinello RA, Sherman JD. COVID-19 outbreak and hospital air quality: a systematic review of evidence on air filtration and recirculation. *Environ Sci Technol* **2021**; 55:4134–47.



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Health hazards posed by feral pigeons

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Animal viruses

Summary A comprehensive literature search of epidemiological studies and reports of transmissions of disease from feral pigeons to humans was performed. There were 176 documented transmissions of illness from feral pigeons to humans reported between 1941 and 2003. Feral pigeons harbored 60 different human pathogenic organisms, but only seven were transmitted to humans. Aerosol transmission accounted for 99.4% of incidents. There was a single report of transmission of *Salmonella enterica* serotype Kiambu to humans from feral pigeons, and no reports of transmission of *Campylobacter* spp. The most commonly transmitted pathogens continue to be *Chlamydia psittaci* and *Cryptococcus neoformans*. Although feral pigeons pose sporadic health risks to humans, the risk is very low, even for humans involved in occupations that bring them into close contact with nesting sites. In sharp contrast, the immunocompromised patient may have a nearly 1000-fold greater risk of acquiring mycotic disease from feral pigeons and their excreta than does the general population.

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Introduction

High numbers of feral pigeons live in almost every large city in the world and they are frequently encountered by humans.¹ However, the health hazard that they pose has not been adequately assessed. Clinicians are confronted by the need to educate people about the risk of contracting disease most often when they are clearing feral pigeon excrements or culling them from buildings. However, many people have casual interactions with pigeons that range from feeding them in public parks to handling tamed birds that nest on window-sills. In addition, immunocompromised patients

need advice about limiting exposure to potential vectors of zoonotic diseases, even when it concerns seemingly innocuous traditions such as feeding pigeons in the park. Extermination that is intended to greatly reduce pigeons around human populations does not appear to work as well as restricting feeding,¹ are protested by those sensitive to the plight of animals, and most importantly, may pose increased hazards to human health from disturbance of the nesting environment and handling of carcasses. On the other hand, animal protection activists sometimes deny that pigeons pose any health hazard.² In spite of the large distribution of feral pigeons and their successful acclimation to humans, there are no reviews of the scientific literature on this topic. This paper aims to give clinicians information that will help them assess the risk to human health from feral pigeons.

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Table 1 Pathogenic organisms identified in feral pigeon populations**Viruses**

Western equine encephalomyelitis (WEE)²³
 Rubella^{24,25}
 St Louis Encephalitis^{23,26}
 West Nile virus (WNV)^{21,22,24}
 Influenza²⁴

Bacteria

*Clostridium perfringens*¹²
*Listeria monocytogenes*²⁷
Salmonella enterica
 serovar Anatum²⁸
 serovar Anatum var. 15¹⁵
 serovar Derby²⁸
 serovar Arizonae²⁹
 serovar 1,4,12:27: g,[m],t:e,n,x²⁹
 serovar Java³⁰
 serogroup E³¹
 serovar Enteritidis³⁰
 serovar Kiambu¹¹
 serovar Typhimurium^{12,16,29-33}
 serovar Typhimurium Typ 690²⁵
 serovar var. Copenhagen^{25,28}
Yersinia spp.²⁵
Campylobacter jejuni^{13,14,16,17,31,34}
Campylobacter coli^{13,17}
Escherichia coli (STEC, VTEC)³⁵⁻³⁷
Coxiella burnetii^{24,25,38,39}
Chlamydophila psittaci^{8,24,25,30,32-34,38-55}

Fungi

*Allescheria boydii*⁵⁶
Aspergillus spp.^{56,57}
Candida albicans^{56,58-63}
Candida glabrata^{59,60,63}
*Torulopsis (Candida) glabrata*²⁹
Candida guilliermondii^{59,60,62,63}
*Candida humicola*⁶³
*Candida intermedia*⁶²

Candida krusei^{56,59,60,62,63}
*Candida lambica*⁶³
*Candida lipolytica*⁶³
Candida lusitanae^{60,62}
Candida parapsilosis^{62,63}
Candida pseudotropicalis^{60,62}
Candida rugosa^{60,62,63}
Candida tropicalis^{59,60,62,63}
*Candida zeylanoides*⁶³
Chrysosporium spp.⁵⁶
*Cryptococcus albidus*⁶²⁻⁶⁴
Cryptococcus laurentii^{62,63,65}
Cryptococcus neoformans^{29,58,62,63,66-76}
*Cryptococcus terreus*⁶²
*Cryptococcus uniguttulatus*⁶⁵
*Debaromyces hansenii*⁶⁵
Geotrichum spp.^{59,63}
*Geotrichum candidum*⁵⁶
*Histoplasma capsulatum*⁷⁷
*Hansenula anomala*⁶³
*Kloeckera apiculata*⁶³
Paecilomyces spp.⁵⁶
*Pichia membranaefaciens*⁶²
Rhizopus spp.⁵⁶
Rhodotorula spp.⁵⁶
*Rhodotorula glutinis*⁶³
Rhodotorula rubra^{29,62,63}
Saccharomyces cerevisiae^{62,63}
*Saccharomyces oleaginosus*⁶²
Saccharomyces telluris^{59,60,62}
Scopulariopsis spp.⁵⁶
Streptomyces spp.⁵⁶
Torulopsis candida^{62,63}
*Trichosporon beigeli*⁶³
*Trichosporon capitatum*⁶³
Trichosporon cutaneum^{56,62,63}
*Trichosporon pullulans*⁶³

Protozoas

Toxoplasma gondii^{30,78,79}

Total 60 pathogens as designated by genus and species.

Methods

The review of older literature, which comprises sources not readily accessible to clinicians by standard scientific publication search engines, was accomplished by perusal of bibliographic references in Italian, French, German, Dutch and English publications (Tables 1 and 2). More recently cited sources were collected by searches with key words like 'pigeon', 'dove' and '*Columba livia*' in the medical database PubMed. Only those papers that showed confirmed, or in the case of one large outbreak presumptive diagnosis of disease in humans,³ are included in this review (Tables 1 and 2). All published reports of transmissions of pathogenic organisms from feral pigeons to humans were included for analysis and tabulation. For the review of food-related infections, the commodity term was used in conjunction with the terms 'food

and outbreak and human' (Table 3). Commodities chosen for comparison ranged from extremely common sources, such as milk to infrequently eaten specialty foods such as snake. For this evaluation, each publication was not perused individually for applicability to food related illness in humans, and thus, it only indicates relative frequency of reports of outbreaks for each commodity.

Results**Epidemiological investigations**

Seventy-seven epidemiological studies of feral pigeon populations identified human pathogenic organisms coming from 60 cities and regions. Analysis revealed that feral pigeons harbored a

Table 2 Association between human practice and illness contracted from feral pigeons

Pathogen	Number of illnesses ^a	Description of contact
<i>Salmonella enterica</i>	1	Environmental exposure ¹¹
<i>Chlamydophila psittaci</i>	29 ^b	Environmental exposure ^{41,42,44,45,80-82}
	10	Handling a sick or dead pigeon ^{40,47,82-84}
	8	Pigeon feeding ^{42,82,83,85,86}
<i>Histoplasma capsulatum</i>	23	Environmental exposure ³
	68	Exposure in a hospital setting ⁷⁷
<i>Aspergillus</i> spp.	13 (13)	Exposure in a hospital setting ⁸⁷⁻⁹⁰
<i>Candida parapsilosis</i>	12 (12)	Exposure in a hospital setting ⁹¹
<i>Cryptococcus neoformans</i>	5 (2)	Environmental exposure ^{67,92-95}
	5 (4)	Exposure in a hospital setting ^{75,96}
	1 (1)	Wound inflicted by a pigeon ⁹⁷
<i>Toxoplasma</i>	1	Environmental exposure ⁷⁸
Total cases	176	

^a Number of patients who were immunoincompetent.

^b Additional cases are reported, but not enumerated^{39,98} (Haag-Wackernagel, unpublished).

total of 60 different human pathogenic organisms (Table 1). Five pathogens were viruses, nine were bacteria, 45 were fungi, and one was a protozoan (Table 1). However, only five pathogens were routinely transmitted to humans (Table 2). There were single case incidences for transmission of *Salmonella enterica* and *Toxoplasma* (Table 2). In general, there was a notable lack of transmission of pathogenic viruses and bacteria to people from feral pigeons.

Confirmation of the link between pigeons and fungal disease

There is a long-recognized link between pigeons and fungal diseases in humans, and, indeed, almost all (17 of 18) investigations of feral pigeon populations were positive for *Cryptococcus* spp. Review of the literature indicated that *Cryptococcus neoformans* and *Chlamydophila psittaci* were the most

widespread zoonotic pathogens in feral pigeon populations (Table 2). *C. neoformans* caused diseases in immunocompromised as well as in immunocompetent patients,⁴ but primarily in immunocompromised patients (Table 2). *C. neoformans* was acquired by 11 patients of whom seven were immunocompromised (Table 2). The Centers for Disease Control (CDC) reports that in the United States *Cryptococcus* spp. result in 0.2–0.9 cases per 100,000 in the general population per year.⁵ However, the CDC also reports that AIDS patients have a 1000-fold higher risk, with an annual reported incidence of 2–4 cases per 1000 persons.⁵ The pigeon is not an amplifying host of *Cryptococcus*, but its excrements offer an ideal environment for its growth.⁶ Therefore, it appears that the risk of illness associated with pigeons from *Cryptococcus* is now largely a function of the immune status of the human population rather than from people just having contact with birds. This is not a new concept,⁷ but the emergence of AIDS over the past 30 years and the associated increase in mycotic disease reiterates that a change in the human population rather than carriage rates by feral pigeons has occurred overtime. Similar to the situation with *Cryptococcus*, *Aspergillus* and *Candida* infections also appear to implicate a decline in human immune function as the primary risk factor for contraction of illness from feral pigeons (Table 2).

Chlamydia and *Histoplasma* infections in humans did not necessarily show an association with immunocompromise of the host (Table 2), although it cannot be ruled out without full knowledge of each individual case. An outbreak of *Chlamydophila psittaci* infection involved at least 35 persons and it was due to human contact with feral pigeons that

Table 3 PubMed references returned for outbreaks per food commodity

Milk	168	Goat	18
Egg	112	Juice	18
Fish	96	Hamburger	16
Vegetable	96	Horse	14
Shellfish	92	Rabbit	11
Fruit	79	Wild boar	10
Chicken	79	Deer	6
Cheese	73	Duck	5
Beef	66	Pigeon	0
Dairy	64	Alligator	0
Pork	48	Snake	0
Turkey	37	Ostrich	0

Searched on October 22, 2003 at www.ncbi.nlm.nih.gov/entrez/query.fcgi. Search terms were 'commodity and food and outbreak and human'.

varied in intensity (Tables 1 and 2). According to the literature, *C. psittaci* has a worldwide average seroprevalence of 45.8% as determined by review of 33 epidemiological investigations. An earlier 1965 review suggested a seroprevalence of 28.7% in feral pigeon populations in different cities and regions.⁸ In preparation for this review, sampling of feral pigeons in Lucerne revealed a mean prevalence of 56% seropositive feral pigeons (H. Wackernagel, unpublished results). All investigations of feral pigeon populations have been seropositive for *C. psittaci* (Table 1), which suggests that this organism is commensally associated with the pigeon host. However, there was no evidence that a high prevalence rate in pigeons is necessarily associated with a high probability of infections in humans that encounter pigeons. Two reports describe infections in humans with *Histoplasma capsulatum* (Table 1), which was the pathogen associated with the highest number of cases in a single outbreak. Because all of the fungal pathogens, including *Cryptococcus*, *Chlamydophila*, and *Histoplasma*, are known to be transmitted by inhalation of aerosolized organisms, the data suggests that 175 of 176 (99.4%) of described transmissions resulted from airborne excreta, which includes dried feces, ocular discharges, and crop milk.⁹ However, other methods of transmission are possible if close contact occurs, as evidenced by one report of primary cutaneous cryptococcosis of a HIV-positive drug abuser following injury inflicted by a feral pigeon (Table 1). Contact is sometimes brief, and the patient does not always recall any encounter with birds.⁹

Pigeons are not reported to be a common source of food-borne illness

Only two reports describe transmission of *Salmonella enterica* (*S. enterica*) to humans from either domesticated or feral pigeons, one of which occurred outside the general time frame of 60 years for this review. Illness in 20 soldiers in the Dutch army occurred in 1933 that clearly implicated *S. enterica* serovar Typhimurium variant Copenhagen as the causative agent that contaminated lemon pudding made with eggs from domestic pigeons.¹⁰ It appears to be the only case of food-borne transmission from pigeons to humans in the literature. Feral pigeons resulted in a case of salmonellosis from *S. enterica* serovar Kiambu¹¹ (Table 2). Given that *S. enterica* serovar Typhimurium variant Copenhagen and *Campylobacter*, which are common food-borne pathogens, are frequently recovered from feral pigeons as well as from domesticated pigeons used for food,¹²⁻¹⁷ it

is surprising that there are no other reports of food-borne transmission to humans from pigeons in the literature.

To pursue the idea further that there is a low risk of transmission of common food-borne bacteria between pigeons and humans, an independent risk assessment was performed. A feral pigeon population of around 5000-8000 birds that was sampled in Basel, Switzerland in preparation for this review harbored *C. psittaci*, *Campylobacter* spp., *S. enterica* serovar Typhimurium variant Copenhagen, and *Aspergillus fumigatus* (Haag-Wackernagel, unpublished data). However, records from the Department of Internal Medicine of the University Hospital in Basel showed that there were no direct transmissions of disease from feral pigeons to humans between 1997 and 2003 (Flueckiger and Haag-Wackernagel, unpublished data). In addition, a search of the literature revealed that, other than the 1933 outbreak, there were no reports of food-borne illness from either domesticated or feral pigeons since 1933 (Table 3). This finding is unexpected given that contact between pigeon and human is a frequent occurrence as compared to what probably happens with wild boar, snake, ostrich and alligator (Table 3). Illness was noted to occur in the literature base for rabbit, which is another feral animal that is sometimes domesticated and bred for food and kept as a pet. Therefore, it appears that the risk of transmission of food-borne disease from pigeon to human is comparatively low, in spite of pigeons being frequent carriers of common food-borne pathogens.

Other suggested associations between pathogens and feral pigeons

One case of *Toxoplasma gondii* is reported (Table 1), which occurred in an elderly woman. Therefore, all immunocompromised patients, including pregnant women who are at higher risk for contracting toxoplasmosis, should be advised to avoid feral pigeon populations and their nesting sites. Currently, there is no experimental evidence that pigeons are an important vector for the recently emerged viral disease of human pathogenic avian influenza¹⁸ and the epidemiological association between feral pigeons and humans in regards to this disease is only speculative.¹⁹ Although it appears that feral pigeons are seropositive for West Nile virus, there is no epidemiological evidence that they are an amplifying vector as are crows.²⁰⁻²²

Discussion

Epidemiological screening programs of animal reservoirs often identify pathogens that have never been, or are seldom, transmitted to humans. In regards to zoonotic disease transmitted from the feral pigeon to humans, all viruses, *Yersinia*, *Salmonella*, *Campylobacter* and *Toxoplasma* are in this category. Therefore, the results of many of the epidemiological investigation herein reviewed were only relevant for assessing the health of the feral pigeon populations rather than for assessing their hazard to human health. Thus, the mere isolation of a pathogen from pigeons does not justify their extermination, although people should be educated about the risk factors for acquiring mycotic disease. The low number of 176 reported transmissions in the literature that spans approximately 60 years underestimates risk, because many cases are not published or the sources of the infections are not recognized. However, in spite of the worldwide distribution of feral pigeons, the close and frequent contact they have with humans, their use as food, and the high prevalence of carriage of human pathogens, zoonotic disease caused by feral pigeons is infrequent. Healthy people who are exposed to feral pigeons and their nesting sites, or who have increased exposure from hobbies or occupations involving feral and domesticated pigeons, should be informed of these risks and advised of appropriate ways to protect themselves. These methods include wearing coveralls, face masks, other respiratory protection, washing hands and by disinfection against excreta dust with antiseptics. If possible, sick pigeons should be avoided, or at the very least, handled with great care to prevent exposure to excreta. The literature reiterates that the immunocompromised patient is at considerably higher risk for contracting opportunistic disease from feral pigeon populations. Since opportunistic pathogens have a multitude of vectors besides feral pigeons, disease prevention is probably best attained by educating the immunocompromised patient to limit contact with all avian sources and to follow guidelines for maintaining hygiene under any circumstance where close contact with pathogenic organisms might occur.

References

1. Haag-Wackernagel D. Die Taube. Basel: Schwabe and Co. AG; 1998.
2. Anonymous. Taubchen, mein Taubchen. In: www.animal-peace.org/Archiv/rft/rft96116.html, vol. 2003. Animal Peace; 2003.
3. White F, Hill H. Disseminated pulmonary calcification. A report of 114 cases with observations of an antecedent pulmonary disease in 15 individuals. *Am Rev Tuberc* 1950;**62**: 1–16.
4. Buchanan KL, Murphy JW. What makes *Cryptococcus neoformans* a pathogen? *Emerg Infect Dis* 1998;**4**:71–83.
5. Anonymous. Cryptococcosis. In: www.cdc.gov/ncidod/dbmd/diseaseinfo/cryptococcosis_t.htm, vol. 2003. Centers for Disease Control; 2002.
6. Kaplan W. Epidemiology of the principal systemic mycoses of man and lower animals and the ecology of their etiologic agents. *J Am Vet Med Assoc* 1973;**163**:1043–1047.
7. Rippon JW. Pathogenesis and epidemiology of opportunistic mycotic infections: a review. *Am J Med Technol* 1977;**43**: 226–228.
8. Meyer K. Ornithosis. In: Biester H, Schwarte L, editors. *Diseases of poultry*. Ames, IA: Iowa State University Press; 1965. p. 657–770.
9. Anonymous. Compendium of measures to control *Chlamydia psittaci* (formerly *Chlamydia psittaci*) infection among humans (Psittacosis) and pet birds. In: www.avma.org/pubhlth/psittacosis.asp, vol. 2003. National Association of State Public Health Veterinarians; 2002.
10. Clarenburg A, Dornickx CGJ. Nahrungmittelvergiftung bei Menschen in Zusammenhang mit Tauben paratyphose. *Zschr Hyg Inf Krankh* 1933;**114**:31–41.
11. Lacassin F, Mino JC, Benoit C, et al. A propos d'un cas de salmonellose aviaire [A case of avian salmonellosis]. *Rev Med Intern* 1995;**16**:77–78.
12. Fukata T, Uemura T, Baba E, et al. Isolation of Clostridia, Salmonellae and Coccidia from wild pigeons in Japan. *Br Vet J* 1986;**142**:291–293.
13. Kinjo T, Morishige M, Minamoto N, et al. Prevalence of *Campylobacter jejuni* in feral pigeons. *Nippon Juigaku Zasshi* 1983;**45**:833–835.
14. Megraud F. Isolation of *Campylobacter* spp. from pigeon feces by a combined enrichment-filtration technique. *Appl Environ Microbiol* 1987;**53**:1394–1395.
15. Sambyal DS, Sharma VK. Screening of free-living animals and birds for *Listeria*, *Brucella* and *Salmonella* infections. *Br Vet J* 1972;**128**:50–55.
16. Woerlen F. Zum Befall der Stadtauben und Mowen mit Salmonellen und thermophilen Campylobacterarten auf dem Gelände eines suddeutschen Schlachthofes. Tierarztl Fakultät, Munchen: Ludwig-Maximilian-Universität; 1990.
17. Fernandez H, Gesche W, Montefusco A, et al. Wild birds as reservoir of thermophilic enteropathogenic *Campylobacter* species in southern Chile. *Mem Inst Oswaldo Cruz* 1996;**91**: 699–700.
18. Perkins L, Swayne D. Pathogenicity of a Hong Kong-origin H5N1 highly pathogenic avian influenza virus for emus, geese, ducks, and pigeons. *Avian Dis* 2002;**46**:53–63.
19. Guan Y, Shortridge KF, Krauss S, et al. H9N2 influenza viruses possessing H5N1-like internal genomes continue to circulate in poultry in southeastern China. *J Virol* 2000;**74**: 9372–9380.
20. McLean RG, Ubico SR, Docherty DE, et al. West Nile virus transmission and ecology in birds. *Ann N Y Acad Sci* 2001;**951**:54–57.
21. Komar N, Burns J, Dean C, et al. Serologic evidence for West Nile virus infection in birds in Staten Island, New York, after an outbreak in 2000. *Vector Borne Zoonotic Dis* 2001;**1**: 191–196.
22. Komar N, Panella NA, Burns JE, et al. Serologic evidence for West Nile virus infection in birds in the New York City vicinity during an outbreak in 1999. *Emerg Infect Dis* 2001;**7**: 621–625.

23. Gruwell J, Fogarty C, Bennett S, et al. The role of peridomestic birds in the transmission of St Louis encephalitis in southern California. *J Wildl Dis* 2000;**36**:13–34.
24. Plissier M, Andre S. Sur l'aptitude du pigeon urbain a developper des anticorps inhibant l'hémagglutination par le virus de la rubeole. *Bul Acad Nat Med (Paris)* 1976;**160**: 224–227.
25. Dorrestein M, Korbel R, Schneeganss D. Einige Befunde zum Gesundheitszustand von freilebenden Stadttauben (*Columba livia*). In: *Tagung der Fachgruppe "Geflügelkrankheiten" der DVG*; 1990. p. 77–87.
26. Kokernot RH, Hayes J, Will RL, et al. Arbovirus studies in the Ohio-Mississippi Basin, 1964–1967. II. St Louis encephalitis virus. *Am J Trop Med Hyg* 1969;**18**:750–761.
27. Sixl W, Stunzner D, Withalm H. Epidemiologic and serologic study of listeriosis in man and domestic and wild animals in Austria. *J Hyg Epidemiol Microbiol Immunol* 1978;**22**: 460–469.
28. Pannwitz E, Pulst H. Vorkommen von Salmonellen bei Stadttauben und Mowen. *Mhefte Vet Med* 1972;**27**:373–375.
29. Agrimi U. Studio degli aspetti sanitari delle popolazioni di piccioni della città di Roma e sviluppo di metodologie incruente di gestione e controllo. Final report of the convention between the Animal Rights Office of Rome and the Superior Institute of Health [Convenzione tra Ufficio Diritti Animali del Comune di Roma e Istituto Superiore di Sanita]; 1999.
30. Pacetti A, Fabbri M, Altabev R, et al. Der Gesundheitszustand der Tauben in der Stadt Bozen. In: *3. Internat. Tag. Infektionskrankheiten in den Alpenländern*; 1994. p. 47–49.
31. Casanovas L, de Simon M, Ferrer MD, et al. Intestinal carriage of campylobacters, salmonellas, yersinias and listerias in pigeons in the city of Barcelona. *J Appl Bacteriol* 1995;**78**: 11–13.
32. Kopschitz M. Der Verseuchungsgrad der Wiener Stadttauben. *Wien tierarztl Mschr* 1976;**63**:304–306.
33. Soldati G, Pavesi M, Fontana M, et al. *Determinazione della prevalenza di alcuni agenti eziologici in piccioni di cattura della città di Modena. Suppl Ric Biol Selvaggina*; 1996. pp. 335–340.
34. Haag D, Gurdan P. Über den hygienischen Zustand der Strassentauben in Basel. *Swiss Vet Schweizerische Zeitschrift für Veterinarmedizin* 1990;**7**:19–22.
35. Dell'Omo G, Morabito S, Quondam R, et al. Feral pigeons as a source of verocytotoxin-producing *Escherichia coli*. *Vet Rec* 1998;**142**:309–310.
36. Schmidt H, Scheef J, Morabito S, et al. A new Shiga toxin 2 variant (Stx2f) from *Escherichia coli* isolated from pigeons. *Appl Environ Microbiol* 2000;**66**:1205–1208.
37. Morabito S, Dell'Omo G, Agrimi U, et al. Detection and characterization of Shiga toxin-producing *Escherichia coli* in feral pigeons. *Vet Microbiol* 2001;**82**:275–283.
38. Rehacek J, Kocianova E, Brezina R. The possible significance of urban populations of the pigeon *Columba livia* f. domestica in propagating *Coxiella burnetii* und *Chlamydia psittaci* in Bratislava. *Biologia (Bratislava)* 1984;**39**:293–300.
39. Kaaserer G, Kaaserer B, Sixl W, et al. Zur Ornithose verwilderter Stadttauben in Innsbruck (Tirol). In: *Internationales Arbeitskolloquium über Naturherde von Infektionskrankheiten in Zentraleuropa*, Graz 24.2–28.2.1976; 1976. p. 373.
40. Meyer K. Pigeons and barn yard fowls as possible sources of human psittacosis or ornithosis. *Schweizerische Medizinische Wochenschrift* 1941;**44**:1377–1379.
41. Levinson D, Gibbs J, Beardwood J. Ornithosis as a cause of sporadic atypical pneumonia. *JAMA* 1944;**126**:1079–1084.
42. Fallett GH. Variete nouvelle de pneumonie atypique. Thesis no 2007, Faculte de Medecine, Geneve: Universite de Geneve; 1950.
43. Lepine P, Sautter V. Sur l'infection des pigeons parisiens par le virus de l'ornithose. *Bull Acad Nat Med* 1951;**135**: 332–338.
44. Shaughnessy H. Psittacosis in wild pigeons. In: Beaudette F, editor. *Psittacosis. Diagnosis, epidemiology, and control*. New Brunswick, NJ: Rutgers University Press; 1955. p. 90–98.
45. Babudieri B. L'ornitosi: sua presenza e frequenza in Italia. *Terapia* 1956;**317**:3–19.
46. Weyer F, Lippelt H. Ein Beitrag zur Frage der Taubenornithose in Deutschland. *Zeitschrift für Hygiene* 1956;**143**: 223–246.
47. Parry W, Griffith A. An epidemiological study in Liverpool. *The Medical Officer* 1962;**23**:181–182.
48. Ortel S. Untersuchungen über Ornithose bei verwilderten Haustauben. *Zentralbl Bakteriol* 1966;**200**:298–303.
49. Brion A, Vacher M. Les pigeons de Paris. *Bulletin Academique veterinaire France* 1970;**43**:311–317.
50. Henry M, Hebrant F, Jadin J. Importance and distribution of serological findings of ornithosis-psittacosis in semi-domestic pigeons. *Bull Soc Pathol Exot Filiales* 1977;**70**:144–151.
51. Milon A, Giral M, Pellerin J, et al. Enquete sur le portage et l'excretion de *Chlamydia psittaci* par les pigeons semi-domestiques (*Columba livia*) de l'agglomeration Toulousaine. *Rev Med Vet* 1983;**134**:559–565.
52. Chiba N, Arikawa J, Takashima I, et al. Isolation and serological survey of chlamydiosis in feral pigeons and crows in Hokkaido. *Nippon Juigaku Zasshi* 1984;**46**:243–245.
53. Batta M, Dhingra P, Dwivedi P, et al. Chlamydiosis in birds from Punjab: serological survey. *Indian J Anim Sci* 1993;**63**: 526–527.
54. Salinas J, Caro MR, Cuello F. Antibody prevalence and isolation of *Chlamydia psittaci* from pigeons (*Columba livia*). *Avian Dis* 1993;**37**:523–527.
55. Pospisil L, Veznik Z, Hirt M, et al. Detection of chlamydia in the intestines and lungs in pigeons and humans. *Epidemiol Mikrobiol Immunol* 1996;**45**:123–126.
56. Ramirez R, Robertstad GW, Hutchinson LR, et al. Mycotic flora in the lower digestive tract of feral pigeons (*Columba livia*) in the El Paso, Texas area. *J Wildl Dis* 1976;**12**:83–85.
57. Bassi M, Chiatante D. The role of pigeon excrement in stone biodeterioration. *Int Biodetn Bull* 1976;**12**:73–79.
58. Weiland E, Bohm KH, Sasu MB. Serological tests on semi-wild pigeons and on pigeons immunized with killed bacterial antigen for antibodies against *Cryptococcus neoformans* (with a contribution to the fluorescence microscopic test for complement fixing antibodies). *Z Med Mikrobiol Immunol* 1971;**156**:159–167.
59. Kocan R, Hasenclever HF. Normal yeast flora of the upper digestive tract of some wild columbids. *J Wildl Dis* 1972;**8**: 365–368.
60. Kocan R, Hasenclever HF. Seasonal variation of the upper digestive tract yeast flora of feral pigeons. *J Wildl Dis* 1974;**10**:263–266.
61. Hasenclever HF, Kogan RM. *Candida albicans* associated with the gastrointestinal tract of the common pigeon (*Columbia livia*). *Sabouraudia* 1975;**13**:116–120.
62. Vidotto V, Gallo MG. Study on the presence of yeasts in the feces of the rock pigeon (*Columba livia* Gmelin 1789) from rural areas. *Parassitologia* 1985;**27**:313–320.
63. Gallo MG, Cabeli P, Vidotto V. Presence of pathogenic yeasts in the feces of the semi-domesticated pigeon (*Columba livia*, Gmelin 1789, urban type) from the city of Turin. *Parassitologia* 1989;**31**:201–212.
64. Kielstein P, Hotzel H, Schmalreck A, et al. Occurrence of

- Cryptococcus* spp. in excreta of pigeons and pet birds. *Mycoses* 2000;**43**:7–15.
65. Mattsson R, Haemig PD, Olsen B. Feral pigeons as carriers of *Cryptococcus laurentii*, *Cryptococcus uniguttulatus* and *Debaryomyces hansenii*. *Med Mycol* 1999;**37**:367–369.
 66. Littman ML, Schneerson SS. *Cryptococcus neoformans* in pigeon excreta in New York City. *Am J Hyg* 1959;**69**:49–59.
 67. Littman ML. Cryptococcosis (torulosis). Current concepts and therapy. *Am J Med* 1959;**27**:976–998.
 68. Emmons CW. Prevalence of *Cryptococcus neoformans* in pigeon habitats. *Public Health Rep* 1960;**75**:362–364.
 69. Littman ML, Borok R. Relation of the pigeon to cryptococcosis: natural carrier state, heat resistance and survival of *Cryptococcus neoformans*. *Mycopathol Mycol Appl* 1968;**35**:329–345.
 70. Partridge BM, Winner HI. *Cryptococcus neoformans* in bird droppings in London. *Lancet* 1965;**14**:1060–1061.
 71. Castanon-Olivares LR, Lopez-Martinez R. Isolation of *Cryptococcus neoformans* from pigeon (*Columba livia*) droppings in Mexico City. *Mycoses* 1994;**37**:325–327.
 72. Currie BP, Freundlich LF, Casadevall A. Restriction fragment length polymorphism analysis of *Cryptococcus neoformans* isolates from environmental (pigeon excreta) and clinical sources in New York City. *J Clin Microbiol* 1994;**32**:1188–1192.
 73. Bohm KH, Abdallah IS, Trautwein G, et al. Demonstration of *Cryptococcus neoformans* in pigeon droppings. *Zentralbl Veterinarmed B* 1967;**14**:419–431.
 74. Yamamoto Y, Kohno S, Noda T, et al. Isolation of *Cryptococcus neoformans* from environments (pigeon excreta) in Nagasaki. *Kansenshogaku Zasshi* 1995;**69**:642–645.
 75. Staib F, Heissenhuber M. *Cryptococcus neoformans* in bird droppings: a hygienic-epidemiological challenge. *AIDS-Forschung* 1989;**12**:649–655.
 76. Focker A, Lumeij J, Houwer D, et al. Isolation of *Cryptococcus neoformans* from the feral pigeon (*Columba livia*) droppings in Amsterdam, The Netherlands. Report of the Faculty of Veterinary Medicine, Utrecht University; 2001.
 77. Dean A, Bates J, Sorrels C, et al. An outbreak of histoplasmosis at an Arkansas courthouse, with five cases of probable reinfection. *Am J Epidemiol* 1978;**108**:36–46. *Am J Epidemiol* 1978;**108**(1): 36–46.
 78. Niederehe H. Toxoplasma-Infektion bei verwilderten Tauben. *Tierarztl Umschau* 1964;**19**:256–257.
 79. Mushi EZ, Binta MG, Chabo RG, et al. Seroprevalence of *Toxoplasma gondii* and *Chlamydia psittaci* in domestic pigeons (*Columba livia domestica*) at Sebele, Gaborone, Botswana. *Onderstepoort J Vet Res* 2001;**68**:159–161.
 80. Fritzsche K. Aktuelle Fragen der Ornithose. In: *Jahreskongress 1960 für ärztliche Fortbildung*, vol. 16.; 1961. p. 75–86.
 81. Anonymous, Killer Pigeons. *Pest Control News* 1998;**46**:21.
 82. Vater G. Ornithose. Strassentauben - Erregerreservoir und Ansteckungsquelle. *Der Praktische Schädlingbekämpfer* 2003;**7/8**:15–21.
 83. Morgan H, Finland M. Serologic findings in patients with primary atypical pneumonia. *Am J Clin Pathol* 1948;**18**:593.
 84. Henry K, Crossley K. Wild-pigeon-related psittacosis in a family. *Chest* 1986;**90**:708–710.
 85. Meiklejohn G, Beck M, Etaton M. Atypical pneumonia caused by psittacosis-like virus. *J Clin Invest* 1944;**23**:167–175.
 86. Seibert RH, Jordan Jr WS, Dingle JH. Clinical variations in the diagnosis of psittacosis. *N Engl J Med* 1956;**254**:925–930.
 87. Gage A, Dean D. Aspergillus infection after cardiac surgery. *Arch Surg* 1970;**101**:384–387.
 88. Burton J, Zachery J, Bessin R, et al. Diagnosis and effective treatment with amphotericin B. *Ann Intern Med* 1972;**77**.
 89. Metha G. *Aspergillus endocarditis* after open heart surgery: an epidemiological investigation. *J Hosp Infect* 1990;**15**:245–253.
 90. Kistemann T, Huneburg H, Exner M, et al. Role of increased environmental *Aspergillus* exposure for patients with chronic obstructive pulmonary disease (COPD) treated with corticosteroids in an intensive care unit. *Int J Hyg Environ Health* 2002;**204**:347–351.
 91. Greaves I, Kane K, Richards N, et al. Pigeons and peritonitis? *Nephrol Dial Transplant* 1992;**7**:967–969.
 92. Procknow J, Benfield J, Rippon J, et al. Cryptococcal hepatitis presenting as a surgical emergency. *JAMA* 1965; 191.
 93. Arasteh K, L'Age M, Futh U, et al. CD4 lymphocyte count in HIV-positive persons exposed to *Cryptococcus neoformans*. *Zentralbl Bakteriol* 1995;**283**.
 94. Lam C, Lam W, Wong Y, et al. Pulmonary cryptococcosis: a case report and review of the Asian-Pacific experience. *Respirology* 2001;**6**:351–355.
 95. Fessel WJ. Cryptococcal meningitis after unusual exposure to birds. *N Engl J Med* 1993;**328**:1354–1355.
 96. Symmers WW. *Cryptococcus neoformans* in bird droppings. *Lancet* 1967;**21**:159–160.
 97. Gatti M, Di Silverio A, Cespa M, et al. Primary unusual cutaneous cryptococcosis in an HIV former drug-abuser patient. *Mycoses* 1997;**40**:101–102.
 98. Babudieri B. Epidemiologie und Virologie der Ornithose beim Menschen. *Archiv Exp Vet Med* 1964;**18**:5–18.



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Exposure to bacterial and fungal bioaerosols in facilities processing biodegradable waste

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The aim of the study was to determine the exposure of workers within biodegradable waste processing facilities to bacteria and fungi to identify any exposures of potential concern to health. Occupational measurements were performed in six composting and three bioenergy (bioethanol or methane/biogas) producing facilities. Bioaerosols were measured from breathing zones with Button aerosol or open face cassette filter samplers, and swab specimens were taken from the nasal mucous membranes of the workers. *Aspergillus fumigatus*, *Bacillus cereus* group, *Campylobacter* spp., *Salmonella* spp., *Streptomyces* spp., and *Yersinia* spp. were determined by real-time polymerase chain reaction (qPCR). *A. fumigatus*, and mesophilic and thermophilic actinobacteria were also cultivated from filters. Bacterial airborne endotoxins collected by IOM samplers were analyzed using a *Limulus* assay. Bioaerosol levels were high, especially in composting compared to bioenergy producing facilities. Endotoxin concentrations in composting often exceeded the occupational exposure value of 90 EU/m³, which may be harmful to the health. In addition to endotoxins, the concentrations of *A. fumigatus* (up to 2.4 × 10⁵ copies/m³) and actinobacteria/*Streptomyces* spp. (up to 1.6 × 10⁶ copies/m³) in the air of composting facilities were often high. Microbial and endotoxin concentrations were typically highest in waste reception and pre-treatment, equal or decreased during processing and handling of treated waste, and lowest in wheel loader cabins and control rooms/outdoors. Still, the parameters measured in wheel loader cabins were often higher than in the control sites, which suggests that the use of preventive measures could be improved. *B. cereus* group, *Salmonella* spp., and *Yersinia* spp. were rarely detected in bioaerosols or nasal swabs. Although *Campylobacter* spp. DNA was rarely detected in air, as a new finding, *Campylobacter ureolyticus* DNA was frequently detected in the nasal mucous membranes of workers, based on partial 16S rDNA sequencing. Moreover, especially *A. fumigatus* and *C. ureolyticus* spp. DNA concentrations in swabs after the work shift were significantly higher than before the shift, which indicates their inhalation or growth during the work shift. Microbial qPCR analysis of bioaerosols and swab samples of nasal mucosa allowed measuring exposure in various work operations and during the work shift, identifying problems for health risk assessment to improve working conditions, and evaluating the effectiveness of preventive measures and personal protection of workers.

KEYWORDS

bioaerosols, bacteria, exposure assessment, fungi, microbial DNA, urban waste management

Introduction

Microorganisms in biodegradable waste can cause infections, acute toxic effects, allergies, and cancer, which has been considered as a serious health problem in the increased recycling of waste material (1). The most common route of entry for biological hazards is inhalation as bioaerosols. Workers may be exposed to bioaerosols when microorganisms are released into the air during the handling of waste. Exposure to bioaerosols in waste management is associated with a wide range of health effects. According to interviews and follow-up studies, workers in the waste management sector experience more work-related symptoms and illnesses than other occupational groups (2, 3). Respiratory symptoms and lung impairment are the most widely studied and probably among the most significant bioaerosol-associated health effects. In particular, the aerobic treatment of waste in composting facilities is associated with adverse acute and chronic respiratory health effects for workers, such as pulmonary irritation and inflammation, chronic bronchitis, and occupational asthma (4–6).

The assessment of exposure to bioaerosols has traditionally been performed using culture-based methods. They are suitable for the simultaneous identification of many different species and are sensitive enough to detect spores of fungi and actinobacteria. However, cultivation is of limited utility in the quantitative assessment of exposure to many pathogens due to non-cultivability or even loss of viability, although cellular components may still induce adverse effects. In addition, pathogenic microbes can be hazardous at extremely low levels that cannot be detected by culture-based methods. Molecular-based diagnostic techniques have much better sensitivity than classical culture-based methods (7, 8). In the real-time polymerase chain reaction (qPCR) method, microbial deoxyribonucleic acid (DNA) as a cell component is a marker for the specific and rapid detection of microorganisms.

The nose is the primary entry route for inhaled air, and the first region of the respiratory tract to come into contact with bioaerosols. Therefore, qPCR detection combined with nasal samples from workers' mucous membranes could be used as a tool to assess exposure to airborne bacteria and fungi in waste management. PCR assays in studies of respiratory viruses and bacteria have provided similar results from both anterior nasal swab specimens and samples collected by nasopharyngeal aspiration (9, 10). Previous studies of nasal fungal and bacterial findings in occupational environments are scarce. Alsaleh et al. (11) have found mold in some nasal samples, when studying respiratory viruses in infants, despite using commercial swab tubes with antifungal agents. They speculated that the fungal findings were due to factors in the living environment of the infants. Furthermore, the carriage of livestock-associated methicillin-resistant *Staphylococcus aureus* to pig farmers and healthcare workers has been demonstrated (12, 13). Mbareche

et al. (14) have shown correlation between the nasopharyngeal bacterial flora of swine workers and the biodiversity of swine barns bioaerosols. These studies demonstrate the transfer of microbes from the work environment to workers via inhalation.

Against the above background, the presence of endotoxins, and airborne microorganisms in composting and bioenergy facilities processing biodegradable waste, and then in the nasal mucous membranes of workers was investigated by cultivation and/or qPCR, with species identification by sequencing when necessary. *A. fumigatus* was measured as an indicator of workers' exposure to fungi, as it is a well-known cause of infectious mycoses, such as bronchopulmonary aspergillosis (15). Actinobacteria of the genus *Streptomyces* are Gram-positive bacteria, which produce resistant spores that can be infectious. Actinobacteria can promote the development of respiratory diseases together with fungi (16). *Bacillus cereus* group, *Campylobacter*, *Salmonella* and *Yersinia* species can be pathogenic bacteria especially in animal waste (17–20). The hypothesis of this study was that waste management workers become exposed to fungal and bacterial pathogens when inhaling bioaerosols through the nose, while the null hypothesis was that no exposure occurs when preventive measures are used. The relevance of the study was to characterize bacterial and fungal exposures for health care, which would lead to improved guidance in waste management companies, where the recycling of waste material is constantly increasing.

Materials and methods

Description of studied facilities

The occupational environments in which this study was conducted were six full-scale composting facilities, and three biogas or bioethanol producing facilities in Finland. Composting is an aerobic treatment in which organic biodegradable waste is recycled into soil fertilizer. Bioenergy facilities produce renewable energy from waste, after which the organic material can be further recycled into soil fertilizer or landscaping. Biogas, mainly a mixture of methane and carbon dioxide, is produced in waste management by anaerobic digestion, and bioethanol by waste fermentation. The facilities treated waste consisting of source-separated municipal biowaste, organic by-products from various agricultural and industrial (bakery, dairy, sugar production) processes, animal manure, and/or wastewater sludge. In the facilities, the transfer of biomass from one site to another was done with wheel loaders equipped with cabins to protect workers. The early stages of composting were indoors, followed by maturation in outdoor windrows (21). Sampling was performed in waste reception and pre-treatment, processing facilities, handling of treated waste, and then in areas with increased protection, including wheel loader cabins, control rooms, dining areas, and outdoors (field edges, parking sites).

Sample collection

Bioaerosol samples from work environments were collected from different stages of the waste treatment processes at fixed measuring points approximately 1.5 m above the floor as close as possible to the process, from the workers' breathing zone, and from the wheel loader cabins. Reference samples were taken from presumed clean and safe work environments, such as a control room or outdoor air, at a distance of more than 300 m upwind from the composting area.

Bioaerosols were measured from workers breathing zones using a filter collection (22). Inhalable bioaerosols for cultivation (18–25 samples/microbe) and qPCR (44 samples) analyses were collected using a Button Aerosol Sampler (SKC Inc., Eighty-Four, PA, USA) at a calibrated flow rate of 4 liters/min in a sample pump with mixed cellulose ester filters (MCE, 1.2 μm , Ø 25 mm, SKC Inc.). The volumes of air samples collected ranged from 0.22 to 1.05 m³, the sampling time being the same as the duration of the work phase. In addition, inhalable bioaerosols were collected for cultivation (20–27 samples/microbe) and qPCR (65 samples) using open face cassettes with polycarbonate filters (PC, 0.4 μm , Ø 37 mm, Whatman International Ltd., Kent, UK) at a calibrated flow rate of 2 liters/min. The volumes of collected air samples varied between 0.11–0.54 m³ depending on the duration of the work. PC and MCE filters used for microbial cultivations were processed within 24 h of sampling, while filters used for qPCR analyses were stored at -80°C until analysis.

Altogether 48 nasal mucous membrane samples from both nostrils of 19 workers (27 samples from composting facility workers and 21 samples from researchers collecting the samples) were taken with nylon flocked swabs (Copan Innovation, Brescia, Italy), first in the morning from the nose of 17 workers, and then after the work shift in the afternoon from the nose of 31 workers. Parallel samples were taken from both nostrils. The swabs were rotated inside the nostril against the internal anterior walls and then placed in the provided transport tube. The swabs were stored at -80°C until qPCR analysis of bacteria and fungi.

All procedures involving humans, including environmental sampling, were conducted in accordance with the ethical standards of the institutional or national research committee, and the 1964 Declaration of Helsinki and its subsequent amendments or comparable ethical standards. The Ethics Committee of Helsinki University Hospital approved the study protocol (HUS/41/13/03/00/2011). All participants provided written informed consent prior to their participation.

Microbial cultivations

Viable bacteria and fungi were cultivated for 3–14 days at specified temperatures on the following culture media. Thermotolerant fungi were cultivated on Rose Bengal (Hagem)

agar (PC filter, 19 samples; MCE filter, 19 samples; $40 \pm 3^{\circ}\text{C}$); thermophilic actinobacteria on half-strength nutrient agar (PC filter, 23 samples; MCE filter, 18 samples; $55 \pm 3^{\circ}\text{C}$); and mesophilic actinobacteria (*Streptomyces* spp.), and other bacteria on tryptone-yeast extract-glucose agar (PC filter, 26 samples; MCE filter, 25 samples; $25 \pm 5^{\circ}\text{C}$) (23–25). After the incubation period, colonies were counted, and *Aspergillus fumigatus* and *Streptomyces* spp. were identified by microscopic examination of morphology. Concentrations of viable microorganisms in bioaerosols were expressed in cfu/m³ (colony forming units per cubic meter of air).

Measurement of endotoxins

All gram-negative bacteria in the waste contain components called endotoxin in their cell walls. In this study, four parallel endotoxin samples were collected from air at 55 different sampling points using an IOM Sampler (SKC Inc.) at a flow rate of 2 liters/min (26). Biologically active endotoxins in air samples were measured using a validated kinetic chromogenic *Limulus* amoebocyte lysate (LAL) assay (Kinetic QCL, Lonza, Walkersville, MD, USA). The collected glass fiber filters (1.0 μm , Ø 25 mm, SKC) were extracted with 5 ml of non-pyrogenic water for 1 h, after which the extracts were centrifuged at 1,000 $\times g$ for 15 min. Supernatants were diluted 1:25 (vol/vol) and analyzed in duplicate for the presence of endotoxin. Standard curves were performed by reconstituting the endotoxin standard of *Escherichia coli* O55:B5 in non-pyrogenic water. The spiked samples were analyzed to determine if inhibition or enhancement affected the endotoxin assay. Results were expressed in EU/m³ (endotoxin units per cubic meter of air).

Real-time PCR

Real-time polymerase chain reaction (qPCR) was used to detect the DNA from cultivable and non-cultivable cells of *A. fumigatus*, *Bacillus cereus* group, *Campylobacter* spp., *Streptomyces* spp., *Yersinia* spp., and *Salmonella* spp. using the same experimental schemes as described in Rainisalo et al. (21). Bacterial and fungal DNA was isolated using the PowerSoil[®] DNA Isolation Kit according to the manufacturer's instructions (Mo Bio Laboratories Inc., Carlsbad, CA, USA). A swab or filter was transferred to the PowerBead tubes instead of soil. Tubes were incubated at 70°C for 10 min to inactivate DNases, followed by cell lysis for 3.5 min at 50 Hz using a TissueLyser LT bead mill (Qiagen, Valencia, CA, USA).

To monitor *A. fumigatus*, a 136 bp fragment of rDNA internal transcribed spacer 1 region was detected using primers AfumiF1 (5'-GCCCGCCGTTTCGAC-3'),

AfumiR1 (5'-GTTGTTGAAAGTTTAACTGATTAC-3') and probe AfumiP1 (5'-CCCCCGAAGACCCCAACA TG-3') (27). *B. cereus* group was followed using primers Pf 5'-GAGTTAGAGAACGGTATTTATGCTGC-3' and Pr 5'-CTACTGCCGCTCCATGAATCC-3', which detect 409 bp fragment of the cereolysin A gene (17). *Campylobacter* spp. (primers C412F, 5'-GGATGACACTTTTCGGA GC-3'; and C1228R, 5'-CATTGTAGCACGTGTGTC-3'; fragment size 816 bp) (18), *Streptomyces* spp. (primers StrepB, 5'-ACAAGCCCTGGAAACGGGT-3'; StrepE, 5'-CACCAGGAATTCCGATCT-3'; fragment size 519 bp) (21, 28), and *Yersinia* spp. (primers Y.16S-86f, 5'-GCGGCAGCGGGAAGTAGTTTA-3'; B.16S-794r, 5'-TACAGCGTGGACTACCAGGT-3'; fragment size 749 bp) (20) were monitored using PCR primers that detect the 16S ribosomal ribonucleic acid (rRNA) gene (16S rDNA). To detect the *Salmonella* species, primers 139 (5'-GTGAAATTATCGCCACGTTTCGGGCAA-3') and 141 (5'-TCATCGCACCGTCAAAGGAACC-3') were used to amplify a 284 bp fragment from the invasion A gene (19). The detection limits based on the lowest positive results were ≤ 7 copies/PCR, corresponding to 101–1,853 copies/swab, and 890–4,069 copies/m³ depending on the filtered air volume. Internal amplification controls (IAC) were from kits designed for the microbes studied and purchased from Okepem Ltd (Finland).

The 20 μ l PCR reaction mixture contained each primer: 0.5 μ M (0.1 μ M probe; *A. fumigatus*)/0.1 μ M (*B. cereus* group)/0.4 μ M (*Campylobacter* spp.)/0.4 μ M (*Streptomyces* spp.)/0.23 μ M (*Yersinia* spp.)/0.4 μ M (*Salmonella* spp.); 1x DyNamoTM HS SYBR Green qPCR Kit (contained hot start version of modified *Tbr* DNA polymerase, SYBR Green 1, optimized PCR buffer, 2.5 mM MgCl₂, dNTP mixture) (Thermo Fisher Scientific Inc., Waltham, MA, USA); 2 μ l of template DNA; and 1 μ l of IAC. Real-time PCRs were performed using iQ5 Real Time PCR Detection System (Bio-Rad Laboratories, Hercules, CA, USA). At least four real-time PCR analyses were performed on at least two DNA isolations from filters and swabs. Controls in duplicate for each PCR experiment were as follows: reagents without template DNA and IAC (no amplification); reagents and IAC without template DNA (IAC amplified); and seven quantification standards in duplicate. The result was evaluated as negative when, according to melting curve analysis, the IAC was amplified without the product of the microbial primers.

To confirm the occurrence of *Campylobacter* spp. in the nasal samples, the amplified 16S rDNA sequences were sequenced as a purchased service at a DNA sequencing laboratory (Institute of Biotechnology, University of Helsinki, Finland) as presented in Pukkila et al. (29). The 16S rDNA sequences were compared to those in the gene library using the Fasta program. The 16S rDNA sequence accession numbers are OP432221-OP432236.

Statistical analyses

Data were analyzed using SPSS Statistics for Windows, version 28.0.0.0 (IBM Corporation, Chicago, IL, United States). Endotoxin concentrations, and microbial DNA copy numbers were statistically analyzed using two-factor (operation, type of facility) Kruskal-Wallis test (KW) followed by pairwise comparisons using Mann-Whitney test (MW). Cultivated microbial numbers in composting facilities were analyzed by one-factor (operation) KW test followed by MW test. Differences in DNA copy numbers due to sampling methods; due to the high-efficiency particulate air (HEPA) filtration systems; before and after the work shifts; and in nasal swabs between facilities types were analyzed by MW. Differences in colony-forming units of *A. fumigatus* and actinobacteria due to sampling methods (Button aerosol or open face cassette filter samplers) were analyzed by *t*-test. Non-parametric statistical analyses were used, if the equality of variances (Levene's test) and/or normal distribution (Kolmogorov-Smirnov test) were not fulfilled. Pearson's two-tailed correlations for positive logarithmic values of colony-forming units and copy numbers were calculated.

Results

Endotoxins, and cultivated *A. fumigatus* and actinobacteria in bioaerosols

Endotoxin concentrations in bioaerosols were high, especially in composting operations compared to bioenergy (biogas or ethanol) producing facilities (KW/MW $p \leq 0.004$; Table 1). Air endotoxin levels in the waste reception and pre-treatment were higher than during waste processing, and in wheel loader cabins and control sites (KW/MW $p \leq 0.034$). The highest air endotoxin concentration of 16,000 EU/m³ was measured during the handling of the treated waste. However, the variation of air endotoxin concentrations was large during waste handling ($< \text{LOD}$ –16,000 EU/m³), which is why this process stage did not differ significantly from the other operations. Air endotoxin concentrations in the wheel loader cabins ranged from below the detection limit to 33 EU/m³, with the exception of two poorly protected cabins with levels ranging from 1,600 to 8,400 EU/m³. Endotoxin concentrations in the air clearly exceeded the occupational exposure limit value of 90 EU/m³ in all studied composting facilities. In biogas facilities, this limit value was exceeded only once in indoor waste reception and pre-treatment.

High numbers of *A. fumigatus* (up to 5.7×10^5 cfu/m³) and actinobacteria (up to 2.5×10^6 cfu/m³) were cultivated from composting facility air samples, regardless of sampling method (*t*-test, $p \geq 0.378$; Button aerosol vs. open face cassettes; Table 1). *A. fumigatus* numbers in the air of composting facilities

TABLE 1 Ranges of variation for endotoxins; for plate counts of *A. fumigatus*, and mesophilic and thermophilic actinobacteria; and for copy numbers of *A. fumigatus*, *Streptomyces* spp., *B. cereus* group, *Campylobacter* spp., *Salmonella* spp., and *Yersinia* spp. DNA in composting and bioenergy production facilities.

Operation	A. Waste reception and pre-treatment	B. Processing	C. Handling of treated waste	D. Wheel loader cabin	E. Control room, outdoors
Endotoxin (LOD 1–8 EU/m³)					
1. Composting (EU/m ³)	670–2,900 (5) ^{2,B,D,E}	3–390 (7) ^{2,A,E}	62–16,000 (4) ²	<LOD–8,400(20) ^{2,A,E}	<LOD–4 (3) ^{2,A,B,D}
2. Bioenergy production (EU/m ³)	8–370 (4) ^{1,B,D,E}	1–20 (3) ^{1,A,E}	<LOD (2) ¹	<LOD–8 (3) ^{1,A,E}	<LOD (4) ^{1,A,B,D}
<i>Aspergillus fumigatus</i>					
1. Composting (cfu/m ³)	4,914–20,915 (7) ^{D,E}	8,598–572,801 (9) ^{D,E}	311–23,804 (7)	172–8,785(13) ^{A,B}	1,195–1,783 (2) ^{A,B}
2. Composting (copies/m ³)	5,099–62,767 (11) ^{3,B,C,D,E}	0–242,844 (13) ^{3,A,D,E}	0–7,137 (8) ^{3,A,D,E}	0–8,444 (8) ^{3,A,B,C,E}	0–120 (15) ^{3,A,B,C,D}
3. Bioenergy production (copies/m ³)	0 (3) ²	0 (8) ²	0 (4) ²	0 (4) ²	0 (7) ²
Mesophilic actinobacteria					
1. Composting (cfu/m ³)	53,681–2,479,339 (7) ^{B,C,D}	129–63,174 (9) ^A	307–21,418 (8) ^A	123–17,193 (20) ^A	996 (1)
2. Bioenergy production (cfu/m ³)	158–309 (2)	262 (1)	ND	ND	81–499 (3)
Thermophilic actinobacteria					
Composting (cfu/m ³)	54–2,380 (7) ^{C,D,E}	4,435–118,256 (7) ^{C,D,E}	54–2,380 (7) ^{A,B}	156–3,361(15) ^{A,B}	548–3,782 (2) ^{A,B}
<i>Streptomyces</i> spp.					
1. Composting (copies/m ³)	51,526–1,645,675 (11) ^{2,B,C,D,E}	0–404,760 (15) ^{2,A,E}	0–70,885 (8) ^{2,A,E}	0–302,855 (27) ^{2,A,E}	0–3,981 (19) ^{2,A,B,C,D}
2. Bioenergy production (copies/m ³)	0–5,289 (3) ¹	0 (8) ¹	0 (4) ¹	0 (4) ¹	0 (10) ¹
<i>Bacillus cereus</i>					
Composting (copies/m ³)	0–430 (11)	0 (15)	0 (8)	0–1,054 (27)	0 (19)
Bioenergy production (copies/m ³)	0 (3)	0 (8)	0 (4)	0 (4)	0 (10)
<i>Campylobacter</i> spp.					
Composting (copies/m ³)	0 (11)	0 (15)	0 (8)	0–802 (27)	0 (19)
Bioenergy production (copies/m ³)	0–15,986 (3)	0 (8)	0 (4)	0 (4)	0 (10)
<i>Salmonella</i> spp.					
Composting (copies/m ³)	0–2,341 (11)	0 (15)	0 (8)	0 (27)	0 (19)
Bioenergy production (copies/m ³)	0 (3)	0 (8)	0 (4)	0 (4)	0 (10)
<i>Yersinia</i> spp.					
Composting (copies/m ³)	0–2,068 (11)	0–2,739 (15)	0–8,624 (8)	0–11,781 (27)	0 (19)
Bioenergy production (copies/m ³)	0–20,055 (3)	0 (8)	0 (4)	0 (4)	0 (10)

Samples were collected from waste reception and pre-treatment, processing, handling of treated waste, wheel loader cabins, and control rooms/outdoors; number of samples in parentheses. Superscript numbers indicate significant differences between composting and bioenergy production, and superscript letters show significant differences between operations (Kruskal-Wallis/Mann-Whitney, $p \leq 0.05$).

ND, Not determined.

were highest in waste reception and pre-treatment and during processing, while significantly lower counts were cultivated from the air of wheel loader cabins, and control rooms/outdoors (MW, $p \leq 0.040$). Similarly, thermophilic actinobacteria in the air of the composting facilities were most abundant in waste reception and pre-treatment, and also during processing, while significantly lower numbers were cultivated from the handling of treated waste, wheel loader cabins, and control rooms/outdoors (KW/MW, $p \leq 0.040$). The concentrations of mesophilic actinobacteria in the air of the composting facilities were highest in waste reception and pre-treatment compared to lower quantities during waste processing and handling of treated waste, and in wheel loader cabins (KW/MW, $p \leq 0.040$). In contrast, *A. fumigatus* could not be cultivated from the air of bioenergy facilities, and the numbers of mesophilic actinobacteria were low (81–499 cfu/m³).

Microbial DNA in bioaerosols

The results of the qPCR assays correlated very well with the results obtained with culture-based methods for the identification and quantification of *A. fumigatus* ($R = 0.696$, $p < 0.001$, $n = 25$) and *Streptomyces* spp. (mesophilic actinobacteria $R = 0.778$, $p < 0.001$, $n = 33$; thermophilic actinobacteria $R = 0.620$, $p < 0.001$, $n = 27$) from air samples collected with a Button or open face cassette aerosol sampler. The air sampling method did not affect the DNA copy number results of any microbes (MW, $p \geq 0.084$, Button aerosol vs. open face cassettes). *A. fumigatus* (up to 2.4×10^5 copies/m³) and *Streptomyces* spp. (up to 1.6×10^6 copies/m³) DNA levels were of the same order of magnitude as the concentrations of cultivable microbes in bioaerosols, and their levels in composting facilities were higher than in bioenergy production (KW/MW, $p < 0.001$; Table 1). No *A. fumigatus* gene copies were detected in the air of bioenergy producing facilities, and *Streptomyces* spp. DNA was only found at the waste reception and pre-treatment.

The number of *A. fumigatus* gene copies in composting facilities was highest in waste reception and pre-treatment, lower and about equal during processing and handling of treated waste, low in wheel loader cabin, and lowest in control room/outdoors (KW/MW, $p \leq 0.037$; Table 1). In composting facilities, *A. fumigatus* DNA levels in well-sealed wheel loader cabins equipped with pressurization and high-efficiency particulate air (HEPA) filtration system were lower than in other wheel loaders equipped with poorly designed equipment (MW, $p = 0.012$). The highest *Streptomyces* spp. DNA copy levels in composting facilities were also observed in waste reception and pre-treatment, lower concentrations were detected during waste processing and handling of treated waste, and in wheel loader cabins, while numbers were lowest in control rooms/outdoors (KW/MW, $p \leq 0.004$).

DNA from *B. cereus* group, *Campylobacter* spp., *Salmonella* spp., and *Yersinia* spp. was rarely detected in air samples from composting and bioenergy producing facilities (Table 1). *B. cereus* group and *Yersinia* spp. DNA was detected once, and *Salmonella* spp. DNA was detected twice in the waste reception and pre-treatment air of composting facilities. *Yersinia* spp. DNA was detected in the air once during compost processing, and twice during handling of treated compost waste. *B. cereus* group and *Yersinia* spp. DNA was detected in the air from the same wheel loader cabin where the highest endotoxin concentration was measured, while *Campylobacter* spp. DNA was found in two other wheel loader cabins at the composting facilities. The DNA of these bacteria was not detected in the control rooms or outdoor. In bioenergy facilities, *Campylobacter* spp. and *Yersinia* spp. DNA was detected only once in waste reception and pre-treatment.

Microbial DNA in nasal samples

As the qPCR analysis of microbial DNA proved to be a reliable assay for air samples, the same methods were used to analyse nasal swabs. These samples were taken from the noses of 19 workers and sampling researchers before and after the work shift. In the composting facilities, *A. fumigatus* DNA was detected in the nasal swab samples of 9 workers after the work shift, and in only two samples before the work shift, the difference being statistically significant (MW, $p = 0.042$; Table 2). In the bioenergy producing facilities, nasal samples were taken from 10 workers, and only one worker produced a positive nasal finding for *A. fumigatus* DNA.

More workers in composting facilities had positive *Streptomyces* spp. DNA findings than in bioenergy facilities (MW, $p = 0.020$; Table 2). A positive result was also observed in most composting plant workers at the beginning of the shift, but the mean amount of *Streptomyces* spp. DNA was about 4-fold higher after the work shift. In composting facilities, 8 positive results for *Streptomyces* spp. DNA were obtained from 16 nasal samples taken before the work shift, while the number of positive swab specimens after the shift was 18 out of 22. In bioenergy facilities, the proportion of positive *Streptomyces* spp. DNA swab samples was only three out of ten nasal samples.

The number of workers with a positive *Campylobacter* spp. DNA nasal sample was 17 of the 27 studied, although *Campylobacter* species were detected in only three air samples. Of these workers, 19 worked in composting facilities and 14 of them has a positive nasal sample. The quantities of *Campylobacter* spp. DNA in nasal samples after the work shift were significantly higher than before the shift (MW, $p = 0.029$; Table 2). Altogether 15 partial *Campylobacter* spp. 16S rDNA sequences were sequenced from nasal swab samples. All sequences were 99.9–100.0 % identical to the *Campylobacter ureolyticus* sequence. Partial 16S rDNA sequence

TABLE 2 The averages $\pm$ S.D., medians, and ranges of DNA copies of *A. fumigatus*, *Streptomyces* spp., *Campylobacter* spp., *Yersinia* spp., *B. cereus* group, and *Salmonella* spp. in nasal swab samples collected in composting facilities before and after the work shift, and in bioenergy facilities.

	1. Composting (copies/m ³)		2. Bioenergy (copies/m ³)
	A. Before	B. After	
<i>Aspergillus fumigatus</i>			
Average ± S.D.	13 ± 40 ^B	118 ± 193 ^A	8 ± 25
Median	0	0	0
Range	0–149	0–722	0–77
<i>Streptomyces</i> spp.			
Average ± S.D.	394 ± 608 ²	1,569 ± 5013 ²	99 ± 169 ¹
Median	66	319	0
Range	0–2147	0–23,887	0–465
<i>Campylobacter</i> spp.			
Average ± S.D.	4,261 ± 6,834 ^B	37,477 ± 937,784 ^A	3,655 ± 5,780
Median	2,051	4,547	861
Range	0–21,406	0–415,745	0–18,433
<i>Yersinia</i> spp.			
Average ± S.D.	73 ± 290	107 ± 502	Not detected
Median	0	0	
Range	0–1,160	0–2,356	
<i>Bacillus cerus</i>	Not detected	Not detected	Not detected
<i>Salmonella</i> spp.	Not detected	Not detected	Not detected

The superscript letters indicate statistically significant differences before and after shifts, and superscript numbers indicate significant differences between composting and bioenergy production facilities (Mann-Whitney, $p \leq 0.05$).

of *Campylobacter* sp. DNA in an air sample from biogas production from pig manure was 99.9 % identical to the DNA of *Campylobacter lanienae* strain 15991b.

Yersinia spp. DNA was detected in the nose of only one worker, and no *B. cereus* group or *Salmonella* spp. DNA was found in nasal swab samples (Table 2).

Discussion

Microbial bioaerosols in air

Biodegradable waste provides a favorable substrate for microorganisms to live and reproduce. These microorganisms can be spread into the air by physically handling the waste, and a large portion of the bioaerosols can be present in the ambient air, as the results showed (Table 1). Bioaerosols formed from waste at composting facilities contained large amounts of mesophilic and thermophilic actinobacteria (*Streptomyces* spp.) and thermotolerant fungi (*A. fumigatus*), all of which play an important role in the transformation processes occurring during organic material decaying (30). Fungi of the genus *Aspergillus*,

and actinobacteria have often been identified as dominant species at different stages of composting, often in the same quantities as measured in this study (7, 31–34). However, in this study, *A. fumigatus* was not detected in bioenergy facilities, although previously up to 1.2×10^4 ITS genes/m³ have been detected mainly in waste reception and shredding, as well as in storage and output sites (35).

DNA of the other studied bacteria, *B. cereus* group, *Campylobacter* spp., *Salmonella* spp., and *Yersinia* spp., was detected in the air only rarely, more often in composting than in bioenergy facilities (Table 1). Nevertheless, *Bacillus* has been reported to belong to the dominant genus in compost bioaerosols (36, 37). In bioenergy facilities, *Yersinia* spp. DNA was detected only once in the air from the waste reception and pre-treatment simultaneously with *Campylobacter* spp. DNA. In composting facilities, *B. cereus* group, *Campylobacter* spp., *Salmonella* spp., and *Yersinia* spp. DNA was detected only in operations involving compost turning, either in the air of the composting space or in poorly protected wheel loader cabins. The concentrations of all studied microorganisms in the bioaerosols of the composting facilities were the highest in waste reception and pre-treatment, and among the lowest in the handling of treated waste, where concentrations could still be quite high. This is consistent with previous results, where bioaerosol concentrations have been highest during on-site agitation activities, such as turning, screening, and shredding (3).

In connection with microbial counts, it is important to recognize that only a small portion of microorganisms are cultivable or viable under bioaerosol sampling and culture conditions, resulting in lower numbers of colony-forming units than the actual total number of microbes. At the same time, large quantities of harmful biologically active cell components, such as endotoxins, can remain in the bioaerosols of composting operations (7, 8). Identification of common composting biomarkers and the causal relationships between bioaerosol exposure and disease outbreaks, as well as defining exposure limits are future requirements (8, 38). As large variations in microbial numbers were observed in this study, in agreement of other published results (3), it may be utmost important to recognize that the quality and treatment history of the waste material affects the microbial numbers and bioactive component quantities in bioaerosols. As unit operations in waste treatment can be difficult to standardize reliably, health risk assessment should be based on the highest commonly occurring concentrations in each operation.

In this study, bioaerosol levels were much higher in composting than in biogas or bioethanol producing facilities (Table 1). Dubuis et al. (39) have also shown that human exposure to bioaerosols in biomethanization facilities is lower than in composting plants. No legally binding limit values have been established for occupational exposure to bioaerosols (8, 38). However, data obtained from the assessment of occupational

exposure to endotoxins, which serves as a marker for the whole group of Gram-negative bacteria, indicate that adverse health effects can be expected after chronic exposure to concentrations above 90 EU/m³ (40). The highest endotoxin concentrations (up to 16,000 EU/m³) were measured when compost was turned (Table 1), which is known to increase bioaerosol production (32). These results support previously published data suggesting that composting site workers may be exposed to high levels of bacterial endotoxins and microbial bioaerosols (31, 39, 41, 42).

Bioaerosols are a health risk, especially when waste is handled openly in the proximity of workers (32). Working inside a sealed cabin with air filtration had a major impact on reducing exposure to bioaerosols. Schlosser et al. (43) have found that, in particular, a pressurization and HEPA filtration system in the vehicle cabins of composting facilities can provide more than 99.9% protection efficiency. Their study emphasized that vehicle cabin protection systems reduced airborne endotoxins more than fungal spores. A similar observation was also found in this study that endotoxins were easier to remove than actinobacteria and fungi from the interior air of the cabins (Table 1). Regardless of the measurement methods, the concentrations of *A. fumigatus* and actinobacteria in the wheel loader cabins of the composting facilities were always significantly lower than in waste reception and pre-treatment. Still, the concentrations of endotoxins, as well as *A. fumigatus* and *Streptomyces* spp. DNA in wheel loader cabins were often higher than in control rooms or outdoors, suggesting that the hygiene could be better maintained.

Microbial DNA in nasal samples

Composting plant workers had more *A. fumigatus* and *Campylobacter* spp. DNA in nasal samples after the work shift than before the shift. The difference in *Streptomyces* spp. DNA concentration in nasal samples before and after the work shift was less clear than the difference in *A. fumigatus* DNA. Most of the workers in composting plants had *Streptomyces* spp. DNA in the nose already at the beginning of the work shift. This means that workers may have been exposed to *Streptomyces* spp. elsewhere. Another possible explanation is that the concentrations of *Streptomyces* spp. DNA in the air (up to 2.5 × 10⁶ cfu/m³) and compost (21) in some waste handling operations were so huge that the nasal cells did not have enough time to disinfect the bacteria on the nasal mucous membranes between work shifts.

The most surprising result of this study was that *Campylobacter* spp. DNA was very common in the nasal mucous membranes of workers at composting facilities processing biodegradable waste. *Campylobacter* spp. 16S rDNAs were sequenced to confirm their occurrence, and the most common species was *C. ureolyticus*. In Southern Ireland, molecular studies on the prevalence of various *Campylobacter*

spp. in patients with gastroenteritis have identified *C. ureolyticus* as the second most common *Campylobacter* species (44). In other studies, this strain has been isolated from a wide variety of human samples, including superficial ulcers and soft tissue infections, urethritis, periodontal disease, and human feces (45, 46). *C. ureolyticus* has also been detected in the direct sequencing of 16S rDNA from template DNA isolated from human skin (47–49).

Campylobacter spp. DNA was detected in an air sample at a biogas plant processing pig manure. The 16S rDNA sequence of *Campylobacter* sp. in this air sample differed from those observed in the nasal swab samples. The bacterial DNA in the air sample was identical to *Campylobacter lanienae* DNA previously isolated from food-producing swine (50). Airborne cultivable *Campylobacter* spp. could not be recovered from bioaerosol samples in another agricultural study, although four of the 35 nasal flora samples from hog producers were *Campylobacter* spp. positive (51). The reason for this rare occurrence of *Campylobacter* spp. in air samples could be that, as preferentially anaerobic bacteria, they are easily destroyed in the air, especially during sampling. In this study, *Campylobacter* spp. DNA levels in air samples were low, close to the detection limit of 1.2 ± 0.6 × 10³ copies/m³ (1–5 copies/PCR). The workers may also have been exposed to *Campylobacter* spp. through skin contact with contaminated hands. Human campylobacteriosis is commonly considered to be a zoonotic disease with infection transfer being mainly mediated via the fecal-oral route (52). Exposure to bioaerosols may have promoted the nasopharyngeal growth of *C. ureolyticus* naturally present in the body, if not derived from bioaerosols.

Whether or not *Campylobacter* spp. are the leading cause of intestinal infections among workers in the waste management sector requires further studies. It is known that *Campylobacter* spp. are the major cause of foodborne diarrheal diseases in humans, and among the most common bacteria causing gastroenteritis worldwide (52). In both developed and developing countries, they cause more cases of diarrhea than *Salmonella* spp. (53). Therefore, *Campylobacter* species must be more common in the environment than is known. Our study, and new data from other studies suggest that *C. ureolyticus* is an emerging *Campylobacter* strain whose clinical importance is still underestimated (45).

DNA findings of other pathogens in nasal samples were sporadic compared to *Campylobacter* spp. DNA. *Yersinia* spp. DNA was detected in the nose of only one worker, who also had high numbers of *Yersinia* spp. DNA in the breathing zone in the cabin, collected by the air filter. In previous studies, *Yersinia enterocolitica* has been infrequently detected in both bioaerosols (2/18) and nasal secretions of hog producers (1/35) (51).

Detection of bioaerosols by the molecular qPCR assay was a sensitive method to assess workers exposure. Using nasal swabs in combination with the qPCR assay may be an even better choice for studying human exposure than taking air samples

alone, as the ambient air is constantly inhaled through the nose. The air sample often represents only one part of the entire work shift. The importance of preferring the collection of nasal swab samples is supported by the observation that the difference in the microbial DNA of the nasal samples before and after the work shift was clear. In most cases, *A. fumigatus* DNA was not present in swab samples taken from the human nose before the work shift. In particular, in workers who did not work in waste management during the days before sampling, no *A. fumigatus* DNA was detected in the morning. Madsen et al. (54) have observed similar results; they measured the presence of fungi and bacteria in the noses of greenhouse workers using nasal lavage. They found that the concentration of fungi, β -glucan, and bacteria in the nasal lavage on Thursday at noon was higher than that on Monday morning. In addition, upper airway inflammation markers have increased in nasal lavage samples of composting facility workers after exposure to bioaerosols from Monday to Thursday (6). Thus, combining bioaerosol and nasal lavage microbial assays with the analysis of respiratory track inflammatory markers could improve human health risk assessment in waste treatment.

Conclusions

The results showed that workers in biodegradable waste processing are exposed to bacteria and fungi that can be harmful to health. Especially in composting facilities, endotoxin concentrations in the air often exceeded the chronic exposure limit value of 90 EU/m³. Further, *A. fumigatus* and *Campylobacter* spp. DNA levels were significantly increased, and *Streptomyces* spp. DNA quantity was elevated in nasal swabs taken after the work shift compared to the levels before the shift. Workers' exposure to microbial hazards was high enough to lead to long-term respiratory diseases. Although the concentrations of endotoxins, *A. fumigatus*, and actinobacteria/*Streptomyces* spp. in wheel loader cabins were typically lower than in waste reception and pre-treatment, the levels were often elevated compared to the control rooms or outdoors, suggesting that hygiene could be better maintained. Waste management workers should be trained to take better care of hygiene, use appropriate protective equipment and all available preventive measures to preclude exposure to bioaerosol-related harmful microbial infections, such as campylobacteriosis.

Composting is well suited for the final treatment of organic process residues, although it has the problem of high bioaerosol concentrations. The number of harmful microbes was low in bioaerosols from closed bioenergy production processes. Therefore, composting could also be developed toward more closed processes to reduce worker exposure, while using wheel loader cabins with properly maintained HEPA filters and slight air overpressure. The studied facilities were simple in structure and the transfer of compost from one site to another was

based on wheel loaders. Automation could reduce exposure to bioaerosols, although workers may face additional hygiene risks from process maintenance and repair interruptions.

The significance of qPCR assays is that they create new applications for determining exposure to pathogenic microorganisms, such as the new finding on the common occurrence of *Campylobacter* spp. in waste treatment was made in this study. Sampling of workers' nasal mucous membranes shows the actual inhalation of microorganisms that may pose a potential risk to their health. These nasal samples can also be used to evaluate how effectively respiratory protection equipment protect workers from bioaerosols.

Data availability statement

The original contributions presented in the study are included in the article, further inquiries can be directed to the corresponding author.

Ethics statement

The studies involving human participants were reviewed and approved by all procedures that involved human participants including environmental sampling were conducted in accordance with the ethical standards of the institutional or national research committee and the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards. The Ethics Committee of Helsinki University Hospital approved the Study Protocol (HUS/41/13/03/00/2011). All responders provided written informed consent prior to their participation. The patients/participants provided their written informed consent to participate in this study.

Author contributions

SL and MHK designed research, sampling, and analysis methods. MK analyzed the samples and organized the database. SL wrote the first draft of the manuscript. All authors contributed to manuscript revision, read, and approved the submitted version.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

References

- Douwes J, Thorne P, Pearce N, Heederik D. Bioaerosol health effects and exposure assessment: progress and prospects. *Ann Occup Hyg.* (2003) 47:187–200. doi: 10.1093/annhyg/meg032
- Bünger J, Schapper-Scheele B, Hilgers R, Hallier E. A. 5-year follow-up study on respiratory disorders and lung function in workers exposed to organic dust from composting plants. *Int Arch Occup Environ Health.* (2007) 80:306–12. doi: 10.1007/s00420-006-0135-2
- Pearson C, Littlewood E, Douglas P, Robertson S, Gant TW, Hansell AL. Exposures and health outcomes in relation to bioaerosol emissions from composting facilities: a systematic review of occupational and community studies. *J Toxicol Environ Health B Crit Rev.* (2015) 18:43–69. doi: 10.1080/10937404.2015.1009961
- Domingo JL, Nadal M. Domestic waste composting facilities: a review of human health risks. *Environ Int.* (2009) 35:382–9. doi: 10.1016/j.envint.2008.07.004
- Chang M-W, Lee C-R, Hung H-F, Teng K-S, Huang H, Chuang C-Y. Bioaerosols from a food waste composting plant affect human airway epithelial cell remodeling genes. *Int J Environ Res Public Health.* (2014) 11:337–54. doi: 10.3390/ijerph110100337
- Heldal KK, Halstensen AS, Thorn J, Djupesland P, Wouters I, Eduard W, et al. Upper airway inflammation in waste handlers exposed to bioaerosols. *Occup Environ Med.* (2003) 60:444–50. doi: 10.1136/oem.60.6.444
- Bru-Adan V, Wéry N, Moletta-Denat M, Boiron P, Delgènes J-P, Godon J-J. Diversity of bacteria and fungi in aerosols during screening in a green waste composting plant. *Curr Microbiol.* (2009) 59:326–35. doi: 10.1007/s00284-009-9438-3
- Franchitti E, Pascale E, Fea E, Anedda E, Traversi D. Methods for bioaerosol characterization: Limits and perspectives for human health risk assessment in organic waste treatment. *Atmosphere.* (2020) 11:452. doi: 10.3390/atmos11050452
- Meerhoff TJ, Houben ML, Coenjaerts FEJ, Kimpen JLL, Hofland RW, Schellevis F et al. Detection of multiple respiratory pathogens during primary respiratory infection: nasal swab versus nasopharyngeal aspirate using real-time polymerase chain reaction. *Eur J Clin Microbiol Infect Dis.* (2010) 29:365–71. doi: 10.1007/s10096-009-0865-7
- Grijalva CG, Griffin MR, Edwards KM, Johnson M, Gil AI, Verástegui H et al. Concordance between RT-PCR-based detection of respiratory viruses from nasal swabs collected for viral testing and nasopharyngeal swabs collected for bacterial testing. *J Clin Virol.* (2014) 60:309–12. doi: 10.1016/j.jcv.2014.04.011
- Alsaleh AN, Whitley DM, Bialasiewicz S, Lambert SB, Ware RS, Nissen MD et al. Nasal swab samples and real-time polymerase chain reaction assays in community-based, longitudinal studies of respiratory viruses: the importance of sample integrity and quality control. *BMC Infect Dis.* (2014) 14:15. doi: 10.1186/1471-2334-14-15
- van Cleef BAGL, van Benthem BHB, Verkade EJM, van Rijen M, Kluytmans-van den Bergh MFQ, Schouls LM, et al. Dynamics of methicillin-resistant *Staphylococcus aureus* and methicillin-susceptible *Staphylococcus aureus* carriage in pig farmers: a prospective cohort study. *Clin Microbiol Infect.* (2014) 20:O764–71. doi: 10.1111/1469-0691.12582
- Gebreyesus A, Gebre-Selassie S, Mihert A. Nasal and hand carriage rate of methicillin resistant *Staphylococcus aureus* (MRSA) among health care workers in Mekelle Hospital, North Ethiopia. *Ethiop Med J.* (2013) 51:41–7.
- Mbareche H, Veillette M, Pilote J, Létourneau V, Duchaine C. Bioaerosols play a major role in the nasopharyngeal microbiota content in agricultural environment. *Int J Environ Res Public Health.* (2019) 16:1375. doi: 10.3390/ijerph16081375
- Millner PD, Marsh PB, Snowden RB, Parr JF. Occurrence of *Aspergillus fumigatus* during composting of sewage sludge. *Appl Environ Microbiol.* (1977) 34:765–72. doi: 10.1128/aem.34.6.765-772.1977
- Huttunen K, Pelkonen J, Nielsen KF, Nuutinen U, Jussila J, Hirvonen M-R. Synergistic interaction in simultaneous exposure to *Streptomyces californicus* and *Stachybotrys chartarum*. *Environ Health Perspect.* (2004) 112:659–65. doi: 10.1289/ehp.6701
- Schraft H, Griffiths MW. Specific oligonucleotide primers for detection of lecithinase-positive *Bacillus* spp. by PCR. *Appl Environ Microbiol.* (1995) 61:98–102. doi: 10.1128/aem.61.1.98-102.1995
- Linton D, Owen RJ, Stanley J. Rapid identification by PCR of the genus *Campylobacter* and of five *Campylobacter* species enteropathogenic for man and animals. *Res Microbiol.* (1996) 147:707–18. doi: 10.1016/S0923-2508(97)85118-2
- Rahn K, De Grandis SA, Clarke RC, McEwen SA, Galán JE, Ginacchio C et al. Amplification of an *invA* gene sequence of *Salmonella typhimurium* by polymerase chain reaction as a specific method of detection of *Salmonella*. *Mol Cell Probes.* (1992) 6:271–9. doi: 10.1016/0890-8508(92)90002-F
- Trebesius K, Harmsen D, Rakin A, Schmelz J, Heesemann J. Development of rRNA-targeted PCR and *in situ* hybridisation with fluorescently labelled oligonucleotides for detection of *Yersinia* species. *J Clin Microbiol.* (1998) 36:2557–64. doi: 10.1128/JCM.36.9.2557-2564.1998
- Rainisalo A, Romantschuk M, Kontro MH. Evolution of clostridia and streptomycetes in full-scale composting facilities and pilot drums equipped with on-line temperature monitoring. *Bioresour Technol.* (2011) 102:7975–83. doi: 10.1016/j.biortech.2011.05.087
- Eduard W, Heederik D. Methods for quantitative assessment of airborne levels of noninfectious microorganisms in highly contaminated work environments. *Am Ind Hyg Assoc J.* (1998) 59:113–27. doi: 10.1080/15428119891010370
- Corbuz R, Gregory PH, Lacey ME. Thermophilic and mesophilic actinomycetes in mouldy hay. *J Gen Microbiol.* (1963) 32:449–55. doi: 10.1099/00221287-32-3-449
- Russell BS. *Mycology Guidebook*. Mycological Society of America. Seattle, WA: University of Washington Press (1974).
- Suutari M, Lignell U, Hyvärinen A, Nevalainen A. Media for cultivation of indoor streptomycetes. *J Microbiol Methods.* (2002) 51:411–6. doi: 10.1016/S0167-7012(02)00100-8
- Laitinen S, Nevalainen A, Kotimaa M, Liesivuori J, Martikainen PJ. Relationship between bacterial counts and endotoxin concentrations in the air of wastewater treatment plants. *Appl Environ Microbiol.* (1992) 58:3774–6. doi: 10.1128/aem.58.11.3774-3776.1992
- Haugland RA, Varma M, Wymer LJ, Vesper SJ. Quantitative PCR analysis of selected *Aspergillus*, *Penicillium* and *Paecilomyces* species. *Syst Appl Microbiol.* (2004) 27:198–210. doi: 10.1078/072320204322881826
- Rintala H, Nevalainen A, Rönkä E, Suutari M. PCR primers targeting the 16S rRNA gene for the specific detection of streptomycetes. *Mol Cell Probes.* (2001) 15:337–47. doi: 10.1006/mcpr.2001.0379
- Pukkila V, Gustafsson J, Tuominen J, Aallonen A, Kontro MH. The most-probable-number enumeration of dichlobenil and 2,6-dichlorobenzamide (BAM) degrading microbes in Finnish aquifers. *Biodegradation.* (2009) 20:679–86. doi: 10.1007/s10532-009-9255-1
- Lacey J, Crook B. Fungal and actinomycete as pollutants of the workplace and occupational allergens. *Ann Occup Hyg.* (1988) 32:515–33. doi: 10.1093/annhyg/32.4.515

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31. van Kampen V, Sander I, Liebers V, Deckert A, Neumann H-D, Buxtrup M et al. Concentration of bioaerosols in composting plants using different quantification methods. *Ann Occup Hyg.* (2014) 58:693–706. doi: 10.1093/annhyg/meu026
32. Bonifait L, Marchand G, Veillette M, M'Bareche H, Dubuis M-E, Pépin C, et al. Workers' exposure to bioaerosols from three different types of composting facilities. *J Occup Environ Hyg.* (2017) 14:815–22. doi: 10.1080/15459624.2017.1335054
33. Robertson S, Douglas P, Jarvis D, Marczylo E. Bioaerosol exposure from composting facilities and health outcomes in workers and in the community: a systematic review update. *Int J Hyg Environ Health.* (2019) 222:364–86. doi: 10.1016/j.ijheh.2019.02.006
34. Persoons R, Parat S, Stoklov M, Perdrix A, Maitre A. Critical working tasks and determinants of exposure to bioaerosols and MVOC at composting facilities. *Int J Hyg Environ Health.* (2010) 213:338–47. doi: 10.1016/j.ijheh.2010.06.001
35. Mbareche H, Veillette M, Dubuis M-E, Bakhiyi B, Marchand G, Zayed J, et al. Fungal bioaerosols in biomethanization facilities. *J Air Waste Manag Assoc.* (2018) 68:1198–210. doi: 10.1080/10962247.2018.1492472
36. Gao M, Yang Z, Guo Y, Chen M, Qiu T, Sun X, et al. The size distribution of airborne bacteria and human pathogenic bacteria in a commercial composting plant. *Front Environ Sci Eng.* (2021) 15:39. doi: 10.1007/s11783-020-1356-4
37. Pascale E, Franchitti E, Zanchi N, Anedda E, Bonetta S, Traversi D. Size-fractionated PM₁₀ and bioaerosol indicator development by different methods in composting plants for risk assessment. *Front Environ Sci.* (2022) 10:777598. doi: 10.3389/fenvs.2022.777598
38. Schlosser O. Bioaerosols and health: current knowledge and gaps in the field of waste management. *Detritus.* (2019) 5:111–25. doi: 10.31025/2611-4135/2019.13786
39. Dubuis M-E, M'Bareche H, Veillette M, Bakhiyi B, Zayed J, Lavoie J, et al. Bioaerosols concentrations in working areas in biomethanization facilities. *J Air Waste Manag Assoc.* (2017) 67:1258–71. doi: 10.1080/10962247.2017.1356762
40. University of Gothenburg. *The Nordic Expert Group (NEG) for Criteria Documentation of Health Risks from Chemical and the Dutch Expert Committee on Occupational Safety (DECOS). 144. Endotoxins. Arbete och Hälsa.* Gothenburg: University of Gothenburg, Sweden (2011). p. 45.
41. Sykes P, Morris RHK, Allen JA, Wildsmith JD, Jones KP. Workers' exposure to dust, endotoxin and β -(1–3) glucan at four large-scale composting facilities. *Waste Mana.* (2011) 31:423–30. doi: 10.1016/j.wasman.2010.10.016
42. Duquenne P, Simon X, Koehler V, Goncalves-Machado S, Greff G, Nicot T, et al. Documentation of bioaerosol concentrations in an indoor composting facility in France. *J Environ Monit.* (2012) 14:409–19. doi: 10.1039/c2em10714g
43. Schlosser O, Huyard A, Rybacki D, Do Quang Z. Protection of the vehicle cab environment against bacteria, fungi and endotoxins in composting facilities. *Waste Manag.* (2012) 32:1106–15. doi: 10.1016/j.wasman.2012.01.013
44. Bullman S, O'Leary J, Corcoran D, Sleator RD, Lucey B. (2012). Molecular-based detection of non-culturable and emerging campylobacteria in patients presenting with gastroenteritis. *Epidemiol Infect.* (2012) 140:684–8. doi: 10.1017/S0950268811000859
45. O'Donovan D, Corcoran GD, Lucey B, Sleator RD. *Campylobacter ureolyticus*: a portrait of the pathogen. *Virulence.* (2014) 15:498–506. doi: 10.4161/viru.28776
46. Man SM, Kaakoush NO, Octavia S, Mitchell H. The internal transcribed spacer region, a new tool for use in species differentiation and delineation of systematic relationships within the *Campylobacter* genus. *Appl Environ Microbiol.* (2010) 76:3071–81. doi: 10.1128/AEM.02551-09
47. Vandamme P, Debruyne L, De Brandt E, Falsen E. Reclassification of *Bacteroides ureolyticus* as *Campylobacter ureolyticus* comb. Nov., and emended description of the genus *Campylobacter*. *Int J System Evol Microbiol.* (2010) 60:2016–22. doi: 10.1099/ijss.0.017152-0
48. Grice EA, Kong HH, Conlan S, Deming CB, Davis J, Young AC, et al. Topographical and temporal diversity of the human skin microbiome. *Science.* (2009) 324:1190–2. doi: 10.1126/science.1171700
49. Kong HH, Oh J, Deming C, Conlan S, Grice EA, Beatson MA, et al. Temporal shifts in the skin microbiome associated with disease flares and treatment in children with atopic dermatitis. *Genome Res.* (2012) 22:850–9. doi: 10.1101/gr.131029.111
50. Schweitzer N, Damjanova I, Kaszanyitzky E, Ursu K, Samu P, Tóth AG et al. Molecular characterization of *Campylobacter lanienae* strains isolated from food-producing animals. *Foodborne Pathog Dis.* (2011) 8:615–21. doi: 10.1089/fpd.2010.0754
51. Létourneau V, Nehmé B, Mériaux A, Massé D, Cormier Y, Duchaine C. Human pathogens and tetracycline-resistant bacteria in bioaerosols of swine confinement buildings and in nasal flora of hog producers. *Int J Hyg Environ Health.* (2010) 213:444–9. doi: 10.1016/j.ijheh.2010.09.008
52. Whitley H, van den Akker B, Giglio S, Bentham R. The role of environmental reservoirs in human campylobacteriosis. *Int J Environ Res Public Health.* (2013) 10:5886–907. doi: 10.3390/ijerph10115886
53. World Health Organization. *Campylobacter.* Geneva: World Health Organization (2020).
54. Madsen AM, Tendal K, Thilsing T, Frederiksen MW, Baelum J, Hansen JV. Fungi, β -glucan, and bacteria in nasal lavage of greenhouse workers and their relation to occupational exposure. *Ann Occup Hyg.* (2013) 57:1030–40. doi: 10.1093/annhyg/met019

5.6.6 Air Quality

Shieldhall Waste Water Treatment Works

The works are situated approximately 400 meters from the proposed development (see Figure 28). The works are the largest Waste Water Treatment Works in Scotland, serving 800,000 people (this is very large).

Conversation with Scottish Water have revealed that there are issues with five storm tanks each of which hold 1,000,000 gallons of storm water. In adverse weather, all water and raw sewage is diverted here. It then needs to be processed but the tanks are too large for odour to be contained and a lot of odour is created and released. This generates a large volume of complaints, especially in the summer. They have attempted to empty the tanks at night but are often compelled to empty them more frequently to allow for more storm water.

All normal sewage inlet channels are covered but money for more comprehensive odour control such as containment of the storm water tanks requires significant capital investment. There are plans to upscale a project injecting an enzyme into the sludge which is claimed to dramatically reduce odour. Scottish Water is looking at options for containment on the site or even relocation but there is no certainty with respect to either scope or program for this at present.

HAI-SCRIBE (Healthcare Associated Infection System for Controlling Risk In the Built Environment):
Odour does not present a direct infection risk, but may force windows and ventilation intakes closed, and this in turn may increase the risk of HAI in the healthcare facility. Clinical areas require good rates of ventilation to provide dilution of pathogens generated within the hospital and to control odours within the hospital.

Odour is unpleasant to patients and visitors. Staff are more likely to become tolerant to the smell as they are continuously exposed to it.

The improvement of air quality in healthcare settings is a constituent of modern airborne hygiene procedures. The vast majority of microbes are associated with particles and air filtration is a solution to preventing spread of infection. The air quality requirements in healthcare settings vary from department to department and, often, even from room to room. Some areas require high-efficiency filtration of airborne micro-organisms to protect patients, staff and visitors (e.g. in operation suites, ICUs, TB isolation rooms), whereas other areas require the filtration of gaseous contaminants, chemicals and odours to provide a safer and more pleasant working environment (e.g. in laboratories, autopsy rooms, dental surgeries and pharmacies). It is thus essential that only very-high-quality filters are installed in these environments.

Increasingly stringent national and European environmental legislation on air quality has resulted in the development of new filters to remove and reduce odours and chemical fumes from the workplace. These filters combine a blend of high-grade carbon and alumina/ potassium permanganate that destroys odours, corrosive gases and fumes such as ammonia, arsine, ethylene, formaldehyde, hydrogen sulphide, nitrogen dioxide and oxide and sulphur dioxide as well as contaminants normally treated with standard carbon products. These Air Processors run with near-silent fans, are odour-free in operation and create a healthy and productive environment for everyone's benefit.

An odour problem will be present at times on the proposed site of the New South Glasgow caused by the waste water treatment works at Shieldhall. Odour is best treated at source and measures to control odour at this site could well be implemented by the Scottish Government and Water Authority. If odour control at the hospital is deemed necessary, activated carbon filtration is the most suitable technology both in terms of effectiveness and cost. However, it would rely on a sealed building with a mechanical ventilation system throughout any odour treated areas.

It is proposed that mechanical ventilation systems are fitted with activated carbon filtration to remove odour from ventilation air. The buildings are to be made air tight to reduce the infiltration of untreated air.

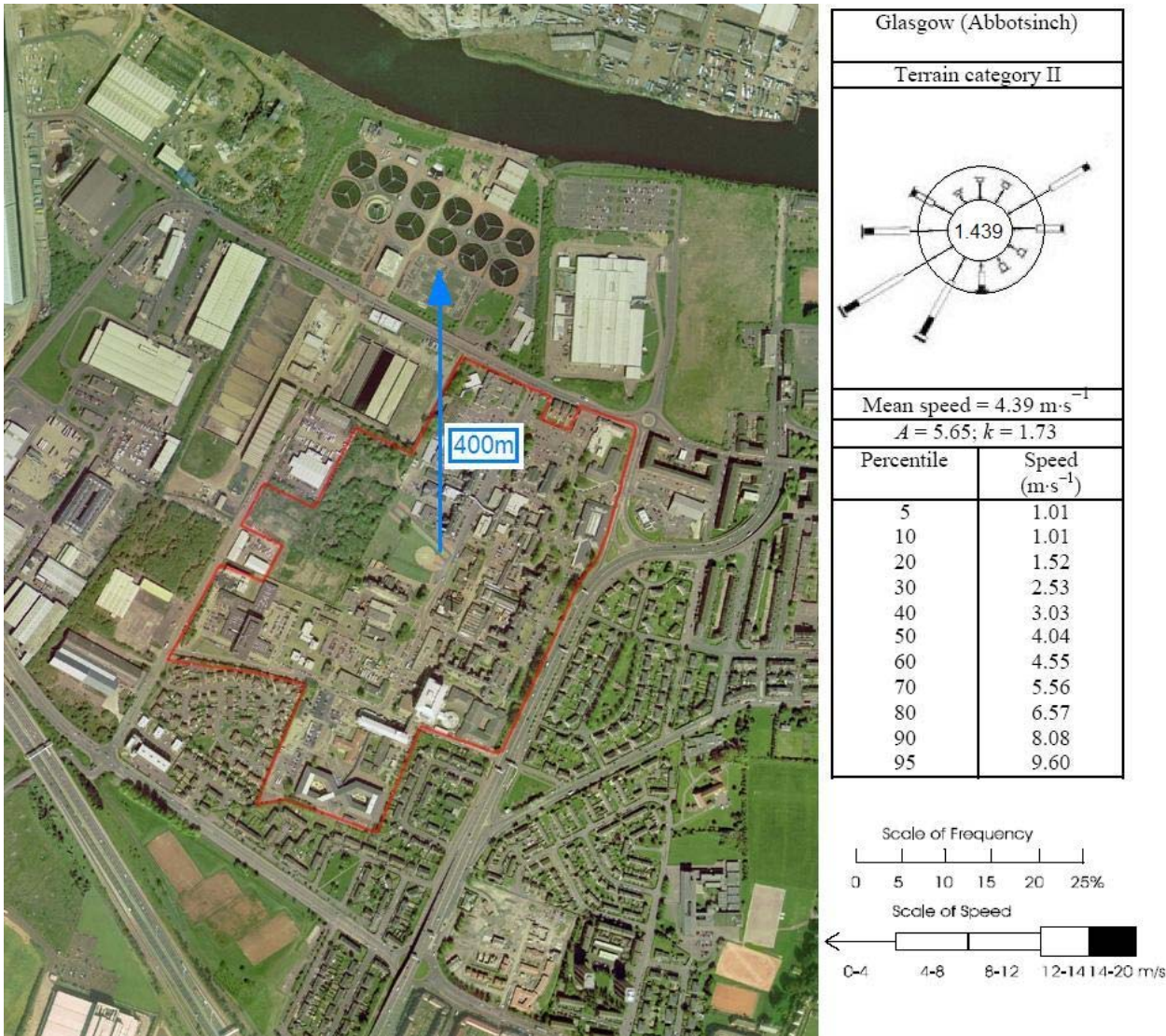


Figure 28

5.6.7 Acoustics and Noise

External Strategy: Environmental and Inter-Building noise

General Considerations

The development of the existing hospital site should not have an avoidable adverse effect on the neighbouring noise-sensitive properties (particularly residential). Current planning policy guidance (e.g. PPG24) states that planning authorities should not place unjustifiable obstacles in the way of development. However, they may wish to consider the use of appropriate conditions, insofar as the development of the hospital may adversely affect future residential developments in the area. A normal condition is that the average predicted noise level from the newly-developed site is less than 10dB below the existing background noise levels at the nearest noise-sensitive façade. BS4142:1997 suggests that satisfying this condition will result in complaints being ‘unlikely’.

It is recommended that a full environmental noise survey of the existing site and surroundings be undertaken to establish the existing conditions in which local residents live.

Compared to a small domestic development, a large site consisting of a number of buildings renders the term ‘environmental noise’ ambiguous. The environmental noise impact on the site from adjacent existing and future roads, rail, waterways and aircraft needs careful consideration. However, the impact of one building on another building also needs to be considered, as does the effect of visitors, deliveries, blue light routes and waste collection.

BAA publications and site measurements suggest commercial aircraft noise is not likely to be an issue. However the air ambulance helicopter landing location is likely to have an impact on the site internally and local residents alike. The landing location atop the Adult Hospital renders it relatively unshielded from local residences, except for the effect of the edges of the building itself. Therefore, a barrier at the perimeter of the helipad and roof is proposed to increase the shielding. The helicopter landing pad will be vibration isolated from the roof structure such that the landing impact does not propagate unreasonably into the building.

Testing and Noise Survey

For purposes of break in, suggest $L_{Aeq,30mins}$ at selected locations around the site, deemed to be representative of the local noise environment. It is a very large site and significant variations in noise level are likely to occur, so results would have to be read in this context.

For break out noise implications, we suggest taking two 24 hour surveys $L_{A90,15mins}$ at separate locations on site boundary to establish background noise levels.

Surveys to be conducted in accordance with BS 4142:1997.

Plant Noise Around the Site

- Generators
- Air handling equipment
- Fans, pumps and compressors
- Pipe work around the site
- Specialist medical equipment
- Transformers and switch rooms
- Vacuum pumps in theatres
- Ultrasonic washers
- Kitchen equipment
- Lifts

Internal Strategy: Noise Transfer and Room Noise

Motivation for Consideration

Noise in real-life operating theatres has been recorded (e.g. Boulter 2007) to exceed 70dB L_{Aeq} (well above HTM2045 recommendations). A long session could potentially exceed the action levels of the Noise At Work regulations, and result in long-term effects on the hearing of staff. High noise levels (e.g. from equipment) is reported to be one of the most likely reasons for complaint by hospital staff.

Studies have also suggested that a good acoustic environment could reduce the likelihood of rehospitalisation (particularly of heart patients).
Communication (English as 2nd language, hard-of-hearing, new/complex information to process)

Privacy issues (maternity, consultation etc) are critically important. Protection of personal health information is implicit in the Human Rights Act, suggesting possible legal recourse, although not many precedents yet.

The possibility of Music Therapy?

Establishing Design Parameters

Suitable upper limits for indoor ambient noise levels from HTM2045-2.

Prediction of source noise levels (external and internal) gives structural sound insulation performance parameters. The care taken over the structure needs to be reflected in the details of doors, windows and structural junctions as well as the constructions generally. The requirement for heavy acoustic doors will be balanced with the ability of users (e.g. patients/children) to use them. Services voids can act as useful buffers between floors, in which sound can be absorbed.

High reverberation time adversely affects internal noise levels and speech intelligibility. Reverberation times can be lowered by including acoustic absorption in the spaces, but it is important to establish any areas of concern regarding cleaning of acoustic absorption, as it is usually inherently porous. Many products are cleanable and designed for use in the healthcare industry. Required reverberation times will be taken from BS8233 and HTM2045-2.

Suggested Design Parameters from HTM 2045-2

AREA	Max unoccupied ambient noise (NR)
Lecture theatre	35
Operating theatre	35
Private office meeting and consultation room	35
Multi bed ward, waiting room	40
General office	40
Staff room, recreation room, cafeteria	45
Corridor, laboratory	50
washroom, toilet, kitchen	50

with mechanical services achieving levels at least 5dB below those specified above.

Location	Recommended Privacy Factor
Maternity, nursery, A&E	80+
Operating theatre, single bed ward, multi-bed ward	80
private office, meeting and consultation room, lecture theatre	
Laboratory, staff room, general office	75
Waiting room, corridor, wash room, toilet, kitchen, recreation room, cafeteria	70

Reverberation time in critical spaces to be controlled to 0.6-1.0 seconds depending on room volume and activity.

Impact sound between occupied areas $L'_{nT,w}$ not to exceed 60dB on average.

Vibration criteria to be confirmed in relation to BS6472.

See the glossary for an explanation of the terms.

Significant Noise Sources

- A&E and outpatients
- Psychiatric
- Maternity and nurseries
- Boilerhouse/laundry/workshop/goods
- Any areas of construction/demolition around the site – to be managed by Contractor
- Waste disposal
- Drawers closing, footsteps, ring binders, trolleys passing over discontinuities in the floor

- Medical equipment
- Raised vocal levels due to ageing population
- Cardio-training treadmills – impact noise to below

Significant Noise- or Vibration-Sensitive Areas

- Children's
- Maternity
- MRI
- Wards generally for sleeping and recuperating
- Library

Design Considerations for Internal Strategy

Sensitive areas generally will be physically separated as far as possible from noise/vibration producing areas. Either with a physical gap, or a buffer zone e.g. corridor, other circulation area or store.

Noise transfer via corridors will be minimised with absorption and lobby doors. Noise within corridors will be reduced through use of acoustic absorption.

Noise transfer between rooms for privacy means careful planning of doors and windows as they are usually weak links.

Acoustic detailing on joints and penetrations, and cross-talk in ducts will be assessed and controlled.

Impact and airborne noise from kitchen facilities – locate kitchen on level below wards.

Advisable to centralise dishwashing and sterilization facilities for large areas and provide attenuation between them and the wards they serve.

Vibration-isolation of MRI and other super-sensitive equipment e.g. microscopes/labs to manufacturers' specifications.

Audiology (especially vestibular function test facilities) in particular will need to be isolated with care.

Testing: Internal impact and airborne noise levels and transfer measurement tests, plant noise, internal reverberation time, public address intelligibility.

Acoustics in Relation to Environmental Design

Exposing areas of structure with high admittance, as thermal mass, helps to reduce the requirement for mechanical cooling by damping out the peak temperature fluctuations in summer. To work properly the thermal mass needs both line-of-sight into the space for radiant cooling effect, and convective access to the air in the space, for convective cooling effect. There is a potential conflict with acoustic absorption which has poor thermal mass properties and is normally mounted at high level, obscuring the thermally-massive substructure. This can be mitigated in a number of ways, including: mounting the absorption at the perimeter of the ceiling; or high level on the walls; or as baffles suspended from the ceiling to allow a free air path around them; or integrating the absorption with suspended services elements such as light fittings.

The choice of predominantly mechanical ventilation is advantageous acoustically, as it affords better control over openings between inside and outside. For instance sound propagation duct routes can be attenuated with attenuators or duct lining.

Design for good daylight can result in tall spaces (with high windows) to enable daylight to penetrate further into the floor plan. This has the adverse acoustic consequence of increasing the reverberation time, as the volume of the space increases. The advantages of better daylight need to be traded off against the potential requirement for larger areas of acoustic absorption.

GLOSSARY OF ACOUSTIC TERMS

A-WEIGHTED SOUND PRESSURE LEVEL, L_A (DBA)

SPL values are weighted in a way that approximates the frequency response of the human ear and allows sound levels to be expressed as a single figure value.

EQUIVALENT CONTINUOUS A-WEIGHTED SPL, $L_{Aeq,T}$ (DBA)

Energy average of the A-weighted sound pressure level over a time period, T. The level of a notional continuous sound that would deliver the same A-weighted sound energy as the actual fluctuating sound over the course of the defined time period, T.

DAILY PERSONAL NOISE EXPOSURE LEVEL, L_{DPNE} (DB(A))

The measure of sound 'dose' used by the Noise at Work Regulations. The value is the sound energy equivalent a constant value for 8 hours. E.g. 90dB for 8 hours has the same value as 93dB for 4 hours.

SOUND LEVEL DIFFERENCE, D (DB)

The difference in sound pressure level between rooms on either side of a partition. D varies with sound frequency.
 $D = L_{P1} - L_{P2}$

WEIGHTED STANDARDIZED LEVEL DIFFERENCE, $D_{NT,W}$ (DB)

A value calculated from the frequency dependent values of the standardized level difference, D_{nT} , according to a weighting method described in EN ISO 717-1. This allows the sound level difference of an element to be expressed in terms of a single value.

WEIGHTED SOUND REDUCTION INDEX, R_w (DECIBELS, DB)

A value calculated from the frequency dependent values of the sound reduction index according to a weighting method described in EN ISO 717-1. This allows the sound reduction of an element to be expressed in terms of a single value.

PRIVACY FACTOR, PF (DB)

The sum of the apparent weighted sound reduction index R'_w and the internal ambient noise criterion (usually NR). PF>80 is 'inaudible'; PF<70 is 'clearly audible and intelligible'

IMPACT SOUND PRESSURE LEVEL, L_i (DB)

Average sound pressure level in a specific frequency band in a room below a floor, when it is excited by a standard tapping machine as defined in BS EN ISO 140-6.

WEIGHTED STANDARDIZED IMPACT SPL, $L'_{nT,W}$ (DB)

A single value calculated from the frequency dependent values of the standardized impact sound pressure level, L'_{nT} , according to a weighting method described in EN ISO 717-2.

ABSORPTION COEFFICIENT, α

The fraction of the incident sound energy that is absorbed on contact with a surface expressed as a fraction between 0 and 1. The higher the value of the absorption coefficient, the more sound that is absorbed by the surface.

REVERBERATION TIME, RT (SECONDS)

The reverberation time of a space is a measure of the rate at which sound decays. It is the time taken for the reverberant sound energy to decay to one millionth of its original intensity (corresponding to a 60dB reduction in the SPL).

5.6.8 Thermal Comfort

General Considerations

High levels of comfort are required for all users; in particular staff and patients. This will have an effect as to how the overall building and the health care provided is perceived, affecting staff performance and patient well being.

Many clinical areas require close control of the room environmental conditions to make the spaces functional. This tends to lead to spaces with air conditioning and/or comfort cooling. Temperature, humidity and air distribution are all carefully controlled and can provide good levels of thermal comfort.

For other areas broader environmental conditions are acceptable and there is the possibility of natural ventilation and mechanical ventilation with or without comfort cooling. To achieve good thermal comfort good zoning, controls, operation and maintenance are essential.

Natural ventilation can provide good thermal comfort throughout the year. For a naturally ventilated space people tend to be more tolerant of high summertime temperatures and their comfort generally. Contact with outside and higher summer air movement improves comfort. The design of ventilation openings is critical. Good solar heat control and exposed thermal mass are pre requisites for natural ventilation to provide satisfactory thermal conditions. Openable windows are often used as part of the natural ventilation strategy, and it is necessary to ensure that other, often contradictory requirements such as restricting openings for safety reasons, are met.

For mechanically ventilated spaces there is less contact with outside and usually little or no direct user control of the summer environment. Often the comfort expectation is raised. The heat gain from fans and duct gain raises the temperature of ventilation air above ambient. In our view for mechanical ventilation systems to internal areas or areas without openable windows peak mechanical comfort cooling is required to provide adequate thermal. Missing a word at the end of the sentence?

HTM(03) places a space temperature limit of >28deg for less than 50 hours in any year as a measure of acceptable thermal comfort.

This type of measure does not recognise the adaptive nature of comfort in relation to the external climate and temperature. In our view, a better measure is of the internal temperature in relation to external air temperature. For naturally ventilated spaces the building should be designed with good solar protection, adequate thermal mass and adequate well designed openings for ventilation such that the mean internal temperature is as close to the mean external temperature as is possible and that the internal peak temperature does not exceed the peak external temperature. If this can be achieved the building will be perceived to have good levels of thermal comfort.

For air conditioned and comfort cooled spaces seasonally adjusted control temperatures should be used. The building should be designed as if it were to be naturally ventilated or so that for perimeter rooms at least it is possible at some future time to successfully naturally ventilate the space Good solar protection and adequate thermal mass reduce the cooling load substantially. The mean summer internal temperature should be at the mean external temperature and the internal peak temperature two or three degrees below the peak external temperature is required for the reasons described above (higher expectation, poor user control) for the building to be perceived to have good levels of thermal comfort.

The summer weather is variable in that some years and hotter than others. During hot years this the HTM(03) limit are difficult and expensive to achieve as they are unrelated to external air temperature. Climate change will make the achievement of these criteria more difficult over the life of the building particularly for natural ventilation solutions. For PFI contractors the HTM(03) limit present an unacceptable technical and commercial risk which leads to a mechanical ventilation solution with comfort cooling in preference to natural ventilation solutions.

5.6.9 Operability

General Considerations

Mechanical and electrical systems shall be automatically controlled. Controls shall be robust, battery backed and distributed as far as is possible so that each system or plant has it's own integral or local controls for resilience.

For clinical areas full system controls and control value presentation will be provided in a secure staff location.

For staff and patient areas, user controls are to be provided to allow trimming of the environmental conditions within the staff/patient space. These include:

- temperature adjustment + or _ 3 about set point, return to set point next reset or start point
- ventilation rate adjustment low, high, boost, return to set point next reset or start point
- light switching and dimming for single room/bed head fittings
- window shading and day light control

For patients control will be available from the bed position.

Room/space conditions will be centrally logged on a twenty minute time base to a system database. Real time display, graphing against time, database retrieval, and archiving software will be provided.

A building energy metering, monitoring, reporting and targeting SCADA data collection and management software will be provided for energy management. Metering will be divided according to zone , building function and service, eg lighting and small power will be separately metered; large equipment loads will be separately metered, zone by zone heating and cooling will be metered. This is to allow energy targeting management and monitoring to be carried out on an ongoing continuous basis.

Building Record/As Installed documentation will be centrally help in a digital format arranged, indexed and maintained to be available through a common access portal over the hospital IT infrastructure using standard software.

Operating Plant monitoring, condition management and maintenance software will look at plant and system operation, condition, operating hours and maintenance intervals to determine and program system maintenance requirements. Maintenance shall be automatically planned and logged to form system and individual items, maintenance records include life cycle costs. Maintenance tasks and records shall be communicated with WiFi communication to operator smart PDAs. O&M information shall be linked to Record System & Asset Information so together they provide an integrated and up to date record of the of the system at any time.

Boiler and chiller plant efficiency and heat output will be continuously measured and logged together with key operating parameters to allow optimisation of operation and efficiency.

Energy and space/room efficiency, availability and time within control parameters are to be collated and presented manually as a system report.

All control functions management systems and system data shall be interconnected on an Ethernet backbone and data servers so that it is available across the hospital IP backbone to PC users with correct permissions. Management software will control access, reading and editing rights in addition to recording usage.

Section 6 – Design Proposals 4 – Compliance, Build Quality and Engineering

6.1 Fire Strategy

The complexity and size of the new build is such that a detailed fire strategy will have to be developed. The TA Team have advised the Board to engage the services of a specialist Fire Consultant to comment on the proposals and work with the Team to help develop the design. This will have to be considered during the next stage.

The Stage 1 PSC has made certain assumptions in respect of both means of escape and fire fighting access but these have not been developed or tested and need further development.

As described above the adult ward arrangement adopts the dual corridor solution to provide alternative horizontal escape from the peninsular ward. The ward is then subdivided lengthwise into two long compartments with fire doors across the links. It is envisaged that these doors would be help open during normal operation with the releases linked to the fire alarm. The end stair is accessible from both compartments independently. The arrangement effectively allows continuous horizontal alternative evacuation to an adjacent compartment and from there into a further compartment and so on. The provision of corridor in each compartment would be sufficient to allow the beds from an adjacent compartment to be accommodated.

In the case of the Children's wards alternative routes are provided with wards again divided into compartments and sub-compartments.

Fire brigade access is possible to all four ground floor faces of the building. Fire fighting shafts within the building will be required. It has not been possible to determine whether dual-use lifts would be acceptable or if dedicated Fire Fighting lifts will be required. This will be subject to agreement with the approval body.

The adult ward plan assumes the end stairs are primarily for escape and fire brigade access. A fire fighting lift is indicated at each of these four locations. Given the distance rule from the fire fighting shaft to any point on an upper storey, it is assumed that one of the shafts in the central core will also have to double for fire fighting access.

The size and scale of the development will also require an engineered approach to resolve access to the base of the fire fighting shafts. It has been Avanti's experience on other projects that the distance from the ground floor entry point, to the vertical shaft can be extended subject to the route being fully protected using pressurisation and other enhanced protection. These issues will require further consideration in the next stage. For other M&E installations associated with Fire Strategy see below.

6.2 Structural Strategy

6.2.1 Introduction

In order to develop and provide all necessary supporting information to establish the Outline Business Case (OBC) for the new hospital facility, an overall civil and structural engineering strategy is required to outline the requirements for the detailed design and construction of the new hospital and associated developments for the site. This Design Substantiation Report (DSR) presents and discusses the considered engineering strategies based on the constraints and restrictions of the existing conditions at the site as far as they are known and the information available to date. The information referred to in the following report also provides relevant input of the design aspects for the public sector comparator (PSC).

6.2.2 Geotechnical, Geochemical & Environmental Considerations

Sinclair Knight Merz has reviewed geotechnical information from a number of past site investigations undertaken over the last 30 years, with the intention to assess and summarise any potential geotechnical issues, ground conditions and foundation options that will be relevant to future development proposals for the facility, and in particular the proposal to build a new high rise structure with basements and subway access. The positioning and extent of previous investigations is summarised on drawing EK02355-S-001-P1.

6.2.3 Review of Available Ground Investigation Reports

The site is situated on an alluvial floodplain approximately 500m south of the River Clyde in Glasgow. Of the nine previous ground investigations carried out at the site, approximately a third of the site's area was covered to depths proving the location of bedrock. The ground at the site consists of made ground that is underlain by alluvium, which is in turn underlain by glacial till and Carboniferous Coal Measures bedrock.

The made ground consists of a mixture of cinders, ash, sands and gravels, and brick, and ranges in thickness between 0.3m and 1.75m. The alluvium generally consist of soft to very soft clays and loose to medium dense silts and silty sands, of

approximately 20m total thickness, but locally thinning to approximately 16m. The alluvium was generally found to be of high to medium compressibility. In one site investigation report it was noted that differential settlements had adversely affected existing buildings at the site.

The glacial till is described as stiff to very stiff and varies in thickness from less than a metre to approximately 15m, with an "average" thickness of approximately 6m. The upper horizon is often weathered but strength increases with depth. Compressibility of the glacial till was found to be low to very low. Bedrock was found at various depths ranging between 15.5mbgl (metres below ground level) to 25.5mbgl. Bedrock was found to consist of inter-bedded layers of sandstone, siltstone, and mudstone with occasional thin seams of coal. A thin layer of igneous rock was found at one location in association with evidence of a fault zone or discontinuity. The strength of bedrock ranged between very weak (coal), moderately weak (mudstones) to moderately strong and strong (siltstones and sandstones).

From desk-top studies undertaken as part of the previous site investigations, no evidence of shallow mining was recorded in the ground investigations and the Coal Authority confirmed that they have no knowledge of mining activities previously taking place beneath the site. However, two reports confirmed that a mine shaft was marked on historical maps within 70m of the investigated areas, but suggested that the position is not related to the existing hospital site. There is also indication of a trial mine shaft more centrally within the proposed site, but it appears only on early plans and is not referred to elsewhere or known to the Southern General Hospital's Estates Team. Further investigation into the location or existence of historical mine shafts is recommended to be carried out.

Groundwater and perched groundwater exists at the site at depths ranging between approximately 1.0 mbgl to 4.0 mbgl. However, where the drift deposits are relatively impervious, groundwater was not encountered until near-bedrock depths. Water strikes at these depths generally produced sub-artesian groundwater rises of between 6m and 10m.

6.2.4 Geotechnical Considerations

All the previous reports have concluded that the soft alluvium underlying the site has the potential to induce excessive settlements if structures were founded on spread foundations. A range of bearing capacities between 60 to 100kN/m², depending on drift geology, has been suggested. To reduce settlement some reports have recommended the use of large sized spread foundations and raft foundations for low rise buildings, but it has also been noted that settlements in excess of 25mm would still occur. All the reports concluded that structures with higher loadings, and settlement sensitive structures, should be either founded in the glacial till or socketed within bedrock by using an appropriate system of piled foundations.

The maximum bearing capacity of the bedrock was tentatively specified as 1.0MN/m² in one report. It is noted that the 1998 Arup report recommended a maximum safe working load of 480kN for 600mm diameter piles founding in 6m of glacial till and a maximum safe working load of 500kN for 220mm diameter mini-piles socketed a minimum of 3m into bedrock.

The majority of the reports recommended the use of bored cast in-situ piles such as the Continuous Flight Auger (CFA) method of emplacement. One report concluded that down-drag of piles would need to be taken into account in the pile design. Vibro-replacement ground treatment of the weak alluvial deposits was discounted due to the presence of cohesive deposits.

For deep excavations, significant basements, or below ground corridors it was generally concluded by most site investigations, that groundwater would likely be an issue but that it could be feasibly controlled by sump pumping and temporary sheet piles.

On the basis of the available information from previous site investigations, it is considered that the whole hospital site is underlain by potentially highly compressible material that would adversely affect structures if founded above or within these compressible deposits. Therefore it is considered that any structures more than two storeys high will require to be founded at either very stiff glacial till or taken down to bedrock level.

The excessive depths to bedrock and the low shear strength of cohesive deposits to significant depth is likely to require building loads to be supported on piled foundations taken down and socketed into the underlying solid deposits. This will require pile lengths in the order of 20m to 25m with adequate socket lengths to provide the required carrying capacity (typically about 3-5m but dependent upon the actual loading).

For the ITN stage and as part of the documentation, a detailed ground investigation will require to be undertaken by GG&CHB Trust to provide a general overview study of the entire site to establish the nature of the ground strata. With respect to the footprint of the proposed building, the location of the offsite mine shaft and the centrally located mine shaft as recorded in historical maps should also be investigated as part of this pre-ITN investigation.

It is expected that further detailed site investigation to suit the outline of the proposed development will be carried out by the preferred bidder prior to financial close.

The site infrastructure will be highly dependent upon any change in topography during earthworks cut-and-fill operations. Should there be any soil retention requirements then the design of such retaining walls and foundations will need great care to guard against sliding in such low strength founding materials.

Given the existing ground conditions, it may be the case that drainage runs need to be laid to steeper gradients than design minima and with regular rocker pipes to enable continued operation should the softer clays settle under the imposed weight of the site infrastructure. This effect will become more prominent if significant areas of the site are raised in level, even by a nominal amount (such as required to provide a piling mat, which in this situation is likely to be thick).

Excavations may be prone to groundwater ingress so consideration to the use of tightly interlocking sheet piles around excavations may be required for any deep excavations, with appropriate allowance for pumping from the base of such excavations.

Where basements are to be formed with service ducts the ground loading will be reduced, which may have a consequential reduction in the heave of the existing cohesive strata. The main issues will be that of water tightness both permanently and during construction. Basements will require to be formed from in-situ reinforced concrete or similar construction with a suitable water-proofing system to retain the external water table under adverse conditions.

6.2.5 Geo-chemical and Environmental Considerations

Minimal ground contamination was encountered in any of the previous site investigations. However, given the existing and previous uses of the site there may well be areas that require any undetected contamination to be addressed. The raised pH levels were established in some areas of the site, but are not such as to require special precautions in normal concrete foundation works, however this needs to be investigated further.

Historically, site investigations were commissioned on a number of occasions and SKM-AH has produced a drawing collating the various site investigations undertaken. This drawing is supported by the interpretative reports produced as part of each investigation. Testing for contaminants was undertaken as part of these investigations and revealed little in the way of contamination at those locations where testing was undertaken. However the locations available for testing were limited by existing services, buildings and other operational areas which necessarily means that large areas of the site have not been tested for contamination. It should also be noted that testing criteria for contamination has become far more stringent over recent years and for that reason the apparent lack of previously identified contamination material should not be assumed to be reflective when benchmarked against current criteria for evaluation.

A number of buildings have been demolished as the site has been developed over the last 100 years. The extent to which the sites were cleared before reconstruction with regard to infilled basements, foundations and the like, is unclear and these locations remain potential sources of contamination and may pollute normal groundwater where this comes into contact with the material.

Likely residual contaminants may include hydro-carbons, asbestos, medical waste or related materials and may be diffuse or in pockets around the site.

We understand that it is GG&CHB's intention to hand the site over to the preferred bidder as a notionally 'clean' site for all development work. It is proposed to achieve this through a series of enabling and remediation works to clear the site and also to relocate active services and discontinue services that are currently on the proposed building footprint. However it should be noted that should there be significant contamination found on-site, the majority of which will be below ground and cannot be readily removed/remediated until the sub-structure works are underway. Notwithstanding the above, a comprehensive detailed site investigation with appropriate sampling and geo-chemical testing of the entire site will be required to identify the likely extent of remediation or removal.

6.2.6 Site Conditions on the Existing Hospital

Ground Engineering Characteristics

The engineering characteristics of the superficial deposits to the site are considered to be such as to economically mitigate against their use as founding layers for anything other than low-rise buildings of two storeys or less.

6.2.7 Ground Conditions Risk Summary

The risk register in support of the OBC should include provisions for the following civil engineering and geotechnical risks:

- Poor ground conditions to an average of 20m depth;

- Moderate to severe risk of ground contamination from a variety of sources given the length of time the site has been used as a hospital;
- Presence of groundwater within excavations;

- Contamination in areas of made ground including potential asbestos, hydrocarbons and heavy metals.
- The depth to sound rock-head may be greater than that currently assumed on the available information, and as such the risk register should include an allowance for this.

6.2.8 Roads Infrastructure for Hospital Site

The development of the highway infrastructure is likely to be required under conditions as part of the Planning approval and the Traffic Impact Assessment/Green Travel Plan for the scheme within the context of the wider transportation issues in Glasgow and environs. The extent of new junctions, new site accesses and all road improvement works will need to be progressed as the proposal for the existing site is developed and as planning comments are received.

At present the scheme maintains current accesses from Govan Road and Hardgate Road and details a new blue-light route from the A739 at the southern end of the site. These road junctions will require Highway Authority and Local Authority approval and should meet all statutory requirements.

Further advice and consultation has been provided by Ironside Farrar, WSP and Keppie Planning to gain Outline Planning approval.

Internal site access roads will comply with the appropriate highway standards, supporting the required design traffic flows.

6.2.9 New Buildings

The following text outlines the assumed engineering development strategies for the new hospital buildings and multi story car parks which are to be used in the outline business case and preferred option for the public sector comparator (PSC).

The multi-storey car park options (at two locations), are to meet the anticipated parking demand for the site given its location in relation to the city of Glasgow and notwithstanding the proposals to provide multi-mode transportation options for patients, staff and other site users.

6.2.10 Standards and Regulations

The new development including both hospital buildings and multi story car parks will need to be designed and constructed in accordance with the relevant Design Standards, Building Regulations, Planning Conditions, statutory and local authority standards and to the CDM2007 Regulations.

6.2.11 External Works

The generally flat/gently sloping nature of the site will generate minimal areas of cut and fill across the building footprint. However, construction levels will require to be established at the necessary design levels including basement areas, service and access ramps and to ensure functional tie-ins for connections to existing buildings that are to be retained as part of the new facility. All proposed water features, retention systems and landscaped areas will also require further areas of lower-lying ground to be excavated and profiled.

Excavated material can be retained on site and used for ground profiling / landscaping works provided that any identified contaminated material is either re-mediated or removed. Retained material will also have to be appropriately assessed in terms of engineering properties for the intended end use on site.

It is noted that although much of the site is hard-standing, there may be an opportunity to retain some topsoil stripped from existing landscaped areas within the site. In such circumstances, the topsoil should be assessed and if suitable, stockpiled for reuse.

With regard to Tree protection Orders (TPOs), it is noted that there are some protected trees within the site. These will have to be incorporated into the eventual landscaping strategy and adequately protected to the requirements of a suitable arboriculturalist's requirements during construction works.

Tie-ins for connections to the existing road network, hard-standing areas and other features will require to be fully integrated with the design levels established across the site.

6.2.12 Proposed Hospital Building Foundations

The Master Plan for the new hospital facility consists of a series of ward towers to a maximum of 13 storeys plus the ground floor, podium and roof structure. The foundations for the hospital building are likely to take the form of reinforced concrete pile foundations socketed to a minimum of 3 metres into the sandstone rock head at a depth of 20-25 metres below ground level. Preliminary assessments indicate that foundations bearing in the glacial till at shallower depths would not be suitable, due to the magnitude of the load expected and consequent short and long-term settlements. Settlement for the piled solution should be designed within acceptable limits. It should also be noted that there is likely to be some degree of underground obstructions encountered when placing these piles which are expected to be existing concrete foundations and other historic features.

If bedrock is deeper than that currently assumed from available information, then deeper piles with longer rock sockets may be required beneath the foundations to reach sound bearing bedrock.

Across the footprint of the proposed structure the existing ground is fairly level. Consequently all basement areas will be consistent across the full footprint of the site as required by operational planning criteria. Basements and tunnels will require water-tight retaining walls and to be founded either to bedrock or with a suitable arrangement of raft foundations to prevent differential settlement. These are likely to be formed of in-situ reinforced concrete construction resisting lateral earth, water and imposed loading pressures. Adequate tanking must be provided to below ground structures where permanent or localised water table levels dictate, under the most adverse conditions anticipated.

6.2.13 Proposed Hospital Building Superstructure

The superstructure of the building is the structural frame that will be responsible for the transfer of gravity, imposed and lateral loads to the ground in a manner that ensures vibration (a key issue for hospitals) and noise transfer are kept to minimum levels. Dynamic loads from the helicopter landing pad proposed on the roof of the building will also have to be taken into consideration with regard to vibration assessment.

With regard to services integration it is recognised that hospital structures need to take cognisance of current service requirements as well as some degree of flexibility for future fit outs and refurbishment during the buildings life span. Services routes will run through the hospital on both horizontal and vertical axes and the structural design of the frame should be sensitive to this requirement. Ease of access and routing of services can be achieved for example by the adoption of flat soffit slab methods of construction or open web construction including a range of proprietary systems.

A nominal structural planning grid of 7.8m x 7.8m (maximum) has been developed by the architect for this Design Substantiation Report in support of the OBC and for the PSC. A column grid of this spacing is likely to be achievable using a number of different construction materials and structural systems. This includes structural steel, in-situ concrete and pre-cast concrete solutions. Attention should be paid to the ability of the final design solution adopted such as to ensure that structural stiffness can be achieved and that the structural footprint is sufficiently flexible to allow the hospital to achieve its necessary space planning targets.

The upper floors of the hospital building cruciform tower and parts of the podium have for the purposes of the PSC, have been nominally assumed to be either a slimfloor steel solution or an in-situ reinforced concrete (RC) flat slabs without down-stands. SKM-AH Drawings NE02355-S-201 & NE02355-S-202 show indicatively how the structural make up might be achieved for the hospital building for each respective type of construction. The drawings show typical details and plans for a ward and operating theatre that will allow flexibility with horizontal services distribution and will reduce overall floor construction depths to a reasonable minimum. Structural columns are centred on the grid as referenced above and such as to reflect the geometry of the building and how the structure will transfer the loads to the foundation systems. It should be noted that in the case of the flat slab construction a slightly deeper than normal slab has been assumed at this stage in order to assist with dynamic loading issues. Detailed design assessment may be able to reduce this depth from 350mm to 300mm but this would require careful consideration of bracing locations and circulation shafts.

Although we would not rule out the possibility of using cellform construction and downstand beams we would note that a lighter form of construction than those discussed above would require extreme care in relation to dynamic response and sensitivity issues associated with vibration, particularly on tall buildings.

Ground or basement floors are envisaged as suspended slabs supported from a grillage of beams on the pile caps on socketed piles in sound bedrock.

Lateral stability of the structure could be achieved through a combination of rigid moment frames, bracing bays or the use of reinforced concrete stair and lift cores.

6.2.14 Proposed Hospital Building Fire Resistance

The structure should be designed to achieve the necessary levels of durability and appropriate periods of fire resistance in accordance with all applicable standards, current codes and best practice guidelines. This should take due consideration of the nature of the facility both in terms of the wide range of occupant types and the different physical aspects of the buildings i.e. the tower, podium and Children's facilities.

6.2.15 Proposed Hospital Building Construction Methodology

The new facility will be constructed within an operational hospital and due cognizance of this should be taken in the selection of plant, materials and the construction methodologies adopted. In addition, the new facility will be completed in phases over several years with staggered decants for different patient groups and staff. Due cognizance should be taken of this in the phasing of the construction works, access arrangements, availability of facilities and services and with suitable consideration of the needs of building occupants adjacent to ongoing construction or fit-out activities. Programmed activities should assess and manage all implications of staged completion to mitigate and minimize the affects on all stakeholders at the existing hospital which remains functional until full and complete transfer of facilities.

Both flat slab construction and slimfloor design are widely recognised forms of construction and have been used successfully for buildings of this nature in the UK. The slimfloor solution may have slight benefits in terms of speed of frame construction, but this is often counter balanced by traditional flat slab concrete frame construction that allows follow on trades to work on the lower floors whilst the structure is still being erected.

Tower cranes will be required for the construction of the building and space exists for these to be sited within the constraints of the site. No overhead restrictions are obvious, other than in the use of the existing operational helipad, based upon visual inspection of the site.

Care should be taken during excavation, in particular with reference to localised groundwater inflows, buried services and the temporary stability of excavations.

6.2.16 Proposed Multi-Storey Car Park Foundations

As with the hospital building the foundations for the MSCP building are likely to take the form of a grillage of beams on pile caps on piles socketed into sound bedrock at 20-25metres beneath the site. Findings from the existing site investigation interpretative reports indicate that foundations bearing in the glacial till at shallower depths would not be suitable due to the magnitude of the load expected and consequential long-term settlement. Settlement for the piled solutions should be within acceptable limits. It should be noted that there is also likely to be some degree of underground obstructions encountered when placing these piles which we would expect to be existing concrete foundations or other historic features.

6.2.17 Proposed Multi-Storey Car Park Superstructure

The proposed multi-storey car park structure (MSCP), is likely to consist of a maximum of 4 storeys plus the ground floor level. The superstructure of the building is the structural frame that will be responsible for the transfer of gravity, imposed and lateral loads to the ground.

A structural planning grid of 7.2 x 17.4m (maximum) has been adopted for the MSCP in support of the OBC and PSC. This grid allows 3 standard parking bays between columns and floor plates that clear span the length of 2 parking bays and the main vehicle corridor and the provision of a suitable width, segregated pedestrian walkway.

The construction of multistorey car park structures lends itself to a variety of precast and insitu forms of construction including, precast concrete, insitu concrete, long span cell form beams, etc. The merits of one form over another is expected to be a matter for detailed design resolution, but for the purposes of the PSC has been suggested as a pre-cast concrete floor supported by a structural steel frame.

Ground floors are envisaged as non suspended ground bearing structures of flexible material such as tarmacadam or asphalt. If basement areas are required then the basement floor construction would require to be reinforced concrete suspended slabs on a grillage of beams on pile caps on piles socketed in to sound bedrock.

Lateral stability of the structure could be achieved through rigid moment frames or by the adoption of reinforced concrete stair and lift cores to provide vertical cantilevers resisting the horizontal loadings to the structure or through appropriate vertical bracing.

Movement joints will need to be incorporated in accordance with good practice to effectively accommodate all thermal, differential and moisture movement. Joints should be located such as to avoid critical structural areas of the building as necessary.

6.2.18 Proposed Multi-Storey Car Park Construction Methodology

Construction will be undertaken within an operational hospital and due cognisance should be taken of this in the selection of plant and in the construction methodologies adopted.

The design proposed for the MSCP is typical of buildings currently under construction in the UK. Standard construction methods and techniques can be combined with modern technological developments within the industry to assist in delivering the proposed design solution. The site and adjacent areas potentially provides sufficient areas of storage and, other than the normal applicable statutory obligations, the site has sufficient access for construction deliveries.

Tower cranes will be required for the construction of the building and space exists for these to be sited within the constraints of the site. Other than helicopter access to and from the existing helipad, no overhead restrictions are obvious upon visual inspection of the site.

Care should be taken during excavation, in particular with reference to localised groundwater inflows, buried services and the temporary stability of excavations.

The design should address the exposure of the structure and discharge of surface water from the MSCP in order that future maintenance is minimised.



6.3 Services Strategy

SITE SERVICES & INTERGRATION WITH EXISTING SERVICES STRATERGY

6.3.1 Water

Read in conjunction with drawings 3757/S10P/000-010, inserted in appendices A. These relay the approximate routes of the existing site infrastructure

Mains water is required for domestic water supply and fire fighting.

The existing site water infrastructure is supplied from 5 no metered, mains connections; 2 from the Govan road; 2 from the A739 bypass road and one from Hardgate road. With the exception of the Hardgate road supply the current site infrastructure does allow for these to be cross connected and thus act as alternative supplies. Existing buried distribution pipework is likely to be of a material and age that now requires replacement. The current infrastructure cross connects fire mains with potable water mains.

Prior to the commencement of the PFI construction phase the buildings within the site boundary are to be demolished and existing potable water connections made redundant or removed.

It is currently proposed that the new PFI hospital buildings will be supplied from dual supplies, one from Govan road and the second from Hardgate road. This is subject to confirmation from Scottish Water (see below). These will need to be installed prior to the completion of the Children’s hospital and sized to supply the Children’s and Adult’s hospitals simultaneously.

Following the completion of the PFI construction phase and the occupation of the new adult hospital, the redundant buildings on the site are to be demolished, with their related potable water supplies made redundant or removed.

Scottish Water have been appointed to complete a detailed survey of the existing infrastructure, including a leakage analysis and some flow and pressure tests, these are currently underway. Following this they are to complete a hydraulic model for the existing site and then adapt this to model the proposed site. The conclusion of their works will establish the off site infrastructure implications. This Scottish Water work is programmed to be complete by the end of July 2007.

The site fire mains will be identified as part of the Scottish Water survey works (see above). The new development is proposed to have new dedicated fire mains connections serving the related supplies/outlets. The existing infrastructure is to be rationalised as part of the pre and post PFI construction works, so as to ensure the remainder of the site is adequately served.

6.3.2 Power

Read in conjunction with drawings 3757/HVP/000-010, inserted in appendices A. These relay the approximate cable routes forming the existing site infrastructure

The existing site is fed from two supplies routed from the A739 road into the Pharmacy HV switch room, from where HV cables are routed around the site to more local HV/LV sub stations. A number of the existing supplies are radial feeds.

The existing hospital MV (11kV) electrical services generally emanate from the existing primary MV switchgear. The existing incoming supply capacity is understood to be about 3MVA and currently operates at about 2.6MVA. The local electrcity supply distribution network operator (DNO) – Core Utilities, (Scottish Power), have indicated that this could be increased to a maximum of 5MVA, and that the existing secondary supply could be upgraded to a dedicated, ‘firm’ supply rated at 5MVA.

Prior to the construction phase of the PFI project, the HV switch room is to be relocated into Pharmacy and a new maternity sub station is to be installed. The infrastructure is to be modified to suit the new HV switch location and the Surgical sub station is to be reefed from the HV circuit that also serves the new maternity sub station. These enabling works allow the buildings on the PFI site to be demolished and disconnected without any disruption to the remaining buildings. The two HV supplies that currently cross the site to the Surgical sub station become redundant and can be removed.

The new hospital buildings are of greater area and serving a greater number of patients with greater intensity/scope of service. The site requirement for power will be substantially increased and the electrical supply capacity and robustness will need to be increased.

We are currently working with Scottish Power to determine the options to increase the site electrical supply. Substantial offsite works will be required and is likely to require an on site Medium Voltage 33kV substation to be established off or on the site. The Scottish Power requirements/proposal is likely to affect the incoming HV arrangement and switch room described above.

Incoming MV Electrical Supply

A reminder of the electrical loads for the development:

- Total site load after site diversity = 15 MVA with redevelopment and “growth factor”
- RHSC = 2.5 MVA
- AAH = 6.5 MVA
- Total PFI load after building diversity with expansion and “growth factor” = 11MVA

The combined Assumed Maximum Demand for the new hospitals as initially built and currently briefed is estimated to be approximately 8.7MVA. Assuming expansion as planned for and a growth factor of approximately 20% in line with HTM-06-01, the Assumed Maximum Demand will be taken to be 11MVA. All 11kV switchgear, cable distribution and standby generation capacity should be sized on this basis.

Dual incomers from DNO rated at 15MVA at 33kV :

The design of the incoming service from the distribution network operator (DNO), and associated 11kV distribution point, has been designed to offer both resilience and flexibility of operation. Maintenance and future replacement of equipment will be possible with little or no disruption to supplies.

Negotiations with the local DNO, Core Utilities (Scottish Power), have suggested that a primary transformer substation will be required to serve the whole South Glasgow Hospital site with separate incoming MV supplies at 33kV both originating from Braehead.

Ideally, dual supplies should originate, if possible, from separate DNO substations, ideally from separate parts of the National Grid with independent cable routes to the hospital site. Where separate MV supplies from separate substations are not available, additional standby generation resilience may be necessary to improve overall resilience.

Primary Transformer Substation

The HV network is supplied from the EHV network at Primary Substations utilising transformers of standard size and phase connection. Typically, twin 12/24MVA (or 20/40MVA) 33/11kV primary transformers feed a two section 11kV busbar. The transformers are to be oil filled and naturally ventilated.

Each incoming feeder is to be connected to a different busbar section. The incoming circuits operate in parallel with the bus section circuit-breaker normally closed. The plan area required will be approximately 18m x 30m (see drawing SK-008).

The DNO has suggested that the options for the establishment of a 33kV/11kV primary substation are:

- 1) New DNO primary substation on the site supplied, installed and operated by Scottish Power, with the client contributing to development costs.
- 2) New private primary substation on the site supplied, installed and operated by the client with Scottish Power supplying electricity at 33kV.

Option (1) is preferred and negotiations with Core Utilities (Scottish Power) are underway at this time to attempt to achieve this.

Metering breakers are to be located either side of a bus section switch. This arrangement will allow the PFI development and existing site to be metered separately and for the DNO to maintain their equipment without disruption to supplies.

The establishment of a primary substation, by the local DNO, with a robust incoming supply at 33kV and delivering power to the site at 11kV has the contractual advantage that the existing site distribution can be kept separate from the MV distribution required as part of the proposed PFI development. For the new PFI hospitals new utility electrical supplies and on site HV infrastructure will be provided. The drawings show new dual supplies coming into a new HV switch room in the energy centre, these are currently shown to serve the PFI site only. The source location of these is subject to the final proposal/agreement of Scottish Power. From the HV switch room the supplies are to feed local transformers positioned on two independent HV rings circling the new hospitals.

Electrical supplies to the PFI hospitals will be backed by on site standby generation.

Following the completion of the PFI construction phase the HV supply to the retained estate can be extended from the Surgical substation back to the new incoming HV switch room so as to provide a ring. Once the adult hospital is occupied a proportion of the retained estate becomes redundant, a new substation is to be installed to serve the remaining listed buildings (effectively replace the existing CMB substation that will be demolished). The existing supplies are to be reefed or made redundant as the related buildings are demolished

6.3.3 Fuel Natural Gas

Read in conjunction with drawings 3757/S32P/000-010, inserted in appendices A. These relay the approximate routes of the existing gas infrastructure

Natural Gas is required for space and water heating, some steam supply for humidification and potentially combined heat and power supply.

The existing site gas infrastructure is supplied from 9 no metered, mains connections; 5 from the Govan road; 2 from the A739 and 2 from Hardgate road. Existing supplies are all radial supplies and the buried distribution pipework is likely to be of a material and age that now requires replacement.

Prior to the commencement of the PFI construction phase a new boiler house is being constructed and the existing catering facility is to be moved off site. This allows for the existing boiler house to be decommissioned and the buildings within the PFI site boundary to be demolished with their existing gas supplies made redundant/removed.

It is currently proposed that the new PFI hospital buildings will be supplied from a new mains connection from Govan road. SGN have confirmed a budget price to provide this, we also understand this confirms that they have reviewed the additional load in relation to their infrastructure and have allowed for any necessary modification works within this budget price. This mains will be routed into the energy centre to feed the new heating and CHP plant (for both Children's and Adult's hospitals) and will then be routed via the underground tunnel to serve any local supplies e.g. autoclaves, humidifiers etc.

Following the completion of the PFI construction phase and the occupation of the new adult hospital, the redundant buildings on the site are to be demolished, with their related gas supplies made redundant and removed

6.3.4 Drainage (foul & surface)

Existing Drainage Networks/Strategies

The existing on-site drainage comprises of both stormwater and combined (foul) systems running generally north towards the entrance to the site to Govan Road. Both of these main drainage networks are not adopted by ScottishWater and are the responsibility of GG&CHB. Please refer to NE02355-C-800-P1 for indicative layouts.

There are a number of connections into these systems from outwith the site which contribute unknown quantities and flowrates of both foul and surface water into these systems. These connections are from the housing at the south of the site, the fast-food Dining area at Moss road and Hardgate road to the west of the site.

Existing Combined (foul) Drainage

The existing main combined (foul) drainage runs generally north-east across the Southern General site. The main pipe comprises of a 375dia vitrified clay pipe which outfalls from the site at Govan road before entering the adjacent Shieldhall treatment works. **Connections of both foul and surface water enter this pipe from developments across the existing site with many (?) being required to be maintained for future use. (Missing a word?)**

Existing Stormwater Drainage

The existing main stormwater drainage comprises of a 600dia pipe to the south of Langlands Drive and a 1200 x 950 brickwork egg pipe continuing from Langlands drive to the hospital perimeter. This network follows the same general route of the main combined (foul) pipe, running south to north before discharging at the adjacent to the Govan road entrance into an open channel and subsequently into the River Clyde. An existing 600dia stormwater pipe from Hardgate road forms a major branch in the stormwater network running east-west across the site.

Phase 1 Drainage Enabling Works

In order to ensure the continued operation of the existing drainage networks during the Phase 1 development works some drainage diversions are required. There are four drainage runs through the proposed site which must be maintained:

Obstetrics/Gynaecology – 150dia stormwater pipe

This pipe runs west to east and connects into the stormwater network running through the proposed Phase 1 development site. Due to lack of levels information it is not possible to definitively propose the route for this diversion. There are two options available which could ensure the satisfactory diversion of this pipe:

-Connection into an existing 225dia pipe to the south of the Maternity wards

-Diversion to the north-east across the boundary of the proposed Phase 1 development with connection into the existing 600dia pipe running from Hardgate road.

Main combined (foul) pipe - 375dia vitrified clay pipe

The diversion of this pipe is required from an existing manhole in Langlands road to the south and around the proposed facility. This will take the form of a 375dia concrete pipe with new manholes at changes of direction, connections to existing branch lines and provision for connections from the proposed facility. The layout of these proposed diversion works is shown indicatively on NE02355-C-801-P1.

Following these works the existing pipe will remain in its present configuration running west to east along the hospital access road before outfalling into the ScottishWater sewer in Govan road. Capacity assessments are currently being carried out by ScottishWater for the Shieldhall treatment works and the existing outfall will be re-used for all foul loadings from the new development and during the phased decent of facilities and personnel within the Southern General site.

Main stormwater pipe - 1200 x 950 brickwork egg pipe

As for the above combined (foul) drainage pipe diversion, the main stormwater run must also be diverted to avoid the south-east corner of the proposed new facility. The route of this diversion will typically follow the combined (foul) diversion along the existing and proposed site roads as shown indicatively on NE02355-C-801-P1. A 1200dia concrete pipe is to be used in order to match the existing capacity of the 1200 x 950 brickwork egg pipe.

Hardgate road – 600dia stormwater pipe

The diversion of this pipe is required around the northern edge of the proposed facility. Only minor diversion works involving two manholes and new 600dia concrete pipe is envisaged. Care must be taken during demolition works at the existing helipad to ensure the existing pipe is not damaged.

The diversion works for these drainage runs should also include the provision for new connection points from the proposed development works as appropriate. These are discussed further at the end of this section.

Proposed Storm and Foul Water Schemes/Strategies

The below ground drainage philosophy has been discussed with the local service provider, ScottishWater. The following section of this DSR outlines their anticipated key requirements and restrictions in order to comply with likely planning conditions and to ensure that their infrastructure can meet the needs of the new facility. The outline strategy proposals are shown indicatively on NE02355-C-802-P1.

Communications with ScottishWater have comprised both face to face meetings and written correspondence. ScottishWater is shortly due to submit to GG&CHB the findings of its assessment of the water supply and sewerage disposal implications at the site for the proposed facility. In the absence of confirmation of ScottishWater's formal findings and based upon existing knowledge of the site, the following anticipates their findings and conclusions.

Foul Water

Foul drainage from the proposed facility will utilise the diverted combined (foul) drain running across the HSGH site. As part of the diversion works connection manholes with tails into the new development should be provided at the north-east corner of the facility. Other connections into the 375dia combined (foul) pipe may be provided around the proposed facility subject to the layout design for the drainage around the building perimeter.

As the existing foul water from the site outfalls into this network, no capacity problems are envisaged. However, a reduction in the amount of stormwater entering this pipe as part of the demolition works of older buildings is expected to greatly outweigh the increase in foul discharge therefore allowing the capacity to be used for the new development. Confirmation from ScottishWater forthcoming report will however be required to confirm this assumption.

Stormwater

A site-wide strategy for managing stormwater across the entire site is required as part of the larger re-development works. At this stage the ability to incorporate this is restricted due to the space constraints imposed by adjacent operational buildings.

In order to comply with Planning regulations and the requirements of both ScottishWater and SEPA, the use of a “management train” approach to dealing with stormwater in a sustainable manner through the use of SUDS (Sustainable Drainage Systems) is required. This must be planned and designed in accordance with published best practice guidance (CIRIA C697 -The SUDS Manual). Appropriately designed, constructed and maintained SUDS are more sustainable than conventional drainage methods because they can mitigate many of the adverse effects of urban stormwater runoff on the environment.

They can achieve this through:

- Reducing runoff rates, thus reducing the risk of downstream flooding
- Reducing the additional runoff volumes and runoff frequencies that tend to be increased as a result of urbanisation, and which can exacerbate flood risk and damage receiving water quality
- Encouraging natural groundwater recharge (where appropriate) to minimise the impacts on aquifers and river baseflows in the receiving catchment
- Reducing pollutant concentrations in stormwater, thus protecting the quality of the receiving water body
- Acting as a buffer for accidental spills by preventing direct discharge of high concentrations of contaminants to the receiving water body
- Contributing to the enhanced amenity and aesthetic value of developed areas
- Providing habitats for wildlife in urban areas and opportunities for biodiversity enhancement.

To mimic natural catchment processes as closely as possible, a “management train” is required. This concept is fundamental to designing a successful SUDS scheme – with drainage techniques in series incrementally reducing pollution, flow rates and volumes of runoff. Through effective control of runoff at source, the need for large flow attenuation and flow control structures is reduced.

The variety of SUDS components and design options are wide ranging and the following should be incorporated where possible to help deal with contaminants and lower/slow the stormwater run-off:

- Source control techniques
- Rainwater harvesting systems – for roofwater re-use for toilets etc
- Filter trenches - to treat run-off from car parking areas
- Swales - to treat run-off from car parking areas
- Pervious pavements - to treat run-off from car parking areas
- Geocellular systems - for stormwater attenuation storage
- Detention basins- for stormwater treatment and attenuation storage
- Ponds- for stormwater treatment and attenuation storage
- Stormwater wetlands- for stormwater treatment and attenuation storage

The larger masterplan for the site includes the provision of a large wetland/pond which may be utilised for attenuation storage as part of the wider development. Due to the staging process of the development this will not be constructed and operational for use at this stage and therefore the use of source control (permeable pavements) and buried tank attenuation should be considered for use prior to discharge into the diverted on-site drainage network.

As the stormwater for the existing buildings and related hardstanding discharges into the existing stormwater network, this is to be reutilised for the proposed facility. The **peak stormwater flows** must be restricted to a worst case that matches the existing discharge rates into this network and ultimately to the River Clyde outfall. This ensures that compliance to the existing agreements with SEPA and ScottishWater for this discharge are not jeopardised. It is likely that Scottish Water and SEPA will accept that this flow into the public system will remain and no further works are required to attenuate this discharge.

It has not been established if Scottish Water/SEPA will restrict the discharge of stormwater from this part of the development to the equivalent flow generated from green-field stormwater run-off. Should this be required as part of these works then significant SUDS techniques incorporating stormwater attenuation will be required. However, there are proposals to provide a number of water features at the site and this would provide ideal attenuation facilities for this and future schemes as/if required in lieu of buried tanks located beneath external areas.

The use of suitable stormwater run-off SUDS treatment techniques may be used in car park areas in lieu of the need for a petrol interceptor. This must be agreed with SEPA. Should more conventional surfacing materials and drainage be utilised, a petrol interceptor should be incorporated to intercept hydrocarbons prior to discharging into stormwater network. This must be alarmed and connected to the facilities management system to ensure suitable maintenance is carried out.

6.3.5 Medical Gases

Read in conjunction with drawings 3757/OXP/000-010, inserted in appendices A. These relay the approximate routes of the existing site oxygen infrastructure

There is currently a centralised oxygen compound currently located behind the existing A&E building. A new compound is to be installed behind the maternity building and connected into the existing oxygen network; this allows the existing pipework that crosses the PFI to be removed prior to the construction phase commencing.

A new oxygen VIE compound is to be provided to supply the new adult and Children’s hospitals; a new ring will be installed around the new buildings.

Following the completion of the PFI construction phase and the occupation of the new adult hospital, the redundant buildings on the site are to be demolished, with their related oxygen supplies (fed from compound behind A&E) made redundant and removed. Should the retained existing buildings require oxygen supplies from the site infrastructure then an additional compound may be necessary to serve these.

Any existing requirements for Nitrous Oxides, Vacuum and Medical Air are supplied by local plant and these will be retained/removed in relation to the spaces they serve. Where these gasses are required by the new PFI project, a view will be taken on whether these are to be centralised or localised in relation to the areas served/demand.

6.3.6 IT

Read in conjunction with drawings 3757/ITP/000-010, inserted in appendices A. These relay the approximate routes of the existing site IT/data infrastructure

There are two main incoming data/telecoms rooms, one in the listed building with utility cables coming in from the A739 bypass road and the other in the Outpatients building with utility cables coming in from the Govan road.

Prior to the commencement of the PFI construction phase the buildings within the site boundary are to be demolished and existing data/telecoms connections made redundant/removed. Some cables cross the site e.g. serving maternity; these are to be rerouted using the existing ducting running towards Hardgate road.

The new PFI site is proposed to be connected back to both incoming telecoms/data rooms so that there are two separate routes back to the centralised equipment. The Children’s hospital is to be used as a location to house new equipment and in the long term this could replace that in the Outpatients building, which will be subsequently demolished post PFI construction. Alternatively the equipment in the Outpatients building will require rehousing when this building is demolished.

6.3.7 Steam/ Condensate

Read in conjunction with drawings 3757/T33/000-010, inserted in appendices B. These relay the approximate routes of the existing site steam infrastructure

The existing site is provided with a limited amount of steam (mainly for heating purposes) from the centralised boiler room. The Estates team have already made a considerable effort to decentralise the heating systems and move away from steam heating. A new steam boiler house is to be installed and connected into the existing steam and condensate mains system, this will allow the decommissioning of the existing boiler house prior to the PFI construction works commencing.

Prior to the commencement of the PFI construction phase the buildings within the site boundary are to be demolished and steam/condensate connections will be made redundant/removed.

Post PFI construction the existing steam heating system is to be reviewed in relation to which areas of the retained buildings use the steam heating. Modifications to the steam system will either then be made accordingly or new LTHW plant installed, allowing the buildings that are to be demolished to be so and their related steam/condensate pipes removed. **This is particularly relevant to the Listed building.** Needs an explanatory sentence to make explicit why it is relevant?

6.3.8 Adaptability and Capacity for Expansion

The schemes above have allowed for future expansion based on the Campus Plan submitted by the Trust for planning in the Winter 2006 and are as follows:

WATER

For the site, this can be analysed once Scottish Water have completed their demand and infrastructure modelling. It is envisaged that the later phases of demolition (post PFI connection) will release existing capacity/usage from the Govan road supplies and the A739 (Moss road) supply. These and/or a connection from the new PFI supply from Govan road could then offer some capacity to provide single feed supplies to the future expansion spaces indicated on the drawings.

The new labs building (planned for construction pre PFI) will also need consideration in relation to the above, this is to be included when Scottish water complete their analysis.

POWER

For the site, in our discussions with Scottish Power we have allowed for a future site capacity (post PFI construction and demolition) of 15kVA. However Scottish Power is considering this in relation to the site wide supply and thus the final solution when agreed with Scottish Power may differ from the strategy outlined above and indicated on the drawings. This is therefore subject to further discussions and feedback from Scottish Power.

For the PFI hospitals, electrical power consumption is likely to rise over the PFI term as electrical equipment and IT usage increase that will result in a corresponding increase in the requirement for spot cooling. Load increases are more likely in the clinical “hot” areas rather than the ward areas. We have included +20% increase from the initial load to MD as HTM 06-01 (Table 2 “Growth Factor”) included within the 15MVA site load and 10MVA associated with the PFI Hospitals and allowed for in the design of the incoming supply switchgear and MV distribution to the hospitals to provide scope for additional supply needs without a major refit.

Greater low or zero carbon electrical and heat generation are likely over the PFI term to reduce carbon emissions from the hospital and as the cost of energy rises, alternatives such as on site generated energy may become economic, eg PV cells, additional or hydrogen based CHP. The centralised energy centre provides an adaptable infrastructure that will be able to respond to these changing needs and circumstances.

NATURAL GAS

For the site, the quotation/confirmation from SGN Connections is an additional load to that of the current existing infrastructure. The pre and post PFI building demolition will release existing capacity/usage from the existing Govan road supplies; these can then provide supplies to the future expansion spaces indicated on the drawings. The load for the new labs building has not been included in our discussions with SGN.

For the PFI hospitals we do not see gas consumption rising significantly over the PFI term. It is likely that the nature of the supplied gas will change over the PFI term as natural gas is replaced by synthetic or “biogas” and that the installations will need to be adapted at this time.

MEDICAL GASES

For the site, should the future expansion spaces require oxygen to be supplied from the centralised plant, then the existing plant located behind the existing A&E building will become redundant at that time. This, therefore, provides capacity to supply these areas and to link into the existing site network as required. This is also a strategy that may be able to serve the Labs building.

IT

The incoming data/telephone lines and centralised equipment capacity are to be reviewed and defined by the client's specialists.

ENVIRONMENTAL STRATEGY AND APPROACH TO INTEGRATED DESIGN

The environmental strategy is based on:

- good environmental conditions are required for staff, patients and visitors
- energy use is to be minimised using systems and plant most appropriate to the hospital environment. As a starting point total energy use including small power and medical equipment loads are not to exceed 55GJ/100cm in any year (delivered energy).
Ongoing energy reductions should at least ensure that energy use per unit volume or area do not increase with time and offset additional load as use changes/develops.
- 20% of the energy use above is to be “low or zero carbon” as defined by the Scottish Building Regulations
- Every five years, the contribution of energy reduction and low or zero carbon energy as a percentage of total consumption is to be increased by five percent.
- system and plant/component selection is to be based on lowest life cycle cost

In order to produce robust solutions the design follows the following hierarchy:

- Make the building energy use as low as possible by investing in the building fabric. This will have a good payback as the building fabric life is long and the installations are not dynamic requiring little additional maintenance over and above standard typical solutions
- select appropriate environmental strategies. Design the building so that it offers flexibility to meet changing needs and economic and social drivers with success in the future

The environmental strategy is based on a sealed building with mechanical ventilation. This follows from an appraisal of the ventilation options for Ward Areas presented to the client in March 2007 which attempted to explain and balance the competing design and operational drivers.

To accommodate the extensive vertical and horizontal services runs that will be required for the new hospital facility both in the tower and podium areas as well as to the laboratory block, the design should take due cognisance of this requirement and for the availability of services openings, corridors/routes and penetrations.

Services routes should be fully integrated with the structural design for the buildings to ensure proactive inclusion to accommodate the full extent and range of service types, services proximity, future adaptations and maintenance. This should address issues including wall and floor penetrations, floor and ceiling routing, protection and containment and to ensure that all structural load paths remain uncompromised under all circumstances.

The establishment of the requirements for the provision of dedicated services routes between different hospital buildings and within separate parts of the adults and Children’s facility should be adopted at an early stage of the design to ensure that full effectiveness and interoperability of all plant rooms, roof mounted equipment, basement plant and link corridors is achieved.

The services strategy should allow for the requirements of the facilities energy centre, electrical sub-stations, gas pressure reduction stations, gas/fire suppressant bottle stores, water tanks, HVAC equipment, helicopter servicing, fire-systems, steam and other mechanical services including all specialist services i.e. medical gases.

The structural building frame that is adopted should be selected on the basis of other site constraints to allow planned and pro-active inclusion for services routes and plant room sizing and location.

6.3.9 Ventilation

Required Conditions

It is important that the ventilation approach for the Adult and Children’s hospitals fulfil the primary requirement to provide adequate:

- supplies of fresh air
- odour dilution
- removal of airborne contaminants or pathogens

Detailed quantified requirements relating to internal environmental conditions can be found in Department of Health Estates & Facilities Division publications. These publications are in the process of being rationalised. The current ventilation standard SHTM 2025 will shortly be superseded by HTM 03-01 ‘specialised ventilation for healthcare properties’. A draft version of this new standard has been circulated. The HVAC design is in accordance with its requirements.

Site Constraints

It is important that the ventilation approach takes into consideration the constraints of the site. These have been identified as:

Smells from adjacent sewage treatment plant

Scottish Water’s Sheildhall Sewage Treatment Plant lies approximately 400m north of the site. Staff and patients using the existing hospital buildings on the site experience a constant low-level of odour from the plant. After heavy rain the odour becomes more pronounced and unpleasant. Although there are intentions to remedy or re-locate the sewage treatment plant, there are no concrete plans or timeframe for this work. There is a major risk, therefore, that the odour issue will not be resolved before the opening of the Hospitals. SHTN 30 ‘Infection Control in the Built Environment’ states that although odour in itself does not present a direct risk, if it leads to ventilation being restricted it may in turn increase the risk of hospital acquired infections.

Construction noise, dust & contamination

The construction of the Adult and Children’s Hospitals is to be staggered. This means that there will be a period when the Children’s’ Hospital is operating and the Adult Hospital is being built. It is important that the ventilation approach limits the intrusion of construction noise, dust and contamination while ensuring adequate ventilation.

It is important that the laboratories on the site do not contaminate ventilation air drawn into the new hospitals. A detailed site airflow assessment needs to be carried out to confirm that this will not be an issue.

Mechanical Ventilation

The Clinical Areas, Wards and the remainder of the main hospital buildings are to be mechanically ventilated throughout. This decision has been made because mechanical ventilation offers the following advantages over natural ventilation:

- smells can be eliminated from incoming air through activated carbon filtration.
- dust can be filtered from incoming air.
- external noise from site construction can be attenuated through the incoming air path
- for clinical areas robust and reliable control of environmental conditions is required for the spaces to function correctly and efficiently. The control airborne infection by room air flow control and dilution by enclosure and mechanical ventilation is essential.

Additionally mechanical ventilation provides the additional benefits of:

- helping to control airborne infection by allowing points of air intake and discharge to be carefully separated to avoid recirculation, good dilution of room contaminants/pathogens, and by allowing pressure differentials to be created to facilitate the flow of air from clean to less clean areas.
- allowing air to air ventilation heat recovery, thereby significantly reducing the running costs and carbon emissions associated with space heating and cooling of ventilation air.
- allowing incoming air to be cooled prior to being supplied to spaces to ensure good thermal conditions. This provides a system that for patient and staff areas do not exceed the draft HTM 04-01. This recommends that temperatures of 28°C are not exceeded for 50 hours a year.
-

In addition, as the heliport is to be constructed on the roof of the Adult Hospital tower, mechanical ventilation will avoid drafts through windows and help limit noise.

High building air tightness is required to exclude infiltration and odour. The buildings will be slightly pressurised.

Energy Reduction Measures

The Hospitals are to incorporate the following measures to reduce energy consumption associated with HVAC systems:

- windows in ward and office areas are to be fitted with external adjustable shading devices such as adjustable mid pane louveres or blinds. These will reduce peak solar heat gains to allow good thermal conditions within well day lit spaces and minimize the requirement for mechanical cooling in these areas. Shading Factor “SF” > 70%.
- exposed thermal mass, where practical, to limit temperature swing and reduce peak temperatures. Patient rooms are to have exposed concrete soffits.
- air to air heat recovery in all air handling units.
- variable ventilation rates by fan speed control for spaces with demand control (eg odour, ammonia)

General Plant Design & Distribution for Infection Control

Each hospital department is to contain its own dedicated air handling plant. Larger departments, such as inpatient wards, are to be zoned with separate air handling plant serving each zone. This is to ensure that in the event of mechanical failure, or during maintenance or refurbishment only a limited area is affected. Critical care units are to be served with back-up air handling plant.

Air handling plant at podium roof level are to serve the main body of the hospitals as well as the lower half of the adult hospital tower. The top half of the tower is to be served by air handling plant installed in the tower roof. Fresh air intake and discharge louveres are to be installed at these levels, carefully separated to avoid recirculation.

Supply and extract ductwork is to be distributed to the hospital departments via risers. Where possible these risers are to be located off main circulation routes to facilitate access for cleaning and maintenance. Horizontal distribution is to be in ceiling voids above corridors, wherever possible, so that access panels can be located outside clinical areas. Similarly, trimmer coils are to be installed above circulation areas wherever possible to avoid potential leaks in clinical areas, which would lead to greater disruption and potential damage to expensive equipment.

The ductwork distribution system is to be a low pressure system. Smoke dampers will be installed through all fire and smoke compartments. Access panels are to be installed in accordance with DW142 to allow adequate inspection, maintenance and cleaning. Flexible ductwork is only to be installed for final connections to grilles and diffusers.

Diffusers and grilles are to be carefully chosen to allow them to be easily removed and cleaned to limit airborne contamination.

Air handling plant is designed to comply with draft HTM 03-01 requirements, and includes, in addition to the base provision of inlet filter, heating coil and fan/attenuators the following:

- inspection, cleaning and maintenance access sections either side of all coils and dampers, upstream of all filters and downstream of all humidifiers.
- blow-through configuration of fans to ensure as much of the unit is under positive pressure as possible.

The following sections are generally to be incorporated into all air handling units:

- fog coils.
- cooling coils
- temporary pre-filters (G1/G2) to allow removal of dust while construction work is ongoing.
- steam injection humidifiers
- activated carbon filters for odour removal

Specialist Ventilation Areas

wards

Ventilation plant will be zoned by elevation and space type/function.

Patient rooms and multi-bed bays are to have local temperature control through the installation of heating trimmer coils on individual room branch pipework. Space humidification and cooling will be by the supply of cooled ventilation air without

individual room temperature control In individual rooms temperature and external motorized solar shading control is to be built into the bed-head controls. In multi-bed bays controls are to be installed at a central location. Temperature control is be primarily automatic with sensors in each space, however local controls are to allow limited adjustment of the set-point for a limited period after which the temperature control returns automatically to its pre-set set-point.

Patient rooms and multi-bed bays are to be kept at a lower pressure relative to their adjacent corridors, and so in addition to the air supplied directly to these spaces additional air will pulled in under doors. Air is to be extracted through ensuite shower rooms as well as additional grilles located above the ensuite shower room doors. The air change rate in these spaces is to achieve the draft HTM 03-01 requirement of six air changes per hour. However, apart from specific wards where clinical experience indicates that odours are likely to be strong and persistent, such as the geriatrics wards, the controls are to set the air change rate at four air changes per hour with local pushbuttons to allow the rate to be boosted to six air changes per hour for a limited period. Buttons are to include bypass key control to allow the air change rate to be locked at six air changes per hour if this proves desirable.

critical and intensive care

These are to be air conditioned spaces with full temperature and humidity control.

operating suites

Each conventional operating suite is to be installed with its own air handling unit. Fresh air is to be delivered in accordance with draft HTM 04-01 at 25 air changes an hour. Operating suites are to be controlled in such a way so that when vacant, ventilation plant is turned off to conserve energy. In the operating theatre air is to be supplied through the high-level terminal canopy and expelled at low-level through pressure stabilizers. Pressure stabilizers are to be installed on all four sides or in all four corners of the room, and to be visible so that they provide a visual indication that the ventilation system is running.

Ultra clean ventilation operating suites are to be delivered with the same amount of fresh air as conventional suites, however an additional recirculation air handling unit is to be installed to increase the flow through the terminal to ensure laminar flow and a count of less than 1 colony forming unit per cubic meter. A high-efficiency HEPA filter is to be installed before the canopy. The recirculation unit is to be remote, to allow inspection and maintenance to be carried out outside the theatre. The canopy is to be of the vertical flow type.

isolation suites

Isolation suites will be dedicated plant designed as HBN 4 Supplement 1 to provide isolation. This relies on an air tight enclosure and a lobby positively pressurised with respect to the room and corridor.

Ventilation System & Fire Strategy

In certain critical care departments it is preferable to maintain the supply ventilation in the case of a fire within the area, for example the continued supply of air to a theatre will maintain it at a positive pressure and protect the patient and staff from the effects of smoke. The ventilation plant is not designed to be automatically shut down on the operation of the fire alarm and detection system, but under the instruction of the fire-and-rescue service and controlled from panels located either at department entrances or adjacent to the main fire alarm indicator panels at the entrances to the buildings.

Fire dampers are to be installed in all ducts penetrating fire compartment and sub-compartment walls. In compartment walls fire dampers are to be actuated on the operation of the alarm and detection system in the compartments either side of the compartment walls. In sub compartment walls dampers are to be activated by thermal release devices.

All supply AHU's are to have a smoke sensor mounted in the main supply duct immediately downstream of the AHU. In the event of a fire in the AHU or smoke being drawn into the system from an outside source the supply air damper is to close and the AHU is to be shut down.

A mechanical smoke extract system is to be installed in the basement of the hospitals. (The installation of a sprinkler system in the basement allows mechanical smoke extract to be considered as an alternative to conventional smoke vents.) This system is to provide at least ten air changes per hour and be capable of handling gas temperatures up to 400°C for an hour.

6.3.10 Heating

HOSPITAL INFRASTRUCTURE

Central Boilers & distribution

The plant for both the Adult and Children's Hospital is to be centralised and located in a separate Energy Centre. The system philosophy is shown on SK021. The plant shown will provide heating for fabric, ventilation and domestic hot water needs for the two hospitals. Separate steam generation plants will be required for humidification and sterilisation.

The heating system located in the Energy Centre will be a Medium Temperature Hot Water System (140/65 °C). The boilers to be used are high efficiency, low Nox, 3 pass high water content boilers with pressurised burners that operate on alternative fuel supplies of natural gas and 35 second light oil. Burners to be digital modulating with variable speed and air damper control capacity control to achieve a high turndown ratio (10 to 1 turndown on natural gas). Low NOx (<70mg/KWhr natural gas) burner with oxygen trim control.

The boiler configuration employs an effective (N+1) redundancy at peak connected design load (effective N+2 at part load). Each boiler is to have its own discreet insulated and clad flue. The flue stack to be an independent stainless structure to allow the flue to discharge above the level of the tower with space to accommodate other services requiring high level discharge.

The MTHW will be distributed via separate highly insulated district heating mains to the Adult and Children's Hospitals run within the basement service route between the Energy Centre/Loading Bay and the Hospitals. Heat exchangers convert the MTHW to LTHW (90/70 °C) locally for room heat emitters and air trimming coils.

It is envisaged that the pipework installation will consist of a mixture of modern and traditional materials. The whole of the heating system will be chemically dosed and treated as appropriate. All pipework and fittings are to be highly insulated to minimise heat loss and heat gain to the hospital spaces. Insulation will be 50% thicker than the minimum economic thickness.

All pumping arrangements will include redundant standby pumping. The majority of the main pump sets will consist of 3 no. pumps rated at 50% duty while the smaller pump sets will consist of smaller run and standby pumps rated at 100% duty.

In order to optimise energy usage 2 port control valve technology and variable speed pumping will be employed throughout. Differential pressure control valves shall be used on all sub-circuit branches.

Gas Combined Heat and Power

At present a 1.5 MWe gas supplied spark ignition reciprocating engine combined heat and power installation has been included in the base scheme. The exact size of the CHP plant will be reviewed once detailed electrical and heat load analyses have been completed for the site and the economic case for CHP can be explored in detail with a turnkey operator. Additional CHP capacity in the future provides scope for increasing the proportion of "low carbon " energy supply.

The CHP unit is to be located in the Energy Centre. Heat will be recovered from the unit engine jacket, engine cooling system and exhaust gases via a shunt pump circuit connected to the main boiler return distribution pipework. Once the exact size of the unit is known it may be beneficial to employ a separate heat recovery boiler. The CHP unit will have its own separate flue. It is envisaged that the unit will operate whenever the heat and power can be fully utilised.

Domestic Hot and Cold Water

The domestic hot and cold water installations will be installed to potable quality standards throughout the whole of the Hospital development.

There shall be dual and separate water supplies to the Adult and Children's Hospitals. The total hot and cold water needs for each building shall be met by water storage located in each building. Each building shall have sufficient water storage to meet 24 hours requirement. The preferred option for the water storage and distribution is as follows.

- Main storage tanks located in basement, no break tanks, pumped distribution system, with duty standby pump sets and controls and generator back electrical supplies to the pumps. Trust approval for this option will be required.

The location and number of independent hot water heat stations is shown on SK023. Each heat station location is sized on a (N+1) basis. Hot water shall be delivered to individual wards and departments via a traditional two pipe circulation system.

The whole of the potable hot and cold water installation will be designed to meet all the legionella requirements. In particular the water storage tank connection arrangements allow for zero dead legs and the heat station installation allows for continual calorifier circulation with zero stratification. All pipework is to be insulated to minimise heat loss or gain as appropriate.

Particular emphasis is to be put into ensuring that there will be the minimum number of hot water returns, that there will be adequate insulation on the cold water installations to avoid temperature build up and that there will be regular flushing of cold water dead legs by means of appliances connected to the same.

The laboratory areas will be provided with similar hot and cold water installations employing separate break tanks and separate calorifiers to ensure full segregation between laboratory and domestic installations thus meeting the requirements of the Water Regulations.

Pipework installation within both hospitals will be run within individual level ceiling voids to ensure any particular ward or department can be isolated at that level only.

Room Heat Emitters

Where room are mechanically ventilated heating and ventilation rates are sufficient to provide good room air mixing/destratification, heating will be provided by air room reheat coil with 2 port water control valve and room temperature controller.

For areas with extensive glazing and/or natural ventilation, heating will be from perimeter heating; either high level radiant panel or low level convector.

6.3.11 Cooling

General Chilled Water

In order to meet the annual cooling requirements of the development and the requirements of HTM 3, chilled water installation will be required.

The preferred chilled water system configurations are shown on SK019.

- The configuration shows discreet chiller installations adjacent to the air handling units they serve. As a (N+1) redundancy philosophy has been utilised for each chiller cluster, a separate process chilled water system will be installed utilising free cooling chillers.

The chilled water equipment shall include chillers, buffer vessels and pressurisation units. Each chiller will be of the fully packaged air-cooled type complete with multiple modular screw compressors. The chiller will be rated as residentially quiet to avoid unobtrusive noise emissions. Chillers to have variable speed head pressure control with load and efficiency optimised head pressure and chilled water flow temperature control to improve seasonal efficiency.

The chilled water circuits will consist of both primary and secondary pumping. In order to optimise energy usage, 2 port control valve technology and variable speed pumping will be employed throughout. Differential pressure control valves shall be used on all sub-circuit branches.

All pumping arrangements will include redundant standby pumping. The majority of the main pump sets will consist of 3 no. pumps rated at 50% duty while the smaller pump sets will consist of smaller run and standby pumps rated at 100% duty.

Chilled water will be distributed through a conventional 2 pipe system to the various demand centres throughout the building. The installation will employ a number of traditional and modern materials. The entire chilled water system will be chemically dosed and treated as appropriate. All pipework is to be insulated to minimise gain.

ITC Cooling

Independent chilled water system as above but with free cooling roof mounted air cooled water chillers. N+2 redundancy with plant backed by the essential electrical supply.

6.3.12 Drainage

The rainwater drainage system in each hospital shall be gravity systems. The rainwater pipework in each hospital shall be housed in vertical risers and will be insulated to prevent condensation and noise transfer.

The soil and waste drainage system in each hospital shall be gravity systems. The systems generally shall be vented to atmosphere above the roof. It is envisaged that the pipework installation will consist of a mixture of modern and traditional materials. Separate chemically resistant drainage will be installed in all specialist areas.

6.3.13 Artificial Lighting

General lighting to all areas by low energy fluorescent light sources. All control gear to be high frequency, high power factor (PF>0.95), low harmonic emission light fittings equipped with electronic control gear. No switch start gear light fittings permitted.

Efficient light sources and luminaires will be used.

Lighting is a substantial user of energy in hospitals and buildings generally. Often the light level and energy use can be varied because natural light is available or because the need for light is reduced. In summer the removal of heat from light fittings is important to prevent overheating of spaces. As lamps age and fittings/lamps get dirty over their cleaning cycle, the light output will fall. Room photocells and dimming can adjust the output of the lamp down when clean, to reduce energy use and heat gain. For each space the potential for lighting controls will be examined and the appropriate lighting controls will be installed.

Lamp and lighting gear monitoring provides a cost effective solution to lamp/gear maintenance.

day lit spaces	fitting dimming controls and room photocells to provide dimming and off control
spaces subject to intermittent occupancy	occupancy detection to switch lights off when the room is not in use
all spaces	fitting dimming controls and room photocells to provide lamp output control as lamps age/fittings get dirty lamp and gear monitoring and alarming for lamp/gear maintenance
external lighting	time and light level control of all external lighting

Design Light Levels:

as HTM/HBN & CIBSE guidance

Lighting Circuits:

Final circuit cabling shall generally consist of LSF insulated single core cables to BS7211 enclosed and protected within metal conduit. All final circuits shall be provided with full size single core circuit protective conductors.

All electrical accessories/socket outlet switch plates shall be stainless steel finish in Category 3, 4 and 5 areas. Offices and administration (non-patient areas) could be of alternative materials (i.e. plastic).

Escape light fittings throughout the building wards will be supported by the secondary power supply system with fittings distributed over at least two (Side A and Side B) interleaved circuits. In the event of a failure on Side A (final circuit, rising busbar, distribution board, main switch panel or supply transformer), then power will still be available from socket outlets connected to Side B circuits.

V40 Emergency Lighting

Generally, secondary lighting to Grade A or Grade B will be provided to all areas of the building depending on clinical risk category. All secondary lighting will be fed from the secondary power power supply (SPS) with reconnection within 15 seconds, following failure of the incoming mains supply (see drawing: V[20]-500). In accordance with HTM 06-01, all areas that require standby lighting will also be provided with emergency lighting.

Emergency escape lighting will be provided to all areas of the buildings to meet the requirements of BS5266 and HTM2011 Generally, emergency lighting will be provided in the form of self contained light fittings with their own integral battery packs to provide up to three hours autonomy in the event of complete power failure.

STATUTORY INSTRUMENTS

2002 No. 2677**HEALTH AND SAFETY****The Control of Substances Hazardous
to Health Regulations 2002**

<i>Made</i>	- - - -	<i>24th October 2002</i>
<i>Laid before Parliament</i>		<i>31st October 2002</i>
<i>Coming into force</i>	- -	<i>21st November 2002</i>

The Secretary of State being the Minister designated⁽¹⁾ for the purpose of section 2(2) of the European Communities Act 1972⁽²⁾ in relation to the abolition of restrictions on the import or export of goods, in the exercise of the powers conferred on him by the said section 2(2) and sections 15(1), (2), (3)(b), (4), (5)(b), (6)(b) and (9), 52(2) and (3) and 82(3)(a) of, and paragraphs 1(1) to (4), 2, 6(1), 8, 9, 11, 14, 15(1), 16 and 20 of Schedule 3 to, the Health and Safety at Work etc. Act 1974⁽³⁾ (“the 1974 Act”) and of all other powers enabling him in that behalf and for the purpose of giving effect without modifications to proposals submitted to him by the Health and Safety Commission under section 11(2)(d) of the 1974 Act after the carrying out by the said Commission of consultations in accordance with section 50(3) of that Act, hereby makes the following Regulations:

Citation and commencement

1. These Regulations may be cited as the Control of Substances Hazardous to Health Regulations 2002 and shall come into force on 21st November 2002.

Interpretation

2.—(1) In these Regulations—

“the 1974 Act” means the Health and Safety at Work etc. Act 1974;

“the Agreement” means the Agreement on the European Economic Area signed at Oporto on 2nd May 1992 as adjusted by the Protocol signed at Brussels on 17th March 1993⁽⁴⁾ and adopted as respects Great Britain by the European Economic Area Act 1993⁽⁵⁾;

(1) [S.I. 1992/2661](#).

(2) [1972 c. 68](#), the definition of the Treaties referred to in section 2(2) of the European Communities Act 1972 was extended by section 1 of the European Economic Area Act [1993 \(c. 51\)](#).

(3) [1974 c. 37](#), sections 11(2), 15(1) and 50(3) were amended by the Employment Protection Act [1975 \(c. 71\)](#), Schedule 15, paragraphs 4, 6 and 16(3) respectively.

(4) The Agreement was amended by Decision 7/94 of the EEA Joint Committee of 21st March 1994 (OJ No. L160, 28.6.94, p. 1). There are other amendments to the Agreement not relevant to these Regulations.

“appointed doctor” means a registered medical practitioner appointed for the time being in writing by the Executive for the purpose of these Regulations;

“approved” means approved for the time being in writing;

“approved classification” of a biological agent means the classification of that agent approved by the Health and Safety Commission;

“approved supply list” has the meaning assigned to it in regulation 2(1) of the CHIP Regulations;

“biological agent” means a micro-organism, cell culture, or human endoparasite, whether or not genetically modified, which may cause infection, allergy, toxicity or otherwise create a hazard to human health;

“carcinogen” means—

- (a) a substance or preparation which if classified in accordance with the classification provided for by regulation 4 of the CHIP Regulations would be in the category of danger, carcinogenic (category 1) or carcinogenic (category 2) whether or not the substance or preparation would be required to be classified under those Regulations; or
- (b) a substance or preparation—
 - (i) listed in Schedule 1, or
 - (ii) arising from a process specified in Schedule 1 which is a substance hazardous to health;

“cell culture” means the in-vitro growth of cells derived from multicellular organisms;

“the CHIP Regulations” means the Chemicals (Hazard Information and Packaging for Supply) Regulations 2002⁽⁶⁾;

“control measure” means a measure taken to reduce exposure to a substance hazardous to health (including the provision of systems of work and supervision, the cleaning of workplaces, premises, plant and equipment, the provision and use of engineering controls and personal protective equipment);

“employment medical adviser” means an employment medical adviser appointed under section 56 of the Health and Safety at Work etc. Act 1974;

“the Executive” means the Health and Safety Executive;

“fumigation” means an operation in which a substance is released into the atmosphere so as to form a gas to control or kill pests or other undesirable organisms and “fumigate” and “fumigant” shall be construed accordingly;

“Group”, in relation to a biological agent, means one of the four hazard Groups specified in paragraph 2 of Schedule 3 to which that agent is assigned;

“hazard”, in relation to a substance, means the intrinsic property of that substance which has the potential to cause harm to the health of a person, and “hazardous” shall be construed accordingly;

“health surveillance” means assessment of the state of health of an employee, as related to exposure to substances hazardous to health, and includes biological monitoring;

“inhalable dust” means airborne material which is capable of entering the nose and mouth during breathing, as defined by BS EN 481 1993;

“maximum exposure limit” for a substance hazardous to health means the maximum exposure limit approved by the Health and Safety Commission for that substance in relation to the

(5) 1993 c. 51.

(6) S.I. 2002/1689.

specified reference period when calculated by a method approved by the Health and Safety Commission;

“medical examination” includes any laboratory tests and X-rays that a relevant doctor may require;

“member State” means a State which is a Contracting Party to the Agreement;

“micro-organism” means a microbiological entity, cellular or non-cellular, which is capable of replication or of transferring genetic material;

“mine” has the meaning assigned to it by section 180 of the Mines and Quarries Act 1954⁽⁷⁾;

“occupational exposure standard” for a substance hazardous to health means the standard approved by the Health and Safety Commission for that substance in relation to the specified reference period when calculated by a method approved by the Health and Safety Commission;

“personal protective equipment” means all equipment (including clothing) which is intended to be worn or held by a person at work and which protects that person against one or more risks to his health, and any addition or accessory designed to meet that objective;

“preparation” means a mixture or solution of two or more substances;

“public road” means (in England and Wales) a highway maintainable at the public expense within the meaning of section 329 of the Highways Act 1980⁽⁸⁾ and (in Scotland) a public road within the meaning assigned to that term by section 151 of the Roads (Scotland) Act 1984⁽⁹⁾;

“registered dentist” has the meaning assigned to it in section 53(1) of the Dentists Act 1984⁽¹⁰⁾;

“relevant doctor” means an appointed doctor or an employment medical adviser;

“respirable dust” means airborne material which is capable of penetrating to the gas exchange region of the lung, as defined by BS EN 481 1993;

“risk”, in relation to the exposure of an employee to a substance hazardous to health, means the likelihood that the potential for harm to the health of a person will be attained under the conditions of use and exposure and also the extent of that harm;

“the risk assessment” means the assessment of risk required by regulation 6(1)(a);

“safety data sheet” means a safety data sheet within the meaning of regulation 5 of the CHIP Regulations;

“substance” means a natural or artificial substance whether in solid or liquid form or in the form of a gas or vapour (including micro-organisms);

“substance hazardous to health” means a substance (including a preparation)—

- (a) which is listed in Part I of the approved supply list as dangerous for supply within the meaning of the CHIP Regulations and for which an indication of danger specified for the substance is very toxic, toxic, harmful, corrosive or irritant;
- (b) for which the Health and Safety Commission has approved a maximum exposure limit or an occupational exposure standard;
- (c) which is a biological agent;
- (d) which is dust of any kind, except dust which is a substance within paragraph (a) or (b) above, when present at a concentration in air equal to or greater than—
 - (i) 10 mg/m³, as a time-weighted average over an 8-hour period, of inhalable dust, or
 - (ii) 4 mg/m³, as a time-weighted average over an 8-hour period, of respirable dust;

⁽⁷⁾ 1954 c. 70, section 180 was modified by S.I. 1974/2013, 1993/1897 and 1999/2024.

⁽⁸⁾ 1980 c. 66.

⁽⁹⁾ 1984 c. 54.

⁽¹⁰⁾ 1984 c. 24.

- (e) which, not being a substance falling within sub-paragraphs (a) to (d), because of its chemical or toxicological properties and the way it is used or is present at the workplace creates a risk to health;

“workplace” means any premises or part of premises used for or in connection with work, and includes—

- (a) any place within the premises to which an employee has access while at work; and
- (b) any room, lobby, corridor, staircase, road or other place—
 - (i) used as a means of access to or egress from that place of work, or
 - (ii) where facilities are provided for use in connection with that place of work, other than a public road.

(2) In these Regulations, a reference to an employee being exposed to a substance hazardous to health is a reference to the exposure of that employee to a substance hazardous to health arising out of or in connection with work at the workplace.

(3) Where a biological agent has an approved classification, any reference in these Regulations to a particular Group in relation to that agent shall be taken as a reference to the Group to which that agent has been assigned in that approved classification.

Duties under these Regulations

3.—(1) Where a duty is placed by these Regulations on an employer in respect of his employees, he shall, so far as is reasonably practicable, be under a like duty in respect of any other person, whether at work or not, who may be affected by the work carried out by the employer except that the duties of the employer—

- (a) under regulation 11 (health surveillance) shall not extend to persons who are not his employees; and
- (b) under regulations 10, 12(1) and (2) and 13 (which relate respectively to monitoring, information and training and dealing with accidents) shall not extend to persons who are not his employees, unless those persons are on the premises where the work is being carried out.

(2) These Regulations shall apply to a self-employed person as they apply to an employer and an employee and as if that self-employed person were both an employer and an employee, except that regulations 10 and 11 shall not apply to a self-employed person.

(3) The duties imposed by these Regulations shall not extend to the master or crew of a sea-going ship or to the employer of such persons in relation to the normal shipboard activities of a ship’s crew under the direction of the master.

Prohibitions relating to certain substances

4.—(1) Those substances described in Column 1 of Schedule 2 are prohibited to the extent set out in the corresponding entry in Column 2 of that Schedule.

(2) The importation into the United Kingdom, other than from another member State, of the following substances and articles is prohibited, namely—

- (a) 2-naphthylamine, benzidine, 4-aminodiphenyl, 4-nitrodiphenyl, their salts and any substance containing any of those compounds in a total concentration equal to or greater than 0.1 per cent by mass;
- (b) matches made with white phosphorus,

and a contravention of this paragraph shall be punishable under the Customs and Excise Management Act 1979⁽¹¹⁾ and not as a contravention of a health and safety regulation.

(3) A person shall not supply during the course of or for use at work a substance or article specified in paragraph (2).

(4) A person shall not supply during the course of or for use at work, benzene or a substance containing benzene unless its intended use is not prohibited by item 11 of Schedule 2.

Application of regulations 6 to 13

5.—(1) Regulations 6 to 13 shall have effect with a view to protecting persons against a risk to their health, whether immediate or delayed, arising from exposure to substances hazardous to health except—

- (a) where and to the extent that the following Regulations apply, namely—
 - (i) the Coal Mines (Respirable Dust) Regulations 1975⁽¹²⁾,
 - (ii) the Control of Lead at Work Regulations 2002⁽¹³⁾,
 - (iii) the Control of Asbestos at Work Regulations 2002⁽¹⁴⁾;
- (b) where the substance is hazardous to health solely by virtue of its radioactive, explosive or flammable properties, or solely because it is at a high or low temperature or a high pressure;
- (c) where the risk to health is a risk to the health of a person to whom the substance is administered in the course of his medical treatment.

(2) In paragraph (1)(c) “medical treatment” means medical or dental examination or treatment which is conducted by, or under the direction of a—

- (a) registered medical practitioner;
- (b) registered dentist; or
- (c) other person who is an appropriate practitioner for the purposes of section 58 of the Medicines Act 1968⁽¹⁵⁾,

and includes any such examination or treatment conducted for the purpose of research.

Assessment of the risk to health created by work involving substances hazardous to health

6.—(1) An employer shall not carry out work which is liable to expose any employees to any substance hazardous to health unless he has—

- (a) made a suitable and sufficient assessment of the risk created by that work to the health of those employees and of the steps that need to be taken to meet the requirements of these Regulations; and
 - (b) implemented the steps referred to in sub-paragraph (a).
- (2) The risk assessment shall include consideration of—
- (a) the hazardous properties of the substance;
 - (b) information on health effects provided by the supplier, including information contained in any relevant safety data sheet;
 - (c) the level, type and duration of exposure;

(11) 1979 c. 2.

(12) S.I. 1975/1433, as amended by S.I. 1978/807.

(13) S.I. 2002/2676.

(14) S.I. 2002/2675.

(15) 1968 c. 67.

- (d) the circumstances of the work, including the amount of the substance involved;
 - (e) activities, such as maintenance, where there is the potential for a high level of exposure;
 - (f) any relevant occupational exposure standard, maximum exposure limit or similar occupational exposure limit;
 - (g) the effect of preventive and control measures which have been or will be taken in accordance with regulation 7;
 - (h) the results of relevant health surveillance;
 - (i) the results of monitoring of exposure in accordance with regulation 10;
 - (j) in circumstances where the work will involve exposure to more than one substance hazardous to health, the risk presented by exposure to such substances in combination;
 - (k) the approved classification of any biological agent; and
 - (l) such additional information as the employer may need in order to complete the risk assessment.
- (3) The risk assessment shall be reviewed regularly and forthwith if—
- (a) there is reason to suspect that the risk assessment is no longer valid;
 - (b) there has been a significant change in the work to which the risk assessment relates; or
 - (c) the results of any monitoring carried out in accordance with regulation 10 show it to be necessary,
- and where, as a result of the review, changes to the risk assessment are required, those changes shall be made.
- (4) Where the employer employs 5 or more employees, he shall record—
- (a) the significant findings of the risk assessment as soon as is practicable after the risk assessment is made; and
 - (b) the steps which he has taken to meet the requirements of regulation 7.

Prevention or control of exposure to substances hazardous to health

7.—(1) Every employer shall ensure that the exposure of his employees to substances hazardous to health is either prevented or, where this is not reasonably practicable, adequately controlled.

(2) In complying with his duty of prevention under paragraph (1), substitution shall by preference be undertaken, whereby the employer shall avoid, so far as is reasonably practicable, the use of a substance hazardous to health at the workplace by replacing it with a substance or process which, under the conditions of its use, either eliminates or reduces the risk to the health of his employees.

(3) Where it is not reasonably practicable to prevent exposure to a substance hazardous to health, the employer shall comply with his duty of control under paragraph (1) by applying protection measures appropriate to the activity and consistent with the risk assessment, including, in order of priority—

- (a) the design and use of appropriate work processes, systems and engineering controls and the provision and use of suitable work equipment and materials;
 - (b) the control of exposure at source, including adequate ventilation systems and appropriate organisational measures; and
 - (c) where adequate control of exposure cannot be achieved by other means, the provision of suitable personal protective equipment in addition to the measures required by sub-paragraphs (a) and (b).
- (4) The measures referred to in paragraph (3) shall include—

- (a) arrangements for the safe handling, storage and transport of substances hazardous to health, and of waste containing such substances, at the workplace;
 - (b) the adoption of suitable maintenance procedures;
 - (c) reducing, to the minimum required for the work concerned—
 - (i) the number of employees subject to exposure,
 - (ii) the level and duration of exposure, and
 - (iii) the quantity of substances hazardous to health present at the workplace;
 - (d) the control of the working environment, including appropriate general ventilation; and
 - (e) appropriate hygiene measures including adequate washing facilities.
- (5) Without prejudice to the generality of paragraph (1), where it is not reasonably practicable to prevent exposure to a carcinogen, the employer shall apply the following measures in addition to those required by paragraph (3)—
- (a) totally enclosing the process and handling systems, unless this is not reasonably practicable;
 - (b) the prohibition of eating, drinking and smoking in areas that may be contaminated by carcinogens;
 - (c) cleaning floors, walls and other surfaces at regular intervals and whenever necessary;
 - (d) designating those areas and installations which may be contaminated by carcinogens and using suitable and sufficient warning signs; and
 - (e) storing, handling and disposing of carcinogens safely, including using closed and clearly labelled containers.
- (6) Without prejudice to the generality of paragraph (1), where it is not reasonably practicable to prevent exposure to a biological agent, the employer shall apply the following measures in addition to those required by paragraph (3)—
- (a) displaying suitable and sufficient warning signs, including the biohazard sign shown in Part IV of Schedule 3;
 - (b) specifying appropriate decontamination and disinfection procedures;
 - (c) instituting means for the safe collection, storage and disposal of contaminated waste, including the use of secure and identifiable containers, after suitable treatment where appropriate;
 - (d) testing, where it is necessary and technically possible, for the presence, outside the primary physical confinement, of biological agents used at work;
 - (e) specifying procedures for working with, and transporting at the workplace, a biological agent or material that may contain such an agent;
 - (f) where appropriate, making available effective vaccines for those employees who are not already immune to the biological agent to which they are exposed or are liable to be exposed;
 - (g) instituting hygiene measures compatible with the aim of preventing or reducing the accidental transfer or release of a biological agent from the workplace, including—
 - (i) the provision of appropriate and adequate washing and toilet facilities, and
 - (ii) where appropriate, the prohibition of eating, drinking, smoking and the application of cosmetics in working areas where there is a risk of contamination by biological agents; and
 - (h) where there are human patients or animals which are, or are suspected of being, infected with a Group 3 or 4 biological agent, the employer shall select the most suitable control and

containment measures from those listed in Part II of Schedule 3 with a view to controlling adequately the risk of infection.

(7) Without prejudice to the generality of paragraph (1), where there is exposure to a substance for which a maximum exposure limit has been approved, control of exposure shall, so far as the inhalation of that substance is concerned, only be treated as being adequate if the level of exposure is reduced so far as is reasonably practicable and in any case below the maximum exposure limit.

(8) Without prejudice to the generality of paragraph (1), where there is exposure to a substance for which an occupational exposure standard has been approved, control of exposure shall, so far as the inhalation of that substance is concerned, only be treated as being adequate if—

- (a) that occupational exposure standard is not exceeded; or
- (b) where that occupational exposure standard is exceeded, the employer identifies the reasons for the standard being exceeded and takes appropriate action to remedy the situation as soon as is reasonably practicable.

(9) Personal protective equipment provided by an employer in accordance with this regulation shall be suitable for the purpose and shall—

- (a) comply with any provision in the Personal Protective Equipment Regulations 2002⁽¹⁶⁾ which is applicable to that item of personal protective equipment; or
- (b) in the case of respiratory protective equipment, where no provision referred to in subparagraph (a) applies, be of a type approved or shall conform to a standard approved, in either case, by the Executive.

(10) Without prejudice to the provisions of this regulation, Schedule 3 shall have effect in relation to work with biological agents.

(11) In this regulation, “adequate” means adequate having regard only to the nature of the substance and the nature and degree of exposure to substances hazardous to health and “adequately” shall be construed accordingly.

Use of control measures etc.

8.—(1) Every employer who provides any control measure, other thing or facility in accordance with these Regulations shall take all reasonable steps to ensure that it is properly used or applied as the case may be.

(2) Every employee shall make full and proper use of any control measure, other thing or facility provided in accordance with these Regulations and, where relevant, shall—

- (a) take all reasonable steps to ensure it is returned after use to any accommodation provided for it; and
- (b) if he discovers a defect therein, report it forthwith to his employer.

Maintenance, examination and testing of control measures

9.—(1) Every employer who provides any control measure to meet the requirements of regulation 7 shall ensure that, where relevant, it is maintained in an efficient state, in efficient working order, in good repair and in a clean condition.

(2) Where engineering controls are provided to meet the requirements of regulation 7, the employer shall ensure that thorough examination and testing of those controls is carried out—

- (a) in the case of local exhaust ventilation plant, at least once every 14 months, or for local exhaust ventilation plant used in conjunction with a process specified in Column 1 of

(16) S.I. 2002/1144.

Schedule 4, at not more than the interval specified in the corresponding entry in Column 2 of that Schedule; or

(b) in any other case, at suitable intervals.

(3) Where respiratory protective equipment (other than disposable respiratory protective equipment) is provided to meet the requirements of regulation 7, the employer shall ensure that thorough examination and, where appropriate, testing of that equipment is carried out at suitable intervals.

(4) Every employer shall keep a suitable record of the examinations and tests carried out in accordance with paragraphs (2) and (3) and of repairs carried out as a result of those examinations and tests, and that record or a suitable summary thereof shall be kept available for at least 5 years from the date on which it was made.

(5) Every employer shall ensure that personal protective equipment, including protective clothing, is:

- (a) properly stored in a well-defined place;
- (b) checked at suitable intervals; and
- (c) when discovered to be defective, repaired or replaced before further use.

(6) Personal protective equipment which may be contaminated by a substance hazardous to health shall be removed on leaving the working area and kept apart from uncontaminated clothing and equipment.

(7) The employer shall ensure that the equipment referred to in paragraph (6) is subsequently decontaminated and cleaned or, if necessary, destroyed.

Monitoring exposure at the workplace

10.—(1) Where the risk assessment indicates that—

- (a) it is requisite for ensuring the maintenance of adequate control of the exposure of employees to substances hazardous to health; or
- (b) it is otherwise requisite for protecting the health of employees,

the employer shall ensure that the exposure of employees to substances hazardous to health is monitored in accordance with a suitable procedure.

(2) Paragraph (1) shall not apply where the employer is able to demonstrate by another method of evaluation that the requirements of regulation 7(1) have been complied with.

(3) The monitoring referred to in paragraph (1) shall take place—

- (a) at regular intervals; and
- (b) when any change occurs which may affect that exposure.

(4) Where a substance or process is specified in Column 1 of Schedule 5, monitoring shall be carried out at least at the frequency specified in the corresponding entry in Column 2 of that Schedule.

(5) The employer shall ensure that a suitable record of monitoring carried out for the purpose of this regulation is made and maintained and that that record or a suitable summary thereof is kept available—

- (a) where the record is representative of the personal exposures of identifiable employees, for at least 40 years; or
- (b) in any other case, for at least 5 years,

from the date of the last entry made in it.

(6) Where an employee is required by regulation 11 to be under health surveillance, an individual record of any monitoring carried out in accordance with this regulation shall be made, maintained and kept in respect of that employee.

(7) The employer shall—

- (a) on reasonable notice being given, allow an employee access to his personal monitoring record;
- (b) provide the Executive with copies of such monitoring records as the Executive may require; and
- (c) if he ceases to trade, notify the Executive forthwith in writing and make available to the Executive all monitoring records kept by him.

Health surveillance

11.—(1) Where it is appropriate for the protection of the health of his employees who are, or are liable to be, exposed to a substance hazardous to health, the employer shall ensure that such employees are under suitable health surveillance.

(2) Health surveillance shall be treated as being appropriate where—

- (a) the employee is exposed to one of the substances specified in Column 1 of Schedule 6 and is engaged in a process specified in Column 2 of that Schedule, and there is a reasonable likelihood that an identifiable disease or adverse health effect will result from that exposure; or
- (b) the exposure of the employee to a substance hazardous to health is such that—
 - (i) an identifiable disease or adverse health effect may be related to the exposure,
 - (ii) there is a reasonable likelihood that the disease or effect may occur under the particular conditions of his work, and
 - (iii) there are valid techniques for detecting indications of the disease or effect,and the technique of investigation is of low risk to the employee.

(3) The employer shall ensure that a health record, containing particulars approved by the Executive, in respect of each of his employees to whom paragraph (1) applies, is made and maintained and that that record or a copy thereof is kept available in a suitable form for at least 40 years from the date of the last entry made in it.

(4) The employer shall—

- (a) on reasonable notice being given, allow an employee access to his personal health record;
- (b) provide the Executive with copies of such health records as the Executive may require; and
- (c) if he ceases to trade, notify the Executive forthwith in writing and make available to the Executive all health records kept by him.

(5) If an employee is exposed to a substance specified in Schedule 6 and is engaged in a process specified therein, the health surveillance required under paragraph (1) shall include medical surveillance under the supervision of a relevant doctor at intervals of not more than 12 months or at such shorter intervals as the relevant doctor may require.

(6) Where an employee is subject to medical surveillance in accordance with paragraph (5) and a relevant doctor has certified by an entry in the health record of that employee that in his professional opinion that employee should not be engaged in work which exposes him to that substance or that he should only be so engaged under conditions specified in the record, the employer shall not permit the employee to be engaged in such work except in accordance with the conditions, if any, specified in the health record, unless that entry has been cancelled by a relevant doctor.

(7) Where an employee is subject to medical surveillance in accordance with paragraph (5) and a relevant doctor has certified by an entry in his health record that medical surveillance should be continued after his exposure to that substance has ceased, the employer shall ensure that the medical surveillance of that employee is continued in accordance with that entry while he is employed by the employer, unless that entry has been cancelled by a relevant doctor.

(8) An employee to whom this regulation applies shall, when required by his employer and at the cost of the employer, present himself during his working hours for such health surveillance procedures as may be required for the purposes of paragraph (1) and, in the case of an employee who is subject to medical surveillance in accordance with paragraph (5), shall furnish the relevant doctor with such information concerning his health as the relevant doctor may reasonably require.

(9) Where, as a result of health surveillance, an employee is found to have an identifiable disease or adverse health effect which is considered by a relevant doctor or other occupational health professional to be the result of exposure to a substance hazardous to health the employer of that employee shall—

- (a) ensure that a suitably qualified person informs the employee accordingly and provides the employee with information and advice regarding further health surveillance;
- (b) review the risk assessment;
- (c) review any measure taken to comply with regulation 7, taking into account any advice given by a relevant doctor, occupational health professional or by the Executive;
- (d) consider assigning the employee to alternative work where there is no risk of further exposure to that substance, taking into account any advice given by a relevant doctor or occupational health professional; and
- (e) provide for a review of the health of any other employee who has been similarly exposed, including a medical examination where such an examination is recommended by a relevant doctor, occupational health professional or by the Executive.

(10) Where, for the purpose of carrying out his functions under these Regulations, a relevant doctor requires to inspect any workplace or any record kept for the purposes of these Regulations, the employer shall permit him to do so.

(11) Where an employee or an employer is aggrieved by a decision recorded in the health record by a relevant doctor to suspend an employee from work which exposes him to a substance hazardous to health (or to impose conditions on such work), he may, by an application in writing to the Executive within 28 days of the date on which he was notified of the decision, apply for that decision to be reviewed in accordance with a procedure approved for the purposes of this paragraph by the Health and Safety Commission, and the result of that review shall be notified to the employee and employer and entered in the health record in accordance with the approved procedure.

Information, instruction and training for persons who may be exposed to substances hazardous to health

12.—(1) Every employer who undertakes work which is liable to expose an employee to a substance hazardous to health shall provide that employee with suitable and sufficient information, instruction and training.

(2) Without prejudice to the generality of paragraph (1), the information, instruction and training provided under that paragraph shall include—

- (a) details of the substances hazardous to health to which the employee is liable to be exposed including—
 - (i) the names of those substances and the risk which they present to health,
 - (ii) any relevant occupational exposure standard, maximum exposure limit or similar occupational exposure limit,

- (iii) access to any relevant safety data sheet, and
- (iv) other legislative provisions which concern the hazardous properties of those substances;
- (b) the significant findings of the risk assessment;
- (c) the appropriate precautions and actions to be taken by the employee in order to safeguard himself and other employees at the workplace;
- (d) the results of any monitoring of exposure in accordance with regulation 10 and, in particular, in the case of a substance hazardous to health for which a maximum exposure limit has been approved, the employee or his representatives shall be informed forthwith, if the results of such monitoring show that the maximum exposure limit has been exceeded;
- (e) the collective results of any health surveillance undertaken in accordance with regulation 11 in a form calculated to prevent those results from being identified as relating to a particular person; and
- (f) where employees are working with a Group 4 biological agent or material that may contain such an agent, the provision of written instructions and, if appropriate, the display of notices which outline the procedures for handling such an agent or material.
- (3) The information, instruction and training required by paragraph (1) shall be—
 - (a) adapted to take account of significant changes in the type of work carried out or methods of work used by the employer; and
 - (b) provided in a manner appropriate to the level, type and duration of exposure identified by the risk assessment.
- (4) Every employer shall ensure that any person (whether or not his employee) who carries out work in connection with the employer's duties under these Regulations has suitable and sufficient information, instruction and training.
- (5) Where containers and pipes for substances hazardous to health used at work are not marked in accordance with any relevant legislation listed in Schedule 7, the employer shall, without prejudice to any derogations provided for in that legislation, ensure that the contents of those containers and pipes, together with the nature of those contents and any associated hazards, are clearly identifiable.

Arrangements to deal with accidents, incidents and emergencies

- 13.—**(1) Subject to paragraph (4) and without prejudice to the relevant provisions of the Management of Health and Safety at Work Regulations 1999⁽¹⁷⁾, in order to protect the health of his employees from an accident, incident or emergency related to the presence of a substance hazardous to health at the workplace, the employer shall ensure that—
- (a) procedures, including the provision of appropriate first-aid facilities and relevant safety drills (which shall be tested at regular intervals), have been prepared which can be put into effect when such an event occurs;
 - (b) information on emergency arrangements, including—
 - (i) details of relevant work hazards and hazard identification arrangements, and
 - (ii) specific hazards likely to arise at the time of an accident, incident or emergency, is available; and
 - (c) suitable warning and other communication systems are established to enable an appropriate response, including remedial actions and rescue operations, to be made immediately when such an event occurs.

⁽¹⁷⁾ S.I. 1999/3242.

(2) The employer shall ensure that information on the procedures and systems required by paragraph (1)(a) and (c) and the information required by paragraph(1)(b) is—

- (a) made available to relevant accident and emergency services to enable those services, whether internal or external to the workplace, to prepare their own response procedures and precautionary measures; and
- (b) displayed at the workplace, if this is appropriate.

(3) Subject to paragraph (4), in the event of an accident, incident or emergency related to the presence of a substance hazardous to health at the workplace, the employer shall ensure that—

- (a) immediate steps are taken to—
 - (i) mitigate the effects of the event,
 - (ii) restore the situation to normal, and
 - (iii) inform those of his employees who may be affected;
- (b) only those persons who are essential for the carrying out of repairs and other necessary work are permitted in the affected area and they are provided with—
 - (i) appropriate personal protective equipment, and
 - (ii) any necessary specialised safety equipment and plant,
 which shall be used until the situation is restored to normal; and
- (c) in the case of an incident or accident which has or may have resulted in the release of a biological agent which could cause severe human disease, as soon as practicable thereafter his employees or their representatives are informed of—
 - (i) the causes of that incident or accident, and
 - (ii) the measures taken or to be taken to rectify the situation.

(4) Paragraph (1) and, provided the substance hazardous to health is not a carcinogen or biological agent, paragraph (3) shall not apply where—

- (a) the results of the risk assessment show that, because of the quantity of each substance hazardous to health present at the workplace, there is only a slight risk to the health of employees; and
- (b) the measures taken by the employer to comply with the duty under regulation 7(1) are sufficient to control that risk.

(5) An employee shall report forthwith, to his employer or to any other employee of that employer with specific responsibility for the health and safety of his fellow employees, any accident or incident which has or may have resulted in the release of a biological agent which could cause severe human disease.

Provisions relating to certain fumigations

14.—(1) This regulation shall apply to fumigations in which the fumigant used or intended to be used is hydrogen cyanide, phosphine or methyl bromide, except that paragraph (2) shall not apply to fumigations using the fumigant specified in Column 1 of Schedule 8 when the nature of the fumigation is that specified in the corresponding entry in Column 2 of that Schedule.

(2) An employer shall not undertake fumigation to which this regulation applies unless he has—

- (a) notified the persons specified in Part I of Schedule 9 of his intention to undertake the fumigation; and
- (b) provided to those persons the information specified in Part II of that Schedule,

at least 24 hours in advance, or such shorter time in advance as the persons required to be notified may agree.

(3) An employer who undertakes a fumigation to which this regulation applies shall ensure that, before the fumigant is released, suitable warning notices have been affixed at all points of reasonable access to the premises or to those parts of the premises in which the fumigation is to be carried out and that after the fumigation has been completed, and the premises are safe to enter, those warning notices are removed.

Exemption certificates

15.—(1) Subject to paragraph (2) the Executive may, by a certificate in writing, exempt any person or class of persons or any substance or class of substances from all or any of the requirements or prohibitions imposed by regulations 4 (to the extent permitted by article 9 of Council Directive [98/24/EC](#)), 8, 9, 11(8), (10) and (11) and 14 of these Regulations and any such exemption may be granted subject to conditions and to a limit of time and may be revoked by a certificate in writing at any time.

(2) The Executive shall not grant any such exemption unless having regard to the circumstances of the case and, in particular, to—

- (a) the conditions, if any, which it proposes to attach to the exemption; and
- (b) any requirements imposed by or under any enactments which apply to the case,

it is satisfied that the health and safety of persons who are likely to be affected by the exemption will not be prejudiced in consequence of it.

Exemptions relating to the Ministry of Defence etc.

16.—(1) In this regulation—

- (a) “Her Majesty’s Forces” means any of the naval, military or air forces of the Crown, whether raised inside or outside the United Kingdom and whether any such force is a regular, auxiliary or reserve force, and includes any civilian employed by those forces;
- (b) “visiting force” has the same meaning as it does for the purposes of any provision of Part I of the Visiting Forces Act 1952⁽¹⁸⁾; and
- (c) “headquarters” means a headquarters for the time being specified in Schedule 2 to the Visiting Forces and International Headquarters (Application of Law) Order 1999⁽¹⁹⁾.

(2) The Secretary of State for Defence may, in the interests of national security, by a certificate in writing exempt—

- (a) any of Her Majesty’s Forces;
- (b) any visiting force;
- (c) members of a visiting force working in or attached to a headquarters; or
- (d) any person engaged in work involving substances hazardous to health, if that person is under the direct supervision of a representative of the Secretary of State for Defence,

from all or any of the requirements or prohibitions imposed by these Regulations and any such exemption may be granted subject to conditions and to a limit of time and may be revoked at any time by a certificate in writing, except that, where any such exemption is granted, suitable arrangements shall be made for the assessment of the health risk created by the work involving substances hazardous to health and for adequately controlling the exposure to those substances of persons to whom the exemption relates.

(3) Regulation 11(11) shall not apply in relation to—

⁽¹⁸⁾ 1952 c. 67.

⁽¹⁹⁾ S.I. 1999/1736.

- (a) any visiting force; or
- (b) members of a visiting force working in or attached to a headquarters.

Extension outside Great Britain

17.—(1) Subject to paragraph (2), these Regulations shall apply to and in relation to any activity outside Great Britain to which sections 1 to 59 and 80 to 82 of the 1974 Act apply by virtue of the Health and Safety at Work etc. Act 1974 (Application outside Great Britain) Order 2001⁽²⁰⁾ as those provisions apply within Great Britain.

(2) These Regulations shall not extend to Northern Ireland except insofar as they relate to imports of substances and articles referred to in regulation 4(2) into the United Kingdom.

Revocation and savings

18.—(1) The Control of Substances Hazardous to Health Regulations 1999⁽²¹⁾ are revoked.

(2) Any record or register required to be kept under the Regulations revoked by paragraph (1) shall, notwithstanding that revocation, be kept in the same manner and for the same period as specified in those Regulations as if these Regulations had not been made, except that the Executive may approve the keeping of records at a place or in a form other than at the place where, or in the form in which, records were required to be kept under the Regulations so revoked.

Extension of meaning of “work”

19. For the purposes of Part I of the 1974 Act the meaning of “work” shall be extended to include any activity involving the consignment, storage or use of a Group 2, 3 or 4 biological agent and the meaning of “at work” shall be extended accordingly, and in that connection the references to employer in paragraphs 5 and 6 of Schedule 3 include references to any persons carrying out such an activity.

Modification of section 3(2) of the 1974 Act

20. Section 3(2) of the 1974 Act shall be modified in relation to an activity involving the consignment, storage or use of any of the biological agents referred to in regulation 19 so as to have effect as if the reference therein to a self-employed person is a reference to any person who is not an employer or an employee and the reference therein to his undertaking includes a reference to such an activity.

Defence

21. Subject to regulation 21 of the Management of Health and Safety at Work Regulations 1999⁽²²⁾, in any proceedings for an offence consisting of a contravention of these Regulations it shall be a defence for any person to prove that he took all reasonable precautions and exercised all due diligence to avoid the commission of that offence.

⁽²⁰⁾ [S.I. 2001/2127](#).

⁽²¹⁾ [S.I. 1999/437](#).

⁽²²⁾ [S.I. 1999/3242](#).

Signed by authority of the Secretary of State.

24th October 2002

N. Brown
Minister of State,
Department for Work and Pensions

SCHEDULE 1

Regulation 2(1)

OTHER SUBSTANCES AND PROCESSES TO WHICH
THE DEFINITION OF “CARCINOGEN” RELATES

Aflatoxins.

Arsenic.

Auramine manufacture.

Calcining, sintering or smelting of nickel copper matte or acid leaching or electrorefining of roasted matte.

Coal soots, coal tar, pitch and coal tar fumes.

Hardwood dusts.

Isopropyl alcohol manufacture (strong acid process).

Leather dust in boot and shoe manufacture, arising during preparation and finishing.

Magenta manufacture.

Mustard gas (β , β' –dichlorodiethyl sulphide).

Rubber manufacturing and processing giving rise to rubber process dust and rubber fume.

Used engine oils.

SCHEDULE 2

Regulation 4(1)

PROHIBITION OF CERTAIN SUBSTANCES
HAZARDOUS TO HEALTH FOR CERTAIN PURPOSES

Column 1 <i>Description of substance</i>	Column 2 <i>Purpose for which the substance is prohibited</i>
1. 2-naphthylamine; benzidine; 4-aminodiphenyl; 4-nitrodiphenyl; their salts and any substance containing any of those compounds, in a total concentration equal to or greater than 0.1 per cent by mass.	Manufacture and use for all purposes including any manufacturing process in which a substance described in Column 1 of this item is formed.
2. Sand or other substance containing free silica.	Use as an abrasive for blasting articles in any blasting apparatus.
3. A substance— (a) containing compounds of silicon calculated as silica to the extent of more than 3 per cent by weight of dry	Use as a parting material in connection with the making of metal castings.

Status: This is the original version (as it was originally made).

Column 1 <i>Description of substance</i>	Column 2 <i>Purpose for which the substance is prohibited</i>
(b) material, other than natural sand, zirconium silicate (zircon), calcined china clay, calcined aluminous fireclay, sillimanite, calcined or fused alumina, olivine; or composed of or containing dust or other matter deposited from a fettling or blasting process.	
4. Carbon disulphide.	Use in the cold-cure process of vulcanising in the proofing of cloth with rubber.
5. Oils other than white oil, or oil of entirely animal or vegetable origin or entirely of mixed animal and vegetable origin.	Use for oiling the spindles of self-acting mules.
6. Ground or powdered flint or quartz other than natural sand.	Use in relation to the manufacture or decoration of pottery for the following purposes: (a) the placing of ware for the biscuit fire; (b) the polishing of ware; (c) as the ingredient of a wash for saggars, trucks, bats, cranks, or other articles used in supporting ware during firing; and (d) as dusting or supporting powder in potters' shops.
7. Ground or powdered flint or quartz other than— (a) natural sand; or (b) ground or powdered flint or quartz which forms parts of a slop or paste.	Use in relation to the manufacture or decoration of pottery for any purpose except— (a) use in a separate room or building for— (i) the manufacture of powdered flint or quartz, or (ii) the making of frits or glazes or the making of colours or coloured slips

Column 1	<i>Description of substance</i>	Column 2	<i>Purpose for which the substance is prohibited</i>
			for the decoration of pottery;
		(b)	use for the incorporation of the substance into the body of ware in an enclosure in which no person is employed and which is constructed and ventilated to prevent the escape of dust.
8.	Dust or powder of a refractory material containing not less than 80 per cent of silica other than natural sand.		Use for sprinkling the moulds of silica bricks, namely bricks or other articles composed of refractory material and containing not less than 80 per cent of silica.
9.	White phosphorus.		Use in the manufacture of matches.
10.	Hydrogen cyanide.		Use in fumigation except when—
		(a)	released from an inert material in which hydrogen cyanide is absorbed;
		(b)	generated from a gassing powder; or
		(c)	applied from a cylinder through suitable piping and applicators other than for fumigation in the open air to control or kill mammal pests.
11.	Benzene and any substance containing benzene in a concentration equal to or greater than 0.1 per cent by mass, other than—		Use for all purposes except—
	(a) motor fuels covered by Council Directive 85/210/EEC (OJ No. L96, 3.4.85, p. 25);	(a)	use in industrial processes; and
	(b) waste covered by Council Directives 75/442/EEC (OJ No. L194, 25.7.75, p. 39), as amended by Council Directive 91/156/EEC (OJ	(b)	for the purposes of research and development or for the purpose of analysis.

Status: This is the original version (as it was originally made).

Column 1 <i>Description of substance</i>	Column 2 <i>Purpose for which the substance is prohibited</i>
	No. L78, 26.3.91, p. 32), and 91/689/EEC (OJ No. L377, 31.12.91, p. 20).
12.	The following substances— Chloroform CAS No. 67-66-3; Carbon Tetrachloride CAS No. 56-23-5; 1,1,2 Trichloroethane CAS No. 79-00-5; 1,1,2,2 Tetrachloroethane CAS No. 79-34-5; 1,1,1,2 Tetrachloroethane CAS No. 630-20-6; Pentachloroethane CAS No. 76-01-7; Vinylidene chloride (1,1 Dichloroethylene) CAS No. 75-35-4; 1,1,1 Trichloroethane CAS No. 71-55-6, and any substance containing one or more of those substances in a concentration equal to or greater than 0.1 per cent by mass, other than— (a) medicinal products; (b) cosmetic products.

In this Schedule—

“aerosol dispenser” means an article which consists of a non-reusable receptacle containing a gas compressed, liquefied or dissolved under pressure, with or without liquid, paste or powder and fitted with a release device allowing the contents to be ejected as solid or liquid particles in suspension in a gas, as a foam, paste or powder or in a liquid state;

“blasting apparatus” means apparatus for cleaning, smoothing, roughening or removing of part of the surface of any article by the use as an abrasive of a jet of sand, metal shot or grit or other material propelled by a blast of compressed air or steam or by a wheel;

“CASNo. ” is the number assigned to a substance by the Chemical Abstract Service;

“cosmetic product” has the meaning assigned to it in regulation 2(1) of the Cosmetic Products (Safety) Regulations 1996(23) (including any aerosol dispenser containing a cosmetic product);

“gassing powder” means a chemical compound in powder form which reacts with atmospheric moisture to generate hydrogen cyanide;

“medicinal product” means a substance or preparation which is—

(a) intended for use as a medicinal product within the meaning of section 130 of the Medicines Act 1968(24); or

(b) a substance or preparation specified in an order made under section 104 or 105 of the Medicines Act 1968 which is for the time being in force and which directs that specified provisions of that Act shall have effect in relation to that substance or preparation as such provisions have effect in relation to medicinal products within the meaning of that Act;

(23) S.I. 1996/2925.

(24) 1968 c. 67.

“use as a parting material” means the application of the material to the surface or parts of the surface of a pattern or of a mould so as to facilitate the separation of the pattern from the mould or the separation of parts of the mould;
 “white oil” means a refined mineral oil conforming to a specification approved by the Executive and certified by its manufacturer as so conforming.

SCHEDULE 3

Regulation 7(10)

ADDITIONAL PROVISIONS RELATING TO WORK WITH BIOLOGICAL AGENTS

PART I

PROVISIONS OF GENERAL APPLICATION TO BIOLOGICAL AGENTS

Interpretation

1. In this Schedule “diagnostic service” means any activity undertaken solely with the intention of analysing specimens or samples from a human patient or animal in which a biological agent is or is suspected of being present for purposes relating to the assessment of the clinical progress, or assistance in the clinical management, of that patient or animal, and “diagnosis” shall be construed accordingly.

Classification of biological agents

2.—(1) Where a biological agent does not have an approved classification, the employer shall provisionally classify that agent in accordance with sub-paragraph (2), having regard to the nature of the agent and the properties of which he may reasonably be expected to be aware.

(2) When provisionally classifying a biological agent the employer shall assign that agent to one of the following Groups according to its level of risk of infection and, if in doubt as to which of two alternative Groups is the most appropriate, he shall assign it to the higher of the two—

- (a) Group 1—unlikely to cause human disease;
- (b) Group 2—can cause human disease and may be a hazard to employees; it is unlikely to spread to the community and there is usually effective prophylaxis or treatment available;
- (c) Group 3—can cause severe human disease and may be a serious hazard to employees; it may spread to the community, but there is usually effective prophylaxis or treatment available;
- (d) Group 4—causes severe human disease and is a serious hazard to employees; it is likely to spread to the community and there is usually no effective prophylaxis or treatment available.

(3) Where an employer is using a biological agent which has an approved classification and the risk of infection for that particular agent is different to that expected, the employer shall reclassify the agent in consultation with the Executive as if performing a provisional classification under sub-paragraph (2).

Special control measures for laboratories, animal rooms and industrial processes

3.—(1) Every employer who is engaged in any of the activities specified in sub-paragraph (3) shall ensure that measures taken to control adequately the exposure of his employees to biological

agents include, in particular, the most suitable combination of containment measures from those listed in Parts II and III of this Schedule as appropriate, taking into account—

- (a) the nature of the activity specified in sub-paragraph (3);
 - (b) the minimum containment level specified in sub-paragraph (4);
 - (c) the risk assessment; and
 - (d) the nature of the biological agent concerned.
- (2) An employer who is engaged in—
- (a) any of the activities specified in sub-paragraph (3)(a) or (b) shall select measures from Part II of this Schedule;
 - (b) the activity specified in sub-paragraph (3)(c) shall select measures from Part III of this Schedule and, subject to sub-paragraph (4), when making that selection he may combine measures from different containment levels on the basis of a risk assessment related to any particular process or part of a process.
- (3) The activities referred to in sub-paragraph (1) are—
- (a) research, development, teaching or diagnostic work in laboratories which involves working with a Group 2, Group 3 or Group 4 biological agent or material containing such an agent;
 - (b) working with animals which have been deliberately infected with a Group 2, Group 3 or Group 4 biological agent or which are, or are suspected of being, naturally infected with such an agent; and
 - (c) industrial processes which involve working with a Group 2, Group 3 or Group 4 biological agent.
- (4) Subject to sub-paragraph (5), the minimum containment level referred to in sub-paragraph (1) shall be—
- (a) level 2 for activities which involve working with a Group 2 biological agent;
 - (b) level 3 for activities which involve working with a Group 3 biological agent;
 - (c) level 4 for activities which involve working with a Group 4 biological agent;
 - (d) level 2 for laboratories which do not intentionally propagate, concentrate or otherwise increase the risk of exposure to a biological agent but work with materials in respect of which it is unlikely that a Group 3 or Group 4 biological agent is present;
 - (e) level 3 or 4, where appropriate, for laboratories which do not intentionally propagate, concentrate or otherwise increase the risk of exposure to a Group 3 or Group 4 biological agent but where the employer knows, or it is likely, that such a containment level is necessary; and
 - (f) level 3 for activities where it has not been possible to carry out a conclusive assessment but where there is concern that the activity might involve a serious health risk for employees.
- (5) The Health and Safety Commission may approve guidelines specifying the minimum containment measures which are to apply in any particular case.
- (6) The Health and Safety Commission shall not approve any guidelines under paragraph (5) unless it is satisfied that the health of any person who is likely to be affected by the use of those guidelines will not be prejudiced.

List of employees exposed to certain biological agents

4.—(1) Subject to sub-paragraph (2), every employer shall keep a list of employees exposed to a Group 3 or Group 4 biological agent, indicating the type of work done and, where known, the

biological agent to which they have been exposed, and records of exposures, accidents and incidents, as appropriate.

(2) Sub-paragraph (1) shall not apply where the results of the risk assessment indicate that—

- (a) the activity does not involve a deliberate intention to work with or use that biological agent; and
- (b) there is no significant risk to the health of employees associated with that biological agent.

(3) The employer shall ensure that the list or a copy thereof is kept available in a suitable form for at least 40 years from the date of the last entry made in it.

(4) The relevant doctor referred to in regulation 11, and any employee of that employer with specific responsibility for the health and safety of his fellow employees, shall have access to the list.

(5) Each employee shall have access to the information on the list which relates to him personally.

Notification of the use of biological agents

5.—(1) Subject to sub-paragraphs (7) and (8), an employer shall not use for the first time one or more biological agents in Group 2, 3 or 4 at particular premises for any of the activities listed in paragraph 3(3) unless he has—

- (a) notified the Executive in writing of his intention to do so at least 20 working days in advance, or such shorter period as the Executive may allow;
- (b) furnished with that notification the particulars specified in sub-paragraph (5); and
- (c) received the acknowledgement required by sub-paragraph (4).

(2) Subject to sub-paragraphs (7) and (9), an employer shall not use a biological agent which is specified in Part V of this Schedule, except where the use of that agent has been notified to the Executive in accordance with sub-paragraph (1), for any of the activities listed in paragraph 3(3) unless he has—

- (a) notified the Executive in writing of his intention to do so at least 20 working days in advance, or such shorter period as the Executive may allow;
- (b) furnished with that notification the particulars specified in sub-paragraph (5); and
- (c) received the acknowledgement required by sub-paragraph (4).

(3) The Executive may accept a single notification under sub-paragraph (2) in respect of the use of more than one biological agent by the same person.

(4) Upon receipt of the notification required by sub-paragraph (1) or (2), the Executive shall, within 20 working days—

- (a) send to the notifier an acknowledgement of receipt; or
- (b) if the notification does not contain all of the particulars specified in sub-paragraph (5)—
 - (i) inform the notifier in writing of the further particulars required, and
 - (ii) within 10 working days of receipt of those further particulars, send to the notifier an acknowledgement of receipt.

(5) The particulars to be included in the notification referred to in sub-paragraphs (1) and (2) shall be—

- (a) the name and address of the employer and the address of the premises where the biological agent will be stored or used;
- (b) the name, qualifications and relevant experience of any employee of that employer with specific responsibility for the health and safety of his fellow employees;
- (c) the results of the risk assessment;

- (d) the identity of the biological agent and, if the agent does not have an approved classification, the Group to which the agent has been assigned; and
 - (e) the preventive and protective measures that are to be taken.
- (6) Where there are changes to processes, procedures or the biological agent which are of importance to health or safety at work and which render the original notification invalid the employer shall notify the Executive forthwith in writing of those changes.
- (7) Sub-paragraphs (1) and (2) shall not apply in relation to a biological agent where an intention to use that biological agent has been previously notified to the Executive in accordance with the Genetically Modified Organisms (Contained Use) Regulations 2000⁽²⁵⁾.
- (8) The requirement in sub-paragraph (1) to notify first use of a biological agent in Group 2 or 3 shall not apply to an employer whose only use of that agent is in relation to the provision of a diagnostic service provided that use will not involve a process likely to propagate, concentrate or otherwise increase the risk of exposure to that agent.
- (9) The requirement in sub-paragraph (2) to notify use of a biological agent specified in Part V of this Schedule shall not apply to an employer whose only use of that agent is in relation to the provision of a diagnostic service provided that use will not involve a process likely to propagate, concentrate or otherwise increase the risk of exposure to that agent.

Notification of the consignment of biological agents

- 6.—(1) An employer shall not consign a Group 4 biological agent or anything containing, or suspected of containing, such an agent to any other premises, whether or not those premises are under his ownership or control, unless he has notified the Executive in writing of his intention to do so at least 30 days in advance or before such shorter time as the Executive may approve and with that notification has furnished the particulars specified in sub-paragraph (4).
- (2) Sub-paragraph (1) shall not apply where—
- (a) the biological agent or material containing or suspected of containing such an agent is being consigned solely for the purpose of diagnosis;
 - (b) material containing or suspected of containing the biological agent is being consigned solely for the purpose of disposal; or
 - (c) the biological agent is or is suspected of being present in a human patient or animal which is being transported for the purpose of medical treatment.
- (3) Where a Group 4 biological agent is imported into Great Britain, the consignee shall give the notice required by sub-paragraph (1).
- (4) The particulars to be included in the notification referred to in sub-paragraph (1) shall be—
- (a) the identity of the biological agent and the volume of the consignment;
 - (b) the name of the consignor;
 - (c) the address of the premises from which it will be transported;
 - (d) the name of the consignee;
 - (e) the address of the premises to which it shall be transported;
 - (f) the name of the transport operator responsible for the transportation;
 - (g) the name of any individual who will accompany the consignment;
 - (h) the method of transportation;
 - (i) the packaging and any containment precautions which will be taken;

(25) [S.I. 2000/2831](#).

- (j) the route which will be taken; and
 (k) the proposed date of transportation.

PART II

CONTAINMENT MEASURES FOR HEALTH AND VETERINARY CARE FACILITIES, LABORATORIES AND ANIMAL ROOMS

<i>Containment measures</i>		<i>Containment levels</i>		
		2	3	4
1	The workplace is to be separated from any other activities in the same building.	No	Yes	Yes
2	Input air and extract air to the workplace are to be filtered using HEPA or equivalent.	No	Yes, on extract air	Yes, on input and double on extract air
3	Access is to be restricted to authorised persons only.	Yes	Yes	Yes, via air-lock key procedure
4	The workplace is to be sealable to permit disinfection.	No	Yes	Yes
5	Specified disinfection procedure.	Yes	Yes	Yes
6	The workplace is to be maintained at an air pressure negative to atmosphere.	No	Yes	Yes
7	Efficient vector control eg rodents and insects.	Yes, for animal containment	Yes, for animal containment	Yes
8	Surfaces impervious to water and easy to clean.	Yes, for bench	Yes, for bench and floor (and walls for animal containment)	Yes, for bench, floor, walls and ceiling
9	Surfaces resistant to acids, alkalis,	Yes, for bench	Yes, for bench and floor (and	Yes, for bench, floor, walls and ceiling

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<i>Containment measures</i>		<i>Containment levels</i>		
		2	3	4
	solvents, disinfectants.		walls for animal containment)	
10	Safe storage of biological agents.	Yes	Yes	Yes, secure storage
11	An observation window, or alternative, is to be present, so that occupants can be seen.	No	Yes	Yes
12	A laboratory is to contain its own equipment.	No	Yes, so far as is reasonably practicable	Yes
13	Infected material, including any animal, is to be handled in a safety cabinet or isolator or other suitable containment.	Yes, where aerosol produced	Yes, where aerosol produced	Yes
14	Incinerator for disposal of animal carcasses.	Accessible	Accessible	Yes, on site

PART III

CONTAINMENT MEASURES FOR INDUSTRIAL PROCESSES

<i>Containment measures</i>		<i>Containment levels</i>		
		2	3	4
1	Viable micro-organisms should be contained in a system which physically separates the process from the environment (closed system).	Yes	Yes	Yes
2	Exhaust gases from the closed system should be treated so as to—	Minimise release	Prevent release	Prevent release

Containment measures		Containment levels		
		2	3	4
3	Sample collection, addition of materials to a closed system and transfer of viable micro-organisms to another closed system, should be performed so as to—	Minimise release	Prevent release	Prevent release
4	Bulk culture fluids should not be removed from the closed system unless the viable micro-organisms have been—	Inactivated by validated means	Inactivated by validated chemical or physical means	Inactivated by validated chemical or physical means
5	Seals should be designed so as to—	Minimise release	Prevent release	Prevent release
6	Closed systems should be located within a controlled area—	Optional	Optional	Yes, and purpose-built
	(a) biohazard signs should be posted;	Optional	Yes	Yes
	(b) access should be restricted to nominated personnel only;	Optional	Yes	Yes, via air-lock
	(c) personnel should wear protective clothing;	Yes, work clothing	Yes	Yes, a complete change
	(d) decontamination and washing facilities	Yes	Yes	Yes

Status: This is the original version (as it was originally made).

Containment measures	Containment levels		
	2	3	4
should be provided for personnel;			
(e) personnel should shower before leaving the controlled area;	No	Optional	Yes
(f) effluent from sinks and showers should be collected and inactivated before release;	No	Optional	Yes
(g) the controlled area should be adequately ventilated to minimise air contamination;	Optional	Optional	Yes
(h) the controlled area should be maintained at an air pressure negative to atmosphere;	No	Optional	Yes

Containment measures		Containment levels		
		2	3	4
	(i) (i)put and extract air to the controlled area should be HEPA filtered;	No	Optional	Yes
	(j) (j)the controlled area should be designed to contain spillage of the entire contents of closed system;	Optional	Yes	Yes
	(k) (k)the controlled area should be sealable to permit fumigation.	No	Optional	Yes
7	Effluent treatment before final discharge.	Inactivated by validated means	Inactivated by validated chemical or physical means	Inactivated by validated physical means

PART IV

BIOHAZARD SIGN

The biohazard sign required by regulation 7(6)(a) shall be in the form shown below—

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PART V

BIOLOGICAL AGENTS WHOSE USE IS TO BE NOTIFIED IN ACCORDANCE WITH PARAGRAPH 5(2) OF PART I OF THIS SCHEDULE

Any Group 3 or 4 agent.

The following Group 2 agents:

Bordetella pertussis

Corynebacterium diphtheriae

Neisseria meningitidis

SCHEDULE 4

Regulation 9(2)(a)

FREQUENCY OF THOROUGH EXAMINATION AND TEST OF LOCAL EXHAUST VENTILATION PLANT USED IN CERTAIN PROCESSES

Column 1 <i>Process</i>	Column 2 <i>Minimum frequency</i>
Processes in which blasting is carried out in or incidental to the cleaning of metal castings, in connection with their manufacture.	1 month
Processes, other than wet processes, in which metal articles (other than of gold, platinum or iridium) are ground, abraded or polished using mechanical power, in any room for more than 12 hours in any week.	6 months
Processes giving off dust or fume in which non-ferrous metal castings are produced.	6 months
Jute cloth manufacture.	1 month

SCHEDULE 5

Regulation 10(4)

SPECIFIC SUBSTANCES AND PROCESSES FOR WHICH MONITORING IS REQUIRED

Column 1 <i>Substance or process</i>	Column 2 <i>Minimum frequency</i>
Vinyl chloride monomer.	Continuous or in accordance with a procedure approved by the Health and Safety Commission.
Spray given off from vessels at which an electrolytic chromium process is carried on, except trivalent chromium.	Every 14 days while the process is being carried on.

SCHEDULE 6

Regulation 11(2)(a) and (5)

MEDICAL SURVEILLANCE

Column 1 <i>Substances for which medical surveillance is appropriate</i>	Column 2 <i>Process</i>
Vinyl chloride monomer (VCM).	In manufacture, production, reclamation, storage, discharge, transport, use or polymerisation.
Nitro or amino derivatives of phenol and of benzene or its homologues.	In the manufacture of nitro or amino derivatives of phenol and of benzene or its homologues and the making of explosives with the use of any of these substances.
Potassium or sodium chromate or dichromate.	In manufacture.
Ortho-tolidine and its salts. Dianisidine and its salts. Dichlorobenzidine and its salts.	In manufacture, formation or use of these substances.
Auramine. Magenta.	In manufacture.
Carbon disulphide. Disulphur dichloride. Benzene, including benzol. Carbon tetrachloride. Trichlorethylene.	Processes in which these substances are used, or given off as vapour, in the manufacture of indiarubber or of articles or goods made wholly or partially of indiarubber.
Pitch.	In manufacture of blocks of fuel consisting of coal, coal dust, coke or slurry with pitch as a binding substance.

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SCHEDULE 7

Regulation 12(5)

LEGISLATION CONCERNED WITH THE LABELLING OF CONTAINERS AND PIPES

The Chemicals (Hazard Information and Packaging for Supply) Regulations 2002 (CHIP) ([SI 2002/1689](#));

The Health and Safety (Safety Signs and Signals) Regulations 1996 ([SI 1996/341](#));

The Radioactive Material (Road Transport) Regulations 2002 ([SI 2002/1093](#));

The Carriage of Dangerous Goods by Rail Regulations 1996 ([SI 1996/2089](#));

The Packaging, Labelling and Carriage of Radioactive Material by Rail Regulations 2002 ([SI 2002/2099](#));

The Carriage of Dangerous Goods (Classification, Packaging and Labelling) and Use of Transportable Pressure Receptacles Regulations 1996 ([SI 1996/2092](#));

The Carriage of Explosives by Road Regulations 1996 ([SI 1996/2093](#));

The Carriage of Dangerous Goods by Road Regulations 1996 ([SI 1996/2095](#)); and

The Good Laboratory Practice Regulations 1999 ([SI 1999/3106](#)).

SCHEDULE 8

Regulation 14(1)

FUMIGATIONS EXCEPTED FROM REGULATION 14

Column 1 <i>Fumigant</i>	Column 2 <i>Nature of fumigation</i>
Hydrogen cyanide.	Fumigations carried out for research. Fumigations in fumigation chambers. Fumigations in the open air to control or kill mammal pests.
Methyl bromide.	Fumigations carried out for research. Fumigations in fumigation chambers. Fumigations of soil outdoors under gas-proof sheeting where not more than 1000 kg is used in any period of 24 hours on the premises. Fumigations of soil under gas-proof sheeting in glasshouses where not more than 500 kg is used in any period of 24 hours on the premises. Fumigations of compost outdoors under gas-proof sheeting where not more than 10 kg of methyl bromide is used in any period of 24 hours on the premises. Fumigations under gas-proof sheeting inside structures other than glasshouses and

Column 1 <i>Fumigant</i>	Column 2 <i>Nature of fumigation</i>
Phosphine.	mushroom houses where not more than 5 kg of methyl bromide is used in each structure during any period of 24 hours. Fumigations of soil or compost in mushroom houses where not more than 5 kg of methyl bromide is used in any one fumigation in any period of 24 hours. Fumigations of containers where not more than 5 kg of methyl bromide is used in any one fumigation in a period of 24 hours. Fumigations carried out for research. Fumigations in fumigation chambers. Fumigations under gas-proof sheeting inside structures where not more than 1 kg of phosphine in each structure is used in any period of 24 hours. Fumigations in containers where not more than 0.5 kg of phosphine is used in any one fumigation in any period of 24 hours. Fumigations in individual impermeable packages. Fumigations in the open air to control or kill mammal pests.

SCHEDULE 9

Regulation 14(2)

NOTIFICATION OF CERTAIN FUMIGATIONS

PART I

PERSONS TO WHOM NOTIFICATIONS MUST BE MADE

1. In the case of a fumigation to be carried out within the area of a harbour authority, advance notification of fumigation shall, for the purposes of regulation 14(2)(a), be given to—

- (a) that authority;
- (b) an inspector appointed under section 19 of the 1974 Act, if that inspector so requires; and
- (c) where the fumigation—

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- (i) is to be carried out on a sea-going ship, the chief fire officer of the area in which the ship is situated and the officer in charge of the office of Her Majesty's Customs and Excise at the harbour, or
 - (ii) is the space fumigation of a building, the chief fire officer of the area in which the building is situated.
2. In the case of a fumigation, other than a fumigation to which paragraph (1) applies, advance notification of fumigation shall be given to—
- (a) the police officer for the time being in charge of the police station for the police district in which the fumigation is carried out;
 - (b) an inspector appointed under section 19 of the 1974 Act, if that inspector so requires; and
 - (c) where the fumigation is to be carried out on a sea-going ship or is the space fumigation of a building, the chief fire officer of the area in which the ship or building is situated.

PART II

INFORMATION TO BE GIVEN IN ADVANCE NOTICE OF FUMIGATIONS

3. The information to be given in a notification made for the purposes of regulation 14(2) shall include the following—
- (a) the name, address and place of business of the fumigator and his telephone number;
 - (b) the name of the person requiring the fumigation to be carried out;
 - (c) the address and description of the premises where the fumigation is to be carried out;
 - (d) the date on which the fumigation is to be carried out and the estimated time of commencement and completion;
 - (e) the name of the operator in charge of the fumigation; and
 - (f) the fumigant to be used.

EXPLANATORY NOTE

(This note is not part of the Regulations)

1. These Regulations re-enact, with modifications, the Control of Substances Hazardous to Health Regulations 1999 (S.I. 1999/437) (“the 1999 Regulations”). The 1999 Regulations imposed duties on employers to protect employees and other persons who may be exposed to substances hazardous to health and also imposed certain duties on employees concerning their own protection from such exposure, and prohibited the import into the United Kingdom of certain substances and articles from outside the European Economic Area.

2. The Regulations, with the exception of regulations 8, 9, 11(8), (10) and (11) and 14, implement as respects Great Britain—

- (a) Council Directive [78/610/EEC](#) (OJ No. L 197, 22.7.78, p.12) on the approximation of the laws, regulations and administrative provisions of the Member States on the protection of the health of workers exposed to vinyl chloride monomer,
 - (b) point 3 of Article 1 of Council Directive [89/677/EEC](#) (OJ No. L 398, 30.12.89, p.19) amending for the 8th time the Marketing and Use Directive insofar as that point relates to the importation, supply or use of benzene and substances containing benzene for such purposes,
 - (c) Council Directive [90/394/EEC](#) (OJ No. L 196, 26.7.90, p.1) on the protection of workers from risks related to exposure to carcinogens at work (sixth individual Directive within the meaning of Article 16(1) of Directive [89/391/EEC](#)) insofar as it relates to carcinogens other than asbestos,
 - (d) that part of Commission Directive [96/55/EC](#) (OJ No. L 231, 12.9.96, p.20) adapting to technical progress for the 2nd time Annex I to Council Directive [76/769/EEC](#) (“the Marketing and Use Directive”) (OJ No. L 262, 27.9.76, p.201) on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations which relates to supply of specified substances for use at work,
 - (e) Council Directive [98/24/EC](#) (OJ No. L 131, 5.5.98, p.11) on the protection of the health and safety of workers from risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive [89/391/EEC](#)) insofar as it relates to risks to health from exposure to substances other than asbestos or lead, and
 - (f) Directive [2000/54/EC](#) (OJ No. L 262, 17.10.2000, p.21) of the European Parliament and of the Council on the protection of workers from risks related to exposure to biological agents at work (seventh individual Directive within the meaning of Article 16(1) of Directive [89/391/EEC](#)).
3. The Regulations are consistent with the provisions of Commission Directive [91/322/EEC](#) (OJ No. L 177, 5.7.91, p.22) on establishing indicative limit values by implementing Council Directive [80/1107/EEC](#) on the protection of workers from risks related to exposure to chemical, physical and biological agents at work.
4. In addition to minor and drafting amendments, the Regulations make the following changes of substance—
- (a) include certain further definitions (regulation 2);
 - (b) extend the matters to be considered when carrying out an assessment of the risk from exposure to substances hazardous to health (regulation 6);
 - (c) detail the measures which the employer must take to prevent or adequately control the exposure of his employees to substances hazardous to health (regulation 7);
 - (d) provide for further duties in respect of care and decontamination of personal protective equipment (regulation 9);
 - (e) provide for the keeping of an individual record of air monitoring where an employee is required to be under health surveillance (regulation 10);
 - (f) extend the duties on employers with respect to health surveillance where an employee is found to have an identifiable disease or adverse health effect caused by exposure to a substance hazardous to health (regulation 11);
 - (g) introduce a duty to ensure that the contents of containers and pipes for substances hazardous to health used at work are clearly identifiable (regulation 12(5));

Status: This is the original version (as it was originally made).

- (h) introduce a duty on the employer to prepare procedures, provide information and establish warning systems to deal with an emergency in the workplace related to the presence of a substance hazardous to health (regulation 13); and
 - (i) apply the extension to the meaning of “work” in Part I of the 1974 Act to all Group 2, 3, or 4 biological agents and transfer certain provisions relating to biological agents which had been in Schedule 3 of the 1999 Regulations to regulations 7 and 12.
5. Copies of the publications mentioned in the Regulations are obtainable as follows—
- (a) a list of the maximum exposure limits and occupational exposure standards which the Health and Safety Commission has approved is available in the publication “EH40, Occupational Exposure Limits” obtainable from HSE Books, PO Box 1999, Sudbury, Suffolk CO10 2WA; and
 - (b) British Standard BS EN 481 1993, referred to in regulation 2(1), relating to workplace atmospheres is obtainable from the British Standards Institution, BSI House, 389 Chiswick High Road, London W4 4AL.
6. A copy of the regulatory impact assessment prepared in respect of these Regulations can be obtained from the Health and Safety Executive, Economic Advisers Unit, Rose Court, 2 Southwark Bridge, London SE1 9HS. A copy of the transposition note in relation to implementation of the Directives set out in paragraph 2 can be obtained from the Health and Safety Executive, International Branch at the same address. Copies of both these documents have been placed in the Library of each House of Parliament.

NHS Greater Glasgow & Clyde



Clinical & Care Governance

Infection Prevention and Control Team 5 December 2017

Paper No: 17/24

Report on Concerns Raised re Queen Elizabeth University Hospital (QEUH) and Royal Hospital for Children (RHC)

Recommendation:- The committee are asked to note the concerns raised in relation to the QEUH and RHC and review the current status and actions being progressed.

Purpose of Paper:-

During September 2017 three consultant microbiologists in the South Sector raised a series of concerns about the facilities in QEUH and RHC and the structure of the Infection Prevention and Control (IPCT) Service within NHS Greater Glasgow and Clyde.

On the 4th of October 2017 Board and Acute Directors including the Board Director of Facilities, the Chief of Medicine for Diagnostics and members to the IPCT Senior Management team met with the consultants to discuss these concerns. The consultant microbiologists tabled a list of concerns and this paper identifies each with an action plan setting out the current situation and the steps taken or in progress to address the issues identified. The minutes of the October meeting are appended to this document with each specific issues raised identified and cross referenced to the action plan.

Key Issues to be considered:-

As above

Any Patient Safety /Patient Experience Issues:- yes

Any Financial Implications from this Paper:- no

Any Staffing Implications from this Paper:- no

Any Equality Implications from this Paper:- no

Any Health Inequalities Implications from this Paper:-no

Has a Risk Assessment been carried out for this issue? If yes, please detail the outcome:-

Highlight the Corporate Plan priorities to which your paper relates:- improving quality efficiency and effectiveness

Below is a list of the key themes raised by the Consultants.

Themes

- Positive Pressured Ventilated Lobbied (PPVL) Isolation Rooms.
- Royal Hospital for Children (RHC) – Protective Isolation – Haematology Oncology Unit.
- RHC – HEPA filters in Paediatric Intensive Care Unit (PICU).
- Queen Elizabeth University Hospital (QEUH) – Ward 4B – Upgrade to the Haematology Ward.
- Single Room Specification and Location of Areas that can be used for Protective Isolation.
- Cleaning of QEUH, RHC and Office Block
- Cleaning of Dishwashers in QEUH and RHC linked to a potential outbreak of exophiala
- Water Quality and Water Testing
- Plumbing in the Neurosurgical Block
- Decontamination of Respiratory Equipment
- Structure of the Infection Prevention and Control Team

Each specific item has been identified in the minute of the meeting and cross referenced in the associated action plan which is tabulated below.

Action Plan

Item	Issue	Current Position	Future Actions
1	PPVL rooms not compliant with SHTM standards	Facilities colleagues confirmed that there are 10 air changes per hour and a positive pressure of 10 pascals in the PPVL rooms which is consistent with SHBN 04-01.	Included in item 2
2	PPVL rooms do not provide appropriate protection for patients with infectious diseases of high consequence (IDHC) e.g. MERS, SARS This issue also exists in the Royal Hospital for Children	IDHC should be nursed in negative pressure rooms. These are not available in QEUH. In order to address this issue in the short term a patient pathway has been agreed by the Infectious Disease (ID) Clinicians whereby patients will be routed either to GRI or Lanarkshire ID unit. Chief Nurse (CN) for Paediatrics discussing with clinical teams a pathway for children.	Heath Protection Scotland (HPS) have been sent information on these rooms and we await their advice on whether they can be used for patients with IDHC or if not what actions could be taken to modify these rooms to provide negative pressure. This advice was sought in 2016 & 17.
3	Lack of isolation rooms in the emergency department.	ED was designed with input from clinical staff and observation of patients was a priority. There are single rooms in ED but not negatively pressured isolation rooms.	Property Procurement Facilities Management (PPFM) has commissioned a feasibility study to ascertain if negatively pressured rooms are technically feasible
4	Rooms not built to the standard expected as a tertiary referral centre.	The transfer of the Infectious Diseases Unit was a late addition to the project and was not fully commissioned as an ID unit at the outset.	Actions as described in item 2.
5	Microbiologists not aware of plans to upgrade areas.	Lead Infection Control Doctor (ICD) was aware of this proposal.	Work continues with input from the Coordinating ICD.
6	HEPA filters in PICU for the protection of patients in the Bone Marrow Transplant Unit (BMTU) that might need critical care during treatment. The BMTU is ward also referred to as ward 2A.	HEPA filters were installed within PICU/Ward 2a week commencing 6 November 2017, within room numbers 12 and 17 – previously installed within room 18. HEPA filter still to be fitted in room 5 (access to be agreed with clinical colleagues). HEPA filters were also fitted into RHC Ward 3c week commencing 13 November 2017 within rooms 9 & 10.	Work commenced mid November 2017, therefore ahead of May 2018, as noted above.

Item	Issue	Current Position	Future Actions
7	HEPA filters in prep room	HEPA filters have not been routinely fitted (as standard) within prep rooms, however HEPA filters are fitted within QEUH Ward 4b. Instruction required to determine whether HEPA filter should be fitted into RHC Ward 2a prep room.	A feasibility study will be undertaken to ascertain if HEPA filters can be installed in the prep room.
8	IVs prepared in treatment room.	IVs are prepared in the preparation room but not chemotherapy which is prepared in a specialist unit.	CN paediatrics confirmed that this was the standard practice.
9	Outbreak of Aspergillus associated with poor air quality	There were two cases of aspergillus associated with the ward in March 2017. This was fully investigated and was possibly associated with a leak into the ceiling space which was not immediately apparent. On review of cases in the new BMTU and the unit previously located in Yorkhill there is no significant increase in the number of cases of this infection. This was fully reported as per Chapter 3 of the National Infection Prevention and Control Manual to Health Protection Scotland.	HPS have been contacted for advice on what would be an appropriate regime for air monitoring in this area.
10	Concern that the statement issued advised that BMT services in RHC were unaffected by issues identified in the adult BMTU.	Clarification from the NHSGGC Comms Team “To the recollection of colleagues involved, the Communications team were not briefed at the time of the release about the adult BMT move of any testing underway at the Royal Hospital for Children. The final line of the press release of 8th July 2015 “Bone Marrow Transplant Service Temporary Relocation” was written to make clear to media that the move of the adult service did not include the paediatric service at the Royal Hospital for Children and that the latter was not moving. “	Clarification issued to the meeting attendees. No further action required. This perhaps appears to be misinterpretation of the media communication.
11	HEPA filters not in place in PICU	Action complete as previously agreed and noted within point 6.	

Item	Issue	Current Position	Future Actions
12	Increase in the number of line infections in Ward 2A	Two years' retrospective data were analysed in May 2017 and it was noted that there was an increase in line related infection. The initial baseline infection rate per 1000 total line days was 3.25 and this had risen to 6.33. A group led by CN Paediatrics first met in May 2017 to review this information and put actions in place to reduce this incidence. The last 4 months (July to October) have shown improvement in infection rates. CN Paediatrics presented a paper to the Board Infection Control Committee on the 27 November 2017 outlining several work streams and the most recent infection rates in this area.	There are currently four work streams in place to look at key initiatives to reduce line infections in BMTU, these include: • Line Insertion and access in theatre. • Access and Maintenance of lines • Staff Education • Patient and Parent engagement Next Steps From 1st December 2017 every CLABSI (line associated infections) will be subject to rigorous review utilising Event Cause Analysis methodology within 72 hours of a reported CLABSI
13	Increase in the number of line infections	IPCT participating in above work. Line related surveillance was subsequently picked up by the Directorate.	Ongoing assessment of surveillance activity and resource within the IPCT to enable IPCT to respond to local clinical needs.
14	Dr Redding concerned that the ongoing work would not accurately pick up any concerns.	• As above work streams in place re line infections. • IPCT audit process is in place and ongoing; this includes audit of the environment, audits of line and urinary catheter care. Audits of standard Infection Control Precautions (SIPS). • IPCT twice weekly visits. • GGC compliant with the National IPCT Manual – this lists all types of infections that should be reviewed and what should be reported if an outbreak or incident occurs. • Weekly report to Board and Acute Directors weekly on an IPC issues throughout GGC.	IPCT and CN Paediatrics will continue to have a clear focus on this area.
15	Microbiologists do not have the information to advise clinical staff on where to place immunocompromised patients.	Director of Regional Services stated that this had never been raised as an issue by clinicians within his service that care for patients who are immunocompromised. Most patients who are immunocompromised are cared for within this directorate. It was agreed by the group that placement of immunocompromised patients was a decision that should be taken by the clinical team looking after the individual patients.	Dr Peters agreed to circulate a document she had used in another board area. David Loudon (Director of PPFM) agreed to send the microbiologists a list of where the PPVL rooms were in the QEUH and RHC. It was agreed that this would be reviewed at the Regional Services Governance Forum

Item	Issue	Current Position	Future Actions
16	Infection rates are not being monitored.	• GGC compliant with the National IPCT Manual – this lists all types of infections that should be reviewed and what should be reported if an outbreak or incident occurs. • Every patient with a notifiable infection is reviewed and monitored. • NHSGGC is fully compliant with all elements of the national Mandatory Surveillance of Infection Programme (mainly specific surgical site and blood stream infections. • Weekly report on exceptions is sent to the Board Directors. • Monthly reports are sent to Senior Management teams. • All outbreak and incidents are reviewed by the Board, Partnership and Acute Infection Control Committees. • The most recent National Point Prevalence Survey in 2016 indicated that both the QEUH and RHC were under the national average in terms of the incidence of Hospital Acquired Infections.	ICM has invited HPS to review the NHSGGC systems for surveillance and reporting of infections – this assessment took place on the 29.11.17, the initial feedback was positive but we await the full report.
17	There are three air changes and chilled beam technology instead of the 6 air changes recommended.	There are three air changes in the single rooms within both QEUH and RHC.	Director of Facilities agreed to take this issue forward with NHS D&G to share learning with regards to this type of technology and draw to their attention concerns regarding cleaning of the beams. Action complete.
18	Use of cleaning agents.	NHSGGC has for several years changed the cleaning regimens each winter to include a chlorine based detergent as a strategy to reduce norovirus outbreaks. This switch commences on the 1st of November and continues until the 30 April each year or longer if the season is prolonged. This is not recommended in the National Infection Control Manual because of lack of scientific evidence but is put in place in GGC based on local site knowledge.	This policy and practice will continue unless new evidence emerges

Item	Issue	Current Position	Future Actions
19	Roles and responsibilities with regards to cleaning of the dishwashers in the ward pantries was not clear.	IPCT held an Incident Management team Meeting (IMT) on 22 nd of September. Dishwashers were removed from use until they could be serviced and re-sampled.	Catering staff agreed to assume the responsibility for cleaning of the dishwashers going forward.
20	Issue with dishwasher not picked up during routine monitoring.	GGC fully compliant with the National Monitoring of Domestic Services	Roles and responsibilities had been clarified and a process is now in place.
21	Cleaning of Temperature Control Values (TCVs)	TCVs are maintained in all high risk areas and plans are in place to carry this out in all areas despite this not being mandatory. Protocols are in place to manage this process.	Agreed works within QEUH-plant room 31, almost complete and being led by Site Maintenance Manager. Anticipated date of completion by end of January 2018.
22	Water testing is not as per national guidance	Board water safety is in place and water systems and processes are monitored as per national guidance.	None
23	Sewage leaks in institute not reported to microbiologists	Leaks in any clinical areas that required advice from an ICD are reported	Ensure reporting is ongoing.
24	Plumbing not replaced in Neuro Surgical Block	The Director of Regional Services advised that there is ongoing work in the neuro building that would because of its complexity, take several years to complete, in the meantime the new operating theatres were due to open in January 2018.	Works are ongoing as planned.
25	Perceived Increase in surgical site infections	Regional Services has funded 1.5 WTE surveillance nurses to carry out prospective surgical site surveillance in this area. For context, there are 3 surveillance nurses that provide this service for the rest of GGC therefore the investment in the INS to monitor SSI is significant. Although it is difficult to obtain benchmark rates for SSI in this area, continuous surveillance will pick out trends and therefore any increase. This is monitored via a group unique to Regional Services – the RS Surgical Site Infection Group. The group in turn reports into the Regional Service Clinical Governance Group	Continue to monitor trends in surgical site infection in this area.

Item	Issue	Current Position	Future Actions
26	Decontamination facilities	Most decontamination of equipment is conducted in the central Decontamination Unit or Endoscopy facilities. Respiratory equipment is easily damaged and advice from manufacturers is often difficult to implement. There should be dedicated facilities with established work flow patterns (dirty to clean). At this point in time the Decontamination group (which is a sub group of the Board Infection Control Committee) has give advice on many items of equipment and had obtained room designs which could be used if space was identified in QEUH and RHC. This has been submitted to management colleagues for consideration. In addition a list of specialist equipment that we require national advice on has been submitted to Health Protection Scotland.	Pursue HPS for advice regarding the list of equipment provided. Establish status of planning for new decontamination areas.
27	Roles of IPCT have changed	The current IPCT all have Job Descriptions which have been in place for several years. There is a clear documented governance structure that has been reviewed by Price Waterhouse Cooper and approved by the Infection prevention Committees within NHSGGC. There is a clear management structure which complies with the recommendations contained within the Vale of Leven Report and the Healthcare Environment Inspectorate Standards	A review of the roles and responsibilities of the Infection Control Doctors in South Glasgow will be undertaken by the Chief of Medicine for Diagnostics. The ICM has invited HPS to undertake a review of IPC surveillance and reporting systems in place.

Minutes of Meeting
Meeting Room L02-001, Teaching & Learning Centre
Queen Elizabeth University Hospital

Wednesday 4th October 2017 at 8:00am

PRESENT

Dr Jennifer Armstrong (Chair)	JA	Medical Director
David Loudon	DL	Director of Property, Procurement & FM
Morag Gardner	MG	Chief Nurse
Sandra McNamee	SMcN	Associate Nurse Director IPC
Ian Powrie	IP	Depute General Manager, Estates
Professor Brian Jones	BJ	Head of Service, Microbiology
Tom Walsh	TW	Infection Control Manager
Anne Harkness	AH	Director, South Sector
Jonathan Best	JB	Acting Chief Operating Officer
Gary Jenkins	GJ	Acting Director, North Sector
Dr Penelope Redding	PR	Consultant Microbiologist
Dr Christine Peters	CP	Consultant Microbiology
Dr Ash Deshpande	AD	Consultant Microbiologist/ICD
Dr Rachel Green	RG	Chief of Medicine, Diagnostics

In Attendance

Ann Lang (Minutes) PA, Infection Prevention and Control

Item	Action
1. Welcome & Introductions Dr Armstrong welcomed everyone to today's meeting to discuss Infection Control and estates issues at QEUH and RHC and round the table introductions were made. The group noted that colleagues from Women's and Children's Directorate were not in attendance but were aware of the issues raised and had helpfully submitted information via email which could inform the relevant areas of the discussion.	
2. Purpose, Format and Conduct of Meeting Dr Armstrong advised that a series of emails have been received from Dr Redding and Dr Peters regarding Infection Control and estates issues on the QEUH and RHC site. Dr Armstrong had requested a document setting out the issues of concern and thanked Drs Redding and Peters for providing the SBAR document which provided a helpful basis for the discussion. Dr Armstrong proposed that the meeting is focused on patient safety and a review and update on the current status of the issues identified. She asked that if there are any comments during the meeting if these could be addressed through the chair and to adhere to the GMC and Board guidance regarding respect, professionalism and working as part of a team. The group agreed the importance of issues raised being discussed in the context of the appropriate roles, responsibilities and governance structures.	

Item	Action
3. Review of SBAR / Concerns It was agreed to go through the items detailed in the SBAR from Dr Redding and Dr Peters, to look at the points raised and address any outstanding issues. Patient Placement Dr Redding outlined that there are challenges for the microbiologists regarding source isolation of infected patients. She said the current situation is that the positive pressure ventilated lobby rooms were not built to SHTM standard and she and others were concerned that they do not provide appropriate protection when managing a small number of patients with significant respiratory pathogens of high consequence such as MERS and MDRTB (Items 1&2). Dr Peters advised that Microbiologists and ICDs and ID colleagues feel there is a lack of provision for isolation rooms in A&E (Item 3). David Loudon replied that this specification was signed off by the board and clinical teams; he also confirmed that remedial work had been carried out due to issues raised at the snagging stage of the build. David also stated that although there were some modifications to the design the rooms did conform to SHTM 04-01 and that it was incorrect to state that this was not the case. Ian Powrie addressed specific points raised in respect of the ventilation specification and agreed to provide the detailed information to support this. Sandra McNamee commented that the inclusion of the Infectious Diseases service was a late amendment to the QEUH project and therefore not commissioned as an ID unit at the outset. The group noted that the Brownlee Clinical Team put a strong clinical case to the board to be co-located on QEUH site with the Intensive Care Unit and other critical clinical services. The issues identified were discussed with HPS at the time and they agreed to advise the Board on what standard these rooms would need to be to accommodate these patients. When this information has been received, estates colleagues will review the advice to determine if these modifications were feasible. Dr Redding stated she would like to see the evidence relating to this. Sandra advised that a follow up meeting took place with HPS on Monday 2nd October and that the relevant information was expected in the next few weeks, however in the meantime a patient pathway has been in place which routes these patients to appropriate isolation rooms in other hospitals. Dr Peters reported that these patients with significant airborne pathogens are being sent from A&E to the isolation rooms in ITU before being transferred to other hospitals as reported by ID colleagues. The group noted that this would be the case for other hospitals within NHS GGC and across NHS Scotland. Dr Peters however intimated that there is a risk of exposure to a large number of patients and staff and reiterated that, in her opinion, the ITU isolation rooms are not adequate for these types of patients. Furthermore other hospitals have not been recently built and are not a tertiary ID referral centre such as the QEUH (Item 4). Dr Redding also recognised that work may be ongoing but the microbiologists are not aware of this (Item 5). Anne Harkness advised that as these issues were raised she met with Directors and ID Physicians and they agreed a pathway for these patients to be transferred to other sites. She also commented that based on the external advice, unless the existing rooms can be modified in some way the only alternative was to build a new Infectious Disease Unit which would require a significant resource. David Loudon confirmed that changing the specification to negative pressure would be reviewed to assess technical feasibility.	

Item	Action
It was agreed to await the response from HPS and to deal with any further issues via the Acute and Board Infection Control Committees and the relevant Directorate Governance Committees. <u>Protective Isolation</u> Currently HEPA filters are not fitted in PICU isolation rooms (Item 6) and in the prep rooms in Ward 2A (Item 7). Dr Redding also commented that IVs are prepared in the treatment room (Item 8). She stated that there has been a perceived high rate of infections in immune compromised patients in Ward 2A and air quality has remained an issue in this ward since it opened. She also commented that there was an outbreak of Aspergillus (Item 9) in the unit and that there is still a risk to patients. Dr Peters said there was a public statement made by NHSGGC that BMT services at RHC are separate and unaffected and that both she and an ICD colleague had objected to the wording of the statement at the time and had asked to step down from ICD roles immediately after it was released. Dr Armstrong advised that she will check with the Comms team regarding the wording in the statement as this required some additional clarity around context (Item 10). With regards to the cases of Aspergillus, Sandra McNamee updated that there were two cases in March and April associated with a leak in the ceiling space. This was investigated and the tiles were removed and replaced with no further cases of Aspergillus. Ian Powrie advised that the HEPA filters were installed in two of the rooms in adult ITU but there has been no request to add these to isolation rooms throughout the adult or children's hospital. Work in RHC, Ward 2A is scheduled to start this month and with the scribe being signed off he can now contact the contractors to start the work. Sandra McNamee confirmed that this was raised at a meeting she attended yesterday and that she was aware that there is a plan to put HEPA filters in two of the rooms in PICU as contingency. (this action is complete) Ian Powrie said that the only reason this had not been done is that there was a requirement for the rooms to be unoccupied for 24 hours whilst this work was done and validation carried out and that up to this time it was not possible because the beds had been fully occupied and that there were ongoing discussions with the team in Ward 2A as to whether these patients could be accommodated in isolation rooms within other wards where HEPA Filters could be fitted to address the overspill contingency. Dr Peters commented that this was necessary in PICU, not just as an overspill for Ward 2A, but for these extremely vulnerable patients if they required intensive care treatment because of their illness (Item 11). Dr Redding advised that the clinical team in Ward 2A have reported that in their experience there seemed to be an increase in the number of line related infections and Sandra advised that this was investigated by Infection Prevention Control and the clinical team when first raised and work had been ongoing for several months (Item 12).	JA

Item	Action
She also reported that IPCT and the Clinical Team were working with Timothy Bradnock, Consultant Paediatric Surgeon to look at improvement work. Sandra noted that there was no effective benchmark available for this area. Dr Peters noted that rates of line infection were important to determine and that IPCT had stated there was no resource to do this (Item 13).	
Jen Rodgers, Chief Nurse has an improvement group looking at PVC and CVC bundles and Sandra said that this should have an impact on the number of infections. Dr Armstrong added that there has been a focused piece of work carried out in Ward 2A and they were on a weekly reporting process to ensure compliance with infection control standards had improved. Dr Redding was concerned that this may not accurately pick up any concerns (Item 14).	
In relation to the chemotherapy being prepared in the treatment rooms Gary Jenkins advised the group that chemo was prepared in a designated area and there was an audit process to confirm this. He also commented that this process had been reviewed recently and offered to provide Dr Redding the document that was produced. Dr Armstrong confirmed that chemo is not being made up in these rooms and is carried out in the Aseptic Dispensing unit. Dr Armstrong agreed to confirm this with Pharmacy.	JA
With regards to safe placement of immunocompromised patients, Dr Peters asked if there was a list of which rooms were of the standard that would be acceptable for this group of patients. She commented that when she worked in Crosshouse Hospital they had a list of where these particular patients could be placed. She said the microbiologists receive calls asking this question by clinical staff (Item 15).	
The group debated the definition and severity of immunocompromised patients and agreed, with input from Sandra McNamee and Prof Jones that this was a decision best considered by the clinical team looking after the individual patients. Dr Armstrong advised that this should be discussed at AICC and Gary Jenkins commented that this has not been raised as an issue via his Regional Clinical Governance Committee. Dr Armstrong recommended that this be addressed through the Regional Clinical Governance Committee. She also said it would be helpful to have a copy of the document that Dr Peters used in Crosshouse. Dr Redding reiterated that Microbiologists need to know which rooms are the most suitable for different categories of patients.	GJ CP
Dr Redding commented that she feels the infection rates are not being monitored (Item 16) and Dr Armstrong replied that the Board and Acute Directors receive a weekly report of all outbreaks and infection control incidents.	
Dr Armstrong agreed to ask the Women & Children directorate to take forward the points raised above.	JA
• <u>Single Side Room Accommodation</u> Dr Redding outlined that air changes per hour for all clinical accommodation in QEUH and RHC are 3 instead of 6 as per guidelines with the inclusion of chilled beam technology. The grills also collect dust as air is entrained over chilled beams which she suggested is not recommended in a healthcare setting (Item 17). Dr Peters advised this initially came to light when investigating issues regarding CF patients.	

Item	Action
David Loudon advised that Dumfries and Galloway have chilled beam technology and Dr Peters stated that Monklands Hospital is at the commissioning stage of a new build and suggested that we share our learning with them. It was agreed that it was important to share the GGC knowledge around chilled beam technology with colleagues in other Boards and David Loudon agreed to take this forward. Ian Powrie informed the group that all chilled beams on site are being cleaned and maintained and Dr Redding asked if the air changes can be changed from 3 to 6 in some rooms but not in all areas and David Loudon advised this was not realistically possible. Ian Powrie confirmed that cleaning and monitoring is being carried out to determine how quickly dust has built up and once this has been established a cleaning schedule will be organised and this can be shared with other hospitals. Dr Redding suggested involving Microbiologists regarding cleaning to look at the microbiological counts. Dr Jones suggested that rates of infection may also be a useful indicator. In this context Sandra McNamee reported that during the point prevalence survey QEUH was under the national average for infections and that all alert organism/conditions were monitored by the IPCT and that there were no indications that this site had a higher than average infection rates. It was noted that infections occurring post discharge would not be picked up by the point prevalence survey.	DL
<u>Cleaning</u> In relation to cleaning Dr Redding stated that cleaning agents were not being used on floors in clinical areas (Item 18). Dr Redding also outlined that dishwashers had not been cleaned, installed or operated according to manufacturing instructions (Item 19). This was brought to light with the investigation into CF patients with Exophiala. Sandra McNamee updated regarding the occurrence of Exophiala in CF patients and said this was referred to HPS as an amber HIIAT score but they downgraded this to a green HIIAT as this is considered to be a ubiquitous organism and the modes of spread, incubation period and occurrence in the population and environment was largely unknown. Dr Peters stated that she had already discussed the outbreak in her role as CF Microbiologist with mycology experts and given the striking epidemiology of increasing numbers, it is a reasonable hypothesis to assume a link to the dishwashers as a possible source. She had also discussed the HIIAT rating with HPS and agreed with green rating as the intervention with dishwasher was rapidly and appropriately dealt with. With reference to the cleaning agents Sandra McNamee responded that Actichlor cleans are used throughout the winter norovirus season which normally runs from November to April. She also stated that Actichlor was used in specific areas at the recommendation of IPCT, for example. Actichlor was used in GGH for a month in the summer due to an increase in CDI across the site. This has also been introduced for general cleaning into the wards with CF patients in QEUH and RHC, PICU, NICU and Ward 2A. At a recent meeting with HPS Sandra said HPS have found no evidence that using Actichlor is effective but further guidance was awaited. With regards to dishwashers in the ward area there had been some debate in the ward regarding whose responsibility it was to clean these but Sandra said this has been addressed. The manufacturer has come in to check the dishwashers and Catering Services have confirmed they will commence a cleaning programme for the dishwashers. It was also noted that Environmental Health Officers prefer dishwashers to be used over hand washing in sinks/basins.	

Item	Action
Dr Peters commented that the audit system did not pick up this problem (Item 20), and raised concerns about gaps in the environmental audit programmes and this was possibly the same with regards to ward refrigerators or other equipment. Sandra McNamee advised that nursing staff have a requirement to check the temperature in fridges and stated again that the catering department have agreed to take responsibility for the ward dishwashers. The group noted that dishwasher maintenance had been overlooked in the overall system but that this had now been rectified.	
• <u>Water Quality and Testing</u> In the SBAR it stated that all taps are fitted with TMVs and the cleaning and maintenance policy has not been reported and Dr Redding stated that we need to ensure this is up-to-date (Item 21) She also commented that the water in Ward 4B has not been tested to a high standard (Item 22).	
The group was assured that there was a Board Water Safety Policy in place that is approved by the appropriate governance committees.	
David Loudon reported that we have strict guidance on how to monitor water systems and processes are in place to comply with ECOPs. Ian Powrie also confirmed that water testing is carried out as per protocol and only exceptions are reported to the Infection Control Teams and this was previously agreed with Dr Inkster.	
He said testing is mainly carried out in high risk areas. David Loudon stated that we are not required to test all taps but a sample and that this was in accordance with guidance. He also confirmed that if requested by an ICD additional sampling was undertaken. Dr Deshpande said that Dr Inkster was managing the water testing and he perceived there was a problem with the environment. He said that he requested gram negative testing but did not receive the results from Estates. Ian Powrie replied that recent changes in staff in both estates and IPC could have been the reason why he did not receive the information. It was agreed that GGC are compliant with the water testing protocol. Dr Peters stated that the issue was not the overall testing protocols but the ICD role in requesting and receiving the results in a timely manner in exceptional circumstances where a water source of infection needed to be investigated.	
In relation to TMVs Ian Powrie advised that these are maintained in all high risk areas and they are working towards carrying this out in all areas. He said the end piece of the taps cannot be removed and an SBAR is in place for this. Estates are finalising the installation of a heat sanitation system and once complete this will be sent to the Board Water Safety Committee for approval.	
In terms of serratia Ian said they would test the water for this if requested by a clinician.	
• <u>Plumbing in Neuro Surgical Block</u> Dr Redding stated that there has been sewage leaking in the theatre suite since before 2015 and is still ongoing and not all incidents have been reported to ICDs (Item 23).	
Gary Jenkins advised that there is ongoing work in the neuro building that would, because of its complexity, take several years to complete. In the meantime the new operating theatres were due to open in January 2018.	

Item	Action
He stated that his directorate has a specific focus on IPC and that they had a dedicated group to look at surgical site infection. He said they funded 1.5 WTE surveillance nurses to carry out prospective surgical site surveillance in this area. Dr Armstrong updated that Dr Inkster carried out a detailed inspection of the area previously and she suggested that SSI surveillance was carried out here. Sandra McNamee advised for context that there are 3 surveillance nurses that cover all of GGC so the resource to actively do this in the INS was significant.	
She acknowledged that the ICDs were concerned about infections in EVD and stated that the clinical teams were currently developing an EVD bundle. Ian Powrie reported that remedial work was carried out in this building over the past year but that there had been an incident with sewage last week.	
There has been a delay in the opening of the ICE theatres as GGC were not satisfied with the standard but a programme of work has been agreed with the clinicians.	
Dr Peters said she requested to know the number of instances from when the theatres closed two years ago due to problems with the pipe work to date and she stated that she was told at the time of the initial problems that the plumbing was to be replaced (Item 24). Gary Jenkins responded that the pipes run through multiple floors and a process is in place with IPC and Capital Planning to take this forward in stages.	
Anne Harkness commented that increases in SSI should be discussed at the Regional Clinical IPC Group which Dr Deshpande is a representative of (Item 25). Ian Powrie advised that he has arranged to meet with Dr Deshpande and Dr Balfour to discuss the INS theatre issue.	
• <u>Decontamination Provision for Respiratory Clinics</u> The SBAR also stated that the decontamination facilities in both Paediatric and adult respiratory clinics have been identified as inadequate on a number of occasions (Item 26). Sandra McNamee informed that remedial actions have been put in place and a list of items has been sent to HPS for advice on how to decontaminate them.	
Dr Peters stated that QEUH ICD had not been informed of timeline for revision works to decontamination area to take place.	
• <u>Infection Control Structure</u> Dr Redding advised that the ICDs in the South Sector had stated that the roles within the Infection Control team are unclear and appear to have changed (Item 27). Dr Armstrong proposed that consideration is given to having a further separate meeting to discuss the issues referred to in this section. Jonathan Best offered to support this discussion.	

Item	Action
4. Agreement of Further Actions / Next Steps - Ian Powrie to provide documents supporting work on PPVL rooms - David Loudon to liaise with colleagues re GGC experience with chilled beams - In relation to safe patient placement and availability of isolation rooms, this is to be raised via the Regional Clinical Governance Committee. - Dr Peters to issue the group a copy of the document listing isolation rooms from Crosshouse Hospital. - Dr Armstrong to relay issues pertaining to Ward 2A to Women & Children directorate. - Dr Armstrong to confirm chemotherapy preparation in Aseptic Unit. - Consideration to be given to a further meeting with a smaller group to discuss the issues contained in the Infection Control Structure section of the SBAR. - Dr Armstrong to check with the Comms team regarding the wording in the public statement regarding BMT services	
5. A.O.C.B. Nil. Dr Armstrong thanked everyone for their attendance today.	

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SOP Objective

To ensure that patients are cared for in the appropriate area in order to minimise the risk of cross-infection, and to protect immune compromised patients from environmental infection.

This SOP applies to all staff employed by NHS Greater Glasgow & Clyde and locum staff on fixed term contracts and volunteer staff.

KEY CHANGES FROM THE PREVIOUS VERSION OF THIS SOP

- Addition 2A RHC and 4B QEUH.

Document Control Summary

Approved by and date	
Date of Publication	
Developed by	IPCT, Estates and Facilities Management.
Related Documents	National IPC Manual http://www.nipcm.hps.scot.nhs.uk/ MERS-cov-information hub https://www.hps.scot.nhs.uk/a-to-z-of-topics/middle-east-respiratory-syndrome-coronavirus/
Distribution/ Availability	NHSGGC Infection Prevention and Control Internet www.nhsggc.org.uk/your-health/public-health/infection-prevention-and-control/
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1. Responsibilities

Health Care Workers (HCW) must:

- Follow this SOP.
- Follow the advice of the Infection Prevention Control Team (IPCT)
- Escalate to line manager if they are unable to follow this SOP.

Managers must:

- Support HCWs in following this SOP.
- Cascade new policies/SOPs to clinical staff.

Infection Prevention and Control Teams must:

- Keep this SOP up-to-date.
- Provide education opportunities on this SOP.

Facilities / Estates Teams must:

- Carry out verifications on all rooms annually or following any works carried out on the room.
- Keep up-to-date verification records.

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2. General Information on Specialist Ventilation

Across NHS Greater Glasgow and Clyde there are a number of specially ventilated rooms designed to protect patients within the healthcare environment from potentially harmful pathogens. The tables below provide a list of wards and rooms on each of the main hospital sites, indicating the type of ventilation and filtration available in each. This will direct staff to the correct placement of patients who are suspected or confirmed to have an airborne or high consequence infectious disease, as well as airborne protective isolation for immune compromised patients. Below is a description of what each type of ventilation means, while Table 1 should be used to guide staff to the type of patient that can be safely cared for in each.

What is a Positive Pressure Ventilated Lobby (PPVL) Room? (HEPA filtered air)

A PPVL room has a flow of air from the lobby which moves into the main room. The contaminated air is extracted via a vent in the en suite toilet when one is available. In all instances in QEUH and RHC there is an additional extract in variable locations in the ceiling of the patient room. The lobby itself is positively pressurised to both the patient's room and the outer corridor providing a barrier between the patient within the room and the surrounding ward. This movement of air effectively prevents infection spreading between the room and the surrounding ward. Some PPVL rooms have an air supply to the lobby via a filter (HEPA filter) providing some further protection for patients who are immunosuppressed within the room. It is important to keep the door to the main room and to the lobby closed when not in use to ensure that this flow of air is maintained. The pressure on the gauge from corridor to lobby should read +8 to +12 PA.

What is a Negatively Pressured Room?

A negative pressure room has a flow of air which moves from the corridor into the room preventing the escape of room air to the surrounding ward. The ventilation within the room is such that it dilutes any airborne pathogens which are circulating. The room provides a negative air flow / 'cascade' from ward corridor to lobby, and lobby to isolation room, whilst allowing control of room temperature. The room is validated for 10 air changes per hour within an isolation room and a pressure differential of -8Pa to -10Pa in relation to the corridor. It is important to keep the door to the main room and the lobby closed when not in use to ensure that this flow of air is maintained.

What is a Bone Marrow Transplant (BMT) Room?

BMT rooms are reserved for use by those patients who are highly susceptible to infection, for example, those undergoing bone marrow transplant. The air supply to the room is via a filter (HEPA filter) to further provide protection to the vulnerable patient within the room from external airborne pathogens such as fungi. These rooms are currently only located within Ward 2A Children Hospital and also Ward 4B in the QEUH, and are reserved for use by BMT patients.

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3. Room Types

Type of Room	Patient allocation / suitability
PPVL with Lobby HEPA	Immunosuppressed patients, i.e. Haem-onc patients, should be prioritised for these rooms
	Immunosuppressed with chickenpox / measles
	Patients with Atypical Mycobacteria
	Patients with infections (non-airborne route)
Negative pressure	Chickenpox, Measles, Pathogens of High Consequence
	Tuberculosis (incl MDRTB and XDRTB) Prioritise airborne infection
BMT Rooms	Bone Marrow Transplant patients These are located in specialist units: QEUH 4B RHC 2A

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4. Signage

Patient bedrooms with specialist ventilation will have a sign at the door indicating the specific ventilation afforded by that particular room. The signs will be one of the following (QEUH):

Negative Pressure Isolation Room

Pressure gauge should be between
-8Pa & -12Pa

If the positive side of the gauge is out of range please contact estates department
Help desk 5555

HEPA FILTERED PPVL Isolation Room

Pressure gauge should be between
+8Pa & +12Pa

If the positive side of the gauge is out of range please contact estates department
Help desk 5555

These templates only and should be modified for local use.

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Table 1. Special Ventilation Rooms – Royal Hospital for Children (RHC)

Location	Room Number	Type of Room	HEPA filter (Lobby supply)	Type of Patient	Comment	En suite Y/N
CDU	17	PPVL	Yes	Prioritise immunosuppressed		Y
CDU	18	Negative Pressure	Yes	Not immunosuppressed	Varicella Zoster, TB, VHF, MERS, Respiratory illnesses	Y
1D	5	Negative Pressure	Yes	Not immunosuppressed	Varicella Zoster, TB, VHF, MERS, Respiratory illnesses	N
1D	12	PPVL	Yes	Prioritise immunosuppressed		N
1D	17	PPVL	Yes	Prioritise immunosuppressed		N
1D	18	PPVL	Yes	Prioritise immunosuppressed		N
1E	13	PPVL	Yes	Prioritise immunosuppressed		Y
1E	14	PPVL	Yes	Prioritise immunosuppressed		Y
2C	5	PPVL	Yes	Prioritise immunosuppressed		Y
2C	6	Negative Pressure	Yes	Not immunosuppressed	Varicella Zoster, TB, VHF, MERS, Respiratory illnesses	Y
3A	15	PPVL	Yes	Prioritise immunosuppressed		Y
3A	16	PPVL	Yes	Prioritise immunosuppressed		Y
3B	19	PPVL	Yes	Prioritise immunosuppressed		Y
3B	5	PPVL	Yes	Prioritise immunosuppressed		Y
3C	9	PPVL	Yes	Prioritise Immunosuppressed		Y
3C	10	PPVL	Yes	Prioritise Immunosuppressed		Y

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Table 2. Special Ventilation Rooms – Adult Queen Elizabeth University Hospital (QEUH)

Location	Room Number	Type of Room	HEPA filter (Lobby Supply)	Type of Patient	Comment	En suite Y/N
HDU UNIT 1	3	PPVL	Yes	Prioritise Immunosuppressed		Y
HDU UNIT 1	4	Negative Pressure	Yes	Not immunosuppressed	Varicella Zoster, TB, VHF, MERS, Respiratory illnesses	Y
HDU UNIT 2	11	PPVL	Yes	Prioritise Immunosuppressed		Y
ICU UNIT 3	23	PPVL	Yes			N
ICU UNIT 3	24	Negative Pressure	Yes	Not immunosuppressed	Varicella Zoster, TB, VHF, MERS, Respiratory illnesses	N
ICU UNIT 4	31	PPVL	Yes			N
ICU UNIT 4	40	PPVL	Yes			N
ICU UNIT 5	43	Negative Pressure	Yes	Not immunosuppressed	Varicella Zoster, TB, VHF, MERS, Respiratory illnesses	Y
ICU UNIT 5	44	Negative Pressure	Yes	Not immunosuppressed	Varicella Zoster, TB, VHF, MERS, Respiratory illnesses	Y
HDU UNIT 6	50	PPVL	Yes	Prioritise Immunosuppressed		Y

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Table 3. Special Ventilation Rooms – Royal Alexandra Hospital (RAH)

Location	Room Number	Type of Room	HEPA Filter (Lobby Supply)	Type of Patient	Comment	En suite Y/N
ICU	2	Negative Pressure	No	Not immunosuppressed	Varicella Zoster, TB, VHF, MERS, Respiratory illnesses	N
ICU	5	Negative Pressure	No	Not immunosuppressed	Varicella Zoster, TB, VHF, MERS, Respiratory illnesses	N

Please note there are no negative pressure isolation rooms in either Vale of Leven Hospital or Inverclyde Royal Hospital.

Table 4. Special Ventilation Rooms – Glasgow Royal Infirmary (GRI)

Location (Wards)	Room Number	Type of Room	HEPA Filter (Lobby Supply)	Type of Patient	Comment	En suite Y/N
6	3/25	Negative Pressure	No	Not immunosuppressed	Varicella Zoster, TB, VHF, MERS, Respiratory illnesses	Y
6	3/39	Negative Pressure	No	Not immunosuppressed	Varicella Zoster, TB, VHF, MERS, Respiratory illnesses	Y
7	3/52	Negative Pressure	No	Not immunosuppressed	Varicella Zoster, TB, VHF, MERS, Respiratory illnesses	Y
16	3/31	Negative Pressure	No	Not immunosuppressed	Varicella Zoster, TB, VHF, MERS, Respiratory illnesses	Y

NB - In ITU due to the variability of different types of isolation facilities any patients who require source or protective isolation will be discussed with IPCT to ascertain isolation priority and placement.

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Table 5. Bone Marrow Transplant (BMT) Rooms – Royal Hospital for Children (RHC)

Location	Room Number	Type of Room	HEPA filter (Lobby supply)	Type of Patient	En suite Y/N
2A	2	HEPA Filtered PPIR	N	Immunosuppressed	Y
2A	3	HEPA Filtered PPIR	SHARED	Immunosuppressed	Y
2A	4	HEPA Filtered PPIR	SHARED	Immunosuppressed	Y
2A	5	HEPA Filtered PPIR	SHARED	Immunosuppressed	Y
2A	6	HEPA Filtered PPIR	SHARED	Immunosuppressed	Y
2A	7	HEPA Filtered PPIR	N	Immunosuppressed	Y
2A	8	HEPA Filtered PPIR	N	Immunosuppressed	Y
2A	9	HEPA Filtered PPIR	N	Immunosuppressed	Y
2A	10	HEPA Filtered PPIR	N	Immunosuppressed	Y
2A	11	HEPA Filtered PPIR	N	Immunosuppressed	Y
2A	12	HEPA Filtered PPIR	N	Immunosuppressed	Y

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Location	Room Number	Type of Room	HEPA filter (Lobby supply)	Type of Patient	En suite Y/N
2A	14	HEPA Filtered PPIR	N	Immunosuppressed	Y
2A	15	HEPA Filtered PPIR	N	Immunosuppressed	Y
2A	16	HEPA Filtered PPIR	N	Immunosuppressed	Y
2A	17	HEPA Filtered PPIR	Y	BMT	Y
2A	18	HEPA Filtered PPIR	Y	BMT	Y
2A	19	HEPA Filtered PPIR	Y	BMT	Y
2A	20	HEPA Filtered PPIR	Y	BMT	Y
2A	21	HEPA Filtered MIBG	-	-	Y
2A	22	HEPA Filtered PPVL	Y	Immunosuppressed	Y
2A	23	HEPA Filtered NPVL	Y	Immunosuppressed	Y
2A	24	HEPA Filtered PPVL	Y	Immunosuppressed	Y
2A	25	HEPA Filtered PPVL	Y	Immunosuppressed	Y

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		Version	Version 5
The most up-to-date version of this SOP can be viewed at the following website: www.nhsggc.org.uk/your-health/public-health/infection-prevention-and-control			

Table 5. Bone Marrow Transplant (BMT) Rooms – Adult Queen Elizabeth University Hospital (QEUH)

Location	Room Number	Type of Room	HEPA filter	Type of Patient	En suite Y/N
4B	All Rooms	Positive Pressure	Y	Immunosuppressed	Y

The most up-to-date version of this SOP can be viewed at the following website:
This is based on information from clinical team and EFM Colleagues
www.nhsggc.org.uk/your-health/infection-prevention-and-control

	NHS GREATER GLASGOW & CLYDE CONTROL OF INFECTION COMMITTEE STANDARD OPERATING PROCEDURE (SOP)	Page	13 of 13
		Effective From	January 2024
	Patient Placement Guidance	Review Date	January 2026
		Version	Version 5
The most up-to-date version of this SOP can be viewed at the following website: www.nhsggc.org.uk/your-health/public-health/infection-prevention-and-control			

5. Definition of immunosuppressed/Immunocompromised

NIPCM definition is “Any person whose immune response is reduced or deficient, usually because they have a disease or are undergoing treatment. People who are immunocompromised are more vulnerable to infection”.

6. Evidence Base

<http://www.nipcm.hps.scot.nhs.uk/>

The most up-to-date version of this SOP can be viewed at the following website:

This is based on information from clinical team and EFM Colleagues

www.nhsggc.org.uk/your-health/infection-prevention-and-control

FACT-JACIE International Standards
for **HEMATOPOIETIC
CELLULAR THERAPY**
Product Collection, Processing, and Administration

SIXTH EDITION



INTERNATIONAL STANDARDS FOR HEMATOPOIETIC CELLULAR THERAPY PRODUCT COLLECTION, PROCESSING, AND ADMINISTRATION



Sixth Edition Version 6.1

NOTICE

These Standards are designed to provide minimum guidelines for programs, facilities, and individuals performing cellular therapy or providing support services for such procedures. These Standards are not intended to establish best practices or include all procedures and practices that a program, facility, or individual should implement if the standard of practice in the community or applicable governmental laws or regulations establish additional requirements. Each program, facility, and individual should analyze its practices and procedures to determine whether additional standards apply. Compliance with these Standards is not an exclusive means of complying with the standard of care in the industry or community or with local, national, or international laws or regulations.

The Foundation for the Accreditation of Cellular Therapy and the Joint Accreditation Committee – ISCT and EBMT expressly disclaim any responsibility for setting maximum standards and further expressly disclaim any responsibility, liability, or duty to member programs, directors, staff, or program donors or patients for any such liability arising out of injury or loss to any person by the failure of member programs, directors, or staff to adhere to the Standards or related guidance.

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INTRODUCTION

The major objective of the *FACT-JACIE International Standards for Hematopoietic Cellular Therapy Product Collection, Processing, and Administration* (the Standards) is to promote quality medical and laboratory practice in hematopoietic progenitor cell transplantation and related therapies using hematopoietic-derived cellular products. These Standards apply to hematopoietic progenitor cells, defined as self-renewing and/or multi-potent stem cells capable of maturation into any of the hematopoietic lineages, lineage-restricted pluri-potent progenitor cells, and committed progenitor cells from hematopoietic sources (bone marrow, umbilical cord blood, peripheral blood, or other tissue source). These Standards also include nucleated cells, including mononuclear cells from any hematopoietic tissue source (marrow, peripheral blood, umbilical cord, and placental blood) collected for therapeutic use other than as hematopoietic progenitor cells. These Standards apply to all phases of collection, processing, storage, and administration of these cells, including donor selection and screening, in vitro manipulation such as removal or enrichment of specific cell populations, and cryopreservation. The FACT-JACIE Standards do not address the collection, processing, or administration of erythrocytes, platelets, mature granulocytes, plasma, or plasma-derived products intended for transfusion support.

For hematopoietic progenitor cells or mononuclear cells derived from umbilical cord and/or placental blood, these Standards apply only to the administration of the cellular therapy product, applying the clinical and processing standards for product preparation and transplantation as appropriate. Standards for cord blood collection and banking are available in a separate document, *NetCord-FACT International Standards for Cord Blood Collection, Banking, and Release for Administration*, available at www.factwebsite.org.

The FACT-JACIE Standards are published under the title *FACT-JACIE International Standards for Hematopoietic Cellular Therapy Product Collection, Processing, and Administration*, which accurately reflects the contributions of both organizations. The Foundation for the Accreditation of Cellular Therapy (FACT) was founded in 1996 by the American Society for Blood and Marrow Transplantation (ASBMT) and the International Society for Cellular Therapy (ISCT). The first edition of Standards was published that same year. The inspection and accreditation program based on these Standards was started in North America in 1997. The Joint Accreditation Committee of ISCT and EBMT (JACIE) was established in 1999. JACIE adopted the first edition of FACT Standards in its entirety. The second edition of FACT Standards (2002) was developed and published following joint review by FACT and JACIE. Subsequent editions of Standards have been jointly developed and approved by FACT and JACIE.

In addition, the use of *Hematopoietic* in the title is to define the scope of these standards due to an increasing number of accredited facilities that also support non-hematopoietic cellular therapies. Facilities pursuing accreditation for hematopoietic services in addition to other specialty services may consult these Standards as a single reference for all fundamental requirements.

Every effort has been made to incorporate into these Standards sound principles of quality medical and laboratory practice in cellular therapy. However, no standards can guarantee the successful outcome of such therapies. FACT-JACIE Standards are minimal guidelines that may be exceeded as deemed appropriate by the responsible personnel in individual facilities. Directors and Medical Directors of the Clinical Program, Marrow Collection Facility, Apheresis Collection Facility, and Processing Facility assume responsibility for adopting FACT-JACIE Standards as appropriate to the program or facility, and for setting more rigorous internal requirements where appropriate. Attempts have been made to conform these Standards to existing U.S. federal regulations and the requirements of the European Union Directives; however, compliance with these Standards does not guarantee compliance with all applicable regulations.

The Standards are structured to align similar standards among the three primary functions within a cellular therapy program: the Clinical Program, Collection Facility, and Processing Facility. Separate

sections exist for Marrow Collection Facilities and Apheresis Collection Facilities to recognize the inherent differences between these two facilities and the closer linkage between the Marrow Collection Facility and the Clinical Program.

Appendices are used to clarify requirements and simplify the Standards. In the sixth edition, standards requiring a minimum number of new patients were replaced by a standard requiring that the Clinical Program comply with a new appendix, the Minimum Number of New Patients for Accreditation. This change was made for clarity. No change was made to the minimum number of new patients required.

The Quality Management (QM) section for each area in the cellular therapy program was expanded in the third edition (2006) to incorporate US FDA regulatory requirements for donor screening, testing, and eligibility determination; labeling; and current Good Tissue Practices. In subsequent editions, the QM standards have been refined for clarity and realigned to reduce redundancy, but allow flexibility in the structure of quality management activities within a program. Under any structure, the Clinical Program must have assurances that QM activities are adequate in all areas that impact the patient or product. Because the clinical team usually plays a direct role in marrow collection, the Clinical Program QM requirements in Part B include marrow collection. A Marrow Collection Facility operating independently of a specific Clinical Program must comply with the QM section in Part B.

The Donor Selection, Evaluation, and Management sections in the Clinical Program and Collection Facility sections reflect the usual delineation of these responsibilities between clinical programs and collection facilities. The Collection Facility standards are focused on donor evaluation and management; the Clinical Standards have emphasis on donor selection. If a Collection Facility is primarily responsible for donor selection, that Collection Facility must comply with the applicable Clinical Program standards. The Donor Selection, Evaluation, and Management sections apply to both related and unrelated donors. Effort was made to clarify which standards apply to both allogeneic and autologous donors, and which standards apply only to allogeneic donors.

FACT-JACIE Standards require compliance with the most recent regulatory requirements and the most current resources from other initiatives in the field. This includes the Transplant Essential Data (TED) forms, the Minimum Essential Data – Form A (MED-A) forms, the Circular of Information (COI) donor testing and biohazard and warning label tables, and the ISBT 128 Standard Terminology. Links to these resources are available on the FACT website.

Both FACT and JACIE recognize the significant benefits of international standardization of coding and labeling in cellular therapy, and support the international efforts to implement ISBT 128. ISBT 128 is the global standard for terminology, identification, coding, and labeling of medical products of human origin, and has been designed to ensure accuracy and safety for the benefit of patients and donors world-wide. FACT-JACIE Standards require the use of this terminology for cellular therapy products as applicable, and require accredited programs to be actively implementing ISBT 128. Terminology current at the time of publication of these Standards is listed in A3 Definitions. Terminology is frequently updated by ICCBBA, the organization responsible for the international maintenance of the ISBT 128 standard. Accredited programs must be registered with ICCBBA, receive notification of these changes, and make appropriate revisions if needed.

Implementation of ISBT 128 will include the use of scanned information at the time of product release from collection, receipt into the laboratory, and at distribution from the processing facility. It is understood that full implementation of ISBT 128 requires a transition period, and that organizations inspected soon after publication of this edition of Standards may not have completed this process. At a minimum, “actively implementing” includes completion of most of the following:

- 1) Registration with ICCBBA;
- 2) Evidence of a written implementation plan that includes a timeline;
- 3) Implementation of the current terminology;

- 4) Identification of information technology needs and solutions;
- 5) Identification or creation of appropriate product codes;
- 6) Label designs according to the requirements of ICCBBA for Cellular Therapy Products;
- 7) Label validation;
- 8) Use of scanned information at the time of product release from collection, receipt into the laboratory, and at distribution from the processing facility.

This sixth edition of Standards includes additional significant changes. A detailed summary is available on the FACT website. Most important to note are:

- 1) Increased emphasis on outcome analysis and improvement.
 - a) Clinical Programs are required to assess at least 30 day, 100 day, and one year survival, and to compare one year survival to national or international outcome data. For US programs, at a minimum, the one year survival should be within the expected range as defined for that program by the CIBMTR Transplant Center-Specific Outcome Data. Corrective action plans will be expected if these outcomes are not achieved.
 - b) Clinical Programs must regularly assess allogeneic transplant recipients for evidence of acute and chronic graft versus host disease according to an established grading scale, and actively evaluate patients for post-transplant late effects.
 - c) Clinical Programs must also regularly assess central venous catheter infections.
- 2) Reporting of autologous transplant results is now recommended.
- 3) New requirements were added for pharmacists and physicians-in-training who are involved in the care of hematopoietic cell therapy patients.
- 4) Continuing education minimum requirements have been specifically defined as ten hours per year in topics related to hematopoietic cell therapies.
- 5) Requirements specific to immune effector cells used to modulate an immune response were added as interim standards.

These Standards (Version 6.0) are effective June 1, 2015. All accredited programs and facilities are expected to be in compliance with these Standards by that date.

ACCREDITATION

The basis for FACT or JACIE accreditation is documented compliance with the current edition of Standards through submitted documents and an on-site inspection. Although there are joint FACT-JACIE Standards, FACT and JACIE maintain separate and parallel accreditation processes. All inspections are conducted by persons qualified by training and experience in the area of cellular therapy they inspect, and who are affiliated with an accredited facility, have completed inspector training, and have a working knowledge of FACT-JACIE Standards and of their application to various aspects of the cellular therapy program.

- 1) A clinical hematopoietic progenitor cell/therapeutic cell transplantation program may apply for accreditation alone or in conjunction with the collection facility and/or the processing facility with which it is associated. All facilities applying together should submit pre-inspection data together. A clinical program must use a collection facility and a processing facility that meet FACT-JACIE Standards and have a clearly defined contractual or reporting relationship.
 - a) Clinical Program accreditation may be for allogeneic transplantation, autologous transplantation, or both.
 - b) Clinical Program accreditation may be for transplantation of adult patients, pediatric patients, or both. As detailed in the Standards, consultants and support services appropriate to the patient population are required.

- 2) A cell collection facility or service (peripheral blood or bone marrow) may apply for accreditation as an integral part of a clinical transplant program, as an independent collection service providing cell collection services for one or more clinical transplant programs, or in conjunction with a cell processing facility if the services of collection and processing/storage are functionally linked. An accredited cell collection facility may provide services for clinical transplant programs that are or are not FACT or JACIE accredited, but shall use a processing facility that meets FACT-JACIE Standards and have a clearly defined contractual or reporting relationship.
- 3) A cell processing facility may apply for accreditation as an integral part of a clinical transplant program, as part of a collection service or facility, or as an independent cell processing facility that processes and stores products for clinical programs or collection facilities. An accredited processing facility may provide services for clinical transplant programs and/or collection services that are or are not FACT or JACIE accredited.
- 4) A clinical program that provides cellular therapy services other than hematopoietic progenitor cell transplantation in addition to hematopoietic cell transplantation requires only a single accreditation according to these Standards.
- 5) A clinical program that provides cellular therapy services other than hematopoietic progenitor cell transplantation may apply for FACT accreditation with a hematopoietic progenitor cell transplantation program provided that the definition of and requirements for a single clinical program are met. A program that utilizes the same group of physicians and serves the same patient population, with common directorship, protocols, and staffing, would meet this requirement.
- 6) A cell collection or processing facility that collects or processes hematopoietic progenitor cell therapy products in addition to other investigational products may apply for FACT accreditation for all activities and document compliance with the FACT-JACIE Standards.
- 7) If a facility does not collect or process hematopoietic cell therapy products but wishes to apply for FACT accreditation, the facility personnel should consult the current edition of the *FACT Common Standards for Cellular Therapies*.

An accreditation cycle is three years for FACT, and is four years for JACIE. Accredited facilities must complete an interim report(s) during the accreditation cycle as directed by FACT or JACIE. Accredited facilities are reinspected routinely every three years (FACT) or four years (JACIE), and may also be reinspected in response to complaints or information that a facility may be non-compliant with FACT-JACIE Standards, in response to significant changes in the program and/or facility, or as determined by FACT or JACIE. Accreditation may be suspended or terminated if a facility fails to comply with the Standards.

TERMINOLOGY, TENETS, ABBREVIATIONS, AND DEFINITIONS

PART A

- A1 Terminology
- A2 Tenets
- A3 Abbreviations
- A4 Definitions

PART A: TERMINOLOGY, TENETS, ABBREVIATIONS, AND DEFINITIONS**A1 TERMINOLOGY**

For purposes of these Standards, the term *shall* means that the standard is to be complied with at all times. The term *should* indicates an activity that is recommended or advised, but for which there may be effective alternatives. The term *may* is permissive and is used primarily for clarity.

A2 TENETS

Basic tenets for compliance with these Standards include, but are not limited to:

- A2.1 Where applicable laws and regulations include more stringent requirements than these Standards, those laws and regulations supersede the Standards. Conversely, when these Standards are more stringent than applicable laws and regulations, the Standards must be followed.
- A2.2 Applicant organizations are responsible for providing verifiable documentation of evidence of compliance with these Standards.
- A2.3 Standards related to services not provided by the applicant do not apply to the applicant organization. The burden to demonstrate that a requirement is not applicable rests with the applicant organization.

A3 ABBREVIATIONS

The following abbreviations cover terms used in these Standards:

ABO	Major human blood group including erythrocyte antigens, A, B, O
AC	Accompany
AF	Affixed
Anti-	Antibody to the antigen designated
APP	Advanced Practice Provider/Professional
ASBMT	American Society for Blood and Marrow Transplantation
ASFA	American Society for Apheresis
ASHI	American Society for Histocompatibility and Immunogenetics
AT	Attached
ATMP	Advanced Therapy Medicinal Product
CAR	Chimeric antigen receptor
CE	(formerly EC) European Conforming
CFR	Code of Federal Regulations
CIBMTR	Center for International Blood and Marrow Transplant Research
CLIA	Clinical Laboratory Improvement Amendments
CME	Continuing Medical Education
CMS	Centers for Medicare & Medicaid Services
CMV	Cytomegalovirus
CNS	Central nervous system
COA	Certificate of Analysis
CRS	Cytokine release syndrome
CTP	Cellular therapy product
DLI	Donor lymphocyte infusion

<i>DNA</i>	Deoxyribonucleic acid
<i>EBMT</i>	European Society for Blood and Marrow Transplantation
<i>ECP</i>	Extracorporeal photopheresis
<i>EFI</i>	European Federation for Immunogenetics
<i>EU</i>	European Union
<i>FACT</i>	Foundation for the Accreditation of Cellular Therapy
<i>FDA</i>	U. S. Food and Drug Administration
<i>GMP</i>	Good Manufacturing Practices
<i>GTP</i>	Good Tissue Practices
<i>GVHD</i>	Graft versus Host Disease
<i>HCT/Ps</i>	Human cells, tissues, or cellular or tissue-based products
<i>HLA</i>	Human leukocyte antigen
<i>HPC</i>	Hematopoietic progenitor cell
<i>IDE</i>	Investigational Device Exemption
<i>IND</i>	Investigational New Drug
<i>ISCT</i>	International Society for Cellular Therapy
<i>JACIE</i>	Joint Accreditation Committee – ISCT and EBMT
<i>MNC</i>	Mononuclear cell
<i>MSC</i>	Mesenchymal stromal cell or mesenchymal stem cell
<i>NC</i>	Nucleated cell
<i>NMDP</i>	National Marrow Donor Program
<i>OSHA</i>	Occupational Safety and Health Administration
<i>QM</i>	Quality management
<i>RBC</i>	Red blood cell
<i>Rh</i>	Rhesus system of human red cell antigens; used in this document to refer to the Rh(D) antigen only, unless otherwise specified
<i>SCTOD</i>	Stem Cell Therapeutics Outcomes Database
<i>SOP</i>	Standard operating procedure
<i>US</i>	United States
<i>USDA</i>	United States Department of Agriculture
<i>WMDA</i>	World Marrow Donor Association

A4 DEFINITIONS

Accompany: To go, be together with, or be available to the appropriate individual(s) electronically, but not affixed or attached. Written or printed information that must accompany a cellular therapy product must be in a sealed package with, or alternatively, be attached or affixed to, the cellular therapy product container.

Accreditation cycle: The period of time from the awarding of accreditation until its expiration as set, and subject to change, by FACT or JACIE. At publication of these Standards, this period is three (3) years for FACT-accredited programs and four (4) years for JACIE-accredited programs.

Advanced practice provider/professional: Physician Assistant, Nurse Practitioner, or other licensed Advanced Practitioner authorized by the applicable legal authority to provide primary patient care with physician oversight. Physician Assistants are formally trained and licensed or certified by the applicable authority to provide diagnostic, therapeutic, and preventive health care services with physician supervision. Advanced Nurse Practitioner includes certified nurse anesthetists, nurse practitioners, certified nurse midwives, and clinical nurse specialists.

Adverse event: Any unintended or unfavorable sign, symptom, abnormality, or condition temporally associated with an intervention that may or may not have a causal relationship with the intervention, medical treatment, or procedure. Adverse reaction is a type of adverse event.

Adverse reaction: A noxious and unintended response suspected or demonstrated to be caused by the collection or infusion of a cellular therapy product or by the product itself.

Affix: To adhere in physical contact with the cellular therapy product container.

Allogeneic: The biologic relationship between genetically distinct individuals of the same species.

Ambulatory setting: An environment of patient care outside of an inpatient hospital.

Apheresis: A medical technology in which the blood of a donor is separated into its component parts, the desired component is removed, and the remaining components are returned to the donor.

Aseptic technique: Practices designed to reduce the risk of microbial contamination of cellular therapy products, reagents, specimens, recipients, and/or donors.

Attach: To fasten securely to the cellular therapy product container by means of a tie tag or comparable alternative. Any information required to be attached to a cellular therapy product container may alternatively be affixed.

Attending physician: The physician who is responsible for the delivery and oversight of care provided to cellular therapy recipients and who meets all qualifications defined in these Standards.

Audit: Documented, systematic evaluation to determine whether approved policies or procedures have been properly implemented and are being followed.

Autologous: Derived from and intended for the same individual.

Available for distribution: The time at which the cellular therapy product may leave the control of the facility.

Biological product deviation: Any event associated with the manufacturing of a cellular therapy product, including testing, processing, packing, labeling, or storage, or with the holding or distribution of a licensed biological product, if that event meets the following criteria:

Either:

- Represents a deviation from current good manufacturing practice (or current good tissue practices), applicable regulations, applicable standards, or established specifications that may affect the safety, purity, or potency of that product; or
- Represents an unexpected or unforeseeable event that may affect the safety, purity, or potency of that product; and
 - Occurs in your facility or another facility under contract with you; and
 - Involves a distributed biological product.

Calibrate: To set measurement equipment against a known standard.

CD34: The 115 kD glycoprotein antigen, expressed by 1-2% of normal bone marrow mononuclear cells, that is defined by a specific monoclonal antibody (anti-CD34) using the standardized cluster of differentiation (CD) terminology.

Cellular therapy: The administration of products with the intent of providing effector cells in the treatment of disease or support of other therapy.

Cellular therapy product: Somatic cell-based product (e.g., mobilized HPC, mononuclear cells, cord blood cells, mesenchymal stromal cells, T cells, natural killer cells) that is procured from a donor and intended for processing and administration.

Chimeric antigen receptor: Artificial receptor that combines an antigen specificity domain coupled with an intracellular signaling domain typically expressed by an immune effector cell (e.g., T cell or natural killer cell).

Chimerism testing: A diagnostic test (e.g., molecular, cytogenetic, or FISH) conducted after allogeneic stem cell or bone marrow transplantation to detect the relative ratio of donor and recipient cell populations in the peripheral blood and/or bone marrow.

Circular of Information: An extension of container labels that includes the use of the cellular therapy product, indications, contraindications, side effects and hazards, dosage, and administration recommendations.

Clinical Program: An integrated medical team housed in a defined location that includes a Clinical Program Director and demonstrates common staff training, protocols, procedures, quality management systems, clinical outcome analysis, and regular interaction among clinical sites.

Collection: Any procedure for procuring and labeling a cellular therapy product regardless of technique or source.

Collection Facility: An entity providing the service of cellular therapy product collection.

Competency: Ability to adequately perform a specific procedure or task according to direction.

Complaint: Any written, oral, or electronic communication about a problem associated with a cellular therapy product or with a service related to the collection, processing, storage, distribution, or administration of a cellular therapy product.

Cord blood: The whole blood, including HPC, collected from placental and umbilical cord blood vessels after the umbilical cord has been clamped.

Corrective action: Action taken to eliminate the root causes of an existing discrepancy or other undesirable situation to prevent recurrence.

Courier: An individual trained and competent in transport or shipping of cellular therapy products.

Critical: The quality of any element employed in cellular therapy product manufacturing to potentially change the identity, purity, potency, or safety of the cellular therapy product if altered or omitted. "Element" includes, but is not limited to, materials, equipment, personnel, documents, or facilities. For example, DMSO is a critical reagent because omitting it from the freezing medium will cause loss of cells during freezing and thawing.

Current Good Tissue Practice: The methods used in, and the facilities and controls used for, the manufacture of cellular therapy products to prevent the introduction or transmission of communicable diseases, including all steps in collection, donor screening and testing, processing, storage, labeling, packaging, and distribution.

Current Good Manufacturing Practice: The set of current practices followed by entities producing drug and biologic products, including cellular therapy products, to ensure that the products

produced meet specific requirements for identity, strength, quality, and purity. In the US, cGMPs are enforced under Section 501(B) of the Federal Food, Drug, and Cosmetic Act (21USC351). Cellular therapy products that are extensively manipulated or that are used for non-homologous purposes are examples of products controlled under cGMP regulations. Similar requirements are delineated by the European Union as EU-GMP, and other countries such as United Kingdom, Australia, Canada, and Singapore have equally well-developed systems of regulations.

Cytokine release syndrome: A non-antigen-specific toxicity that occurs as a result of high-level immune activation. For example, a reaction from the release of cytokines from cells targeted by an antibody or immune effector cells.

Designee: An individual with appropriate education, experience, or expertise who is given the authority to assume a specific responsibility. The person appointing the designee retains ultimate responsibility.

Distribution: Any transportation or shipment of a cellular therapy product that has been determined to meet release criteria or urgent medical need requirements.

Donor: A person who is the source of cells or tissue for a cellular therapy product.

Donor advocate: An individual distinct from the cellular therapy recipient's primary treating physician whose main obligation is to protect the interests, well-being, and safety of the donor. The donor advocate may help the donor understand the process, the procedures, and the potential risks and benefits of donation.

Donor lymphocyte infusion (DLI): A type of therapy given to a patient who has already received an allogeneic hematopoietic progenitor cell transplant from the same donor. The donor lymphocytes may kill remaining cancer cells, facilitate full donor chimerism, or provide a source of antigen specific immunity. The DLI cell source may be whole blood, bone marrow, mononuclear cells collected by apheresis with or without mobilization, cord blood, or cellular subsets purified from these source products. The active cell type may include T lymphocytes, NK cells, or B lymphocytes. May also be referred to as donor leukocyte infusion.

Electronic record: A record or document consisting of any combination of text, graphics, or other data that is created, stored, modified, or transmitted in digital form by a computer.

Critical electronic record: Electronic record system under facility control that is used as a substitute for paper, to make decisions, to perform calculations, or to create or store information used in critical procedures.

Eligible: An allogeneic cellular therapy product donor for whom all the donor screening and testing have been completed in accordance with applicable laws and regulations and who has been determined to be free of risk factor(s) for relevant communicable diseases.

Engraftment: The reconstitution of recipient hematopoiesis with blood cells and platelets from a donor.

Errors and Accidents: Any unforeseen or unexpected deviations from applicable regulations, standards, or established specifications that may affect the safety, purity, or potency of a cellular therapy product.

Establish and maintain: A process to define, document in writing (including electronically), implement, follow, review, and, as needed, revise on an ongoing basis.

Exceptional release: Removal of a product that fails to meet specified criteria from quarantine or in-process status for distribution through a defined approval process.

Expansion: Growth of one or more cell populations in an *in vitro* culture system.

Extracorporeal photopheresis: An apheresis technique in which the patient's blood is collected into a specialized instrument, centrifuged, and separated into a leukocyte-depleted fraction (which is returned to the patient unmanipulated) and mononuclear "buffy coat" enriched plasma. The mononuclear cell-enriched fraction is incubated with 8-methoxypsoralen in the presence of ultraviolet A (UVA) radiation, and, upon completion of the procedure, reinfused into the patient.

Facility: A location where activities covered by these Standards are performed, including but not limited to determination of donor eligibility or suitability, product collection, processing, storage, distribution, issue, or administration.

Fellow: A physician who is in a training program in a medical specialty after completing residency, usually in a hospital or academic setting.

Fresh: A cellular therapy product that has never been cryopreserved.

Hematopoietic progenitor cells (HPC): A cellular therapy product that contains self-renewing and/or multi-potent stem cells capable of maturation into any of the hematopoietic lineages, lineage-restricted pluri-potent progenitor cells, and committed progenitor cells, regardless of tissue source (bone marrow, umbilical cord blood, peripheral blood, or other tissue source).

Hematopoietic progenitor cellular therapy: The administration of HPC product with the intent of providing effector functions in the treatment of disease or in support of other therapy.

Human cells, tissues, or cellular or tissue-based products (HCT/Ps): Articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient.

Immune effector cell: A cell that has differentiated into a form capable of modulating or effecting a specific immune response.

Ineligible: An allogeneic cellular therapy product donor for whom all the donor screening and testing has been completed in accordance with the applicable laws and regulations and who has identified risk factor(s) for relevant communicable diseases.

Institutional Review Board or Ethics Committee: A Board or Committee established by an institution in accordance with the regulations of the relevant governmental agency to review biomedical and behavioral research that involves human subjects and is conducted at or supported by that institution.

ISBT 128: A global standard for the identification, labeling, and information transfer of human blood, cell, tissue, and organ products.

Key position: A job category with responsibilities that significantly affect the provision of service or product safety and quality.

Label: Written, printed, or graphic material affixed to, attached to, or accompanying a cellular therapy product container or package. Labels must contain the information as defined by applicable standards, laws, and regulations.

Labeling: The process of creating and applying the cellular therapy product label, including confirmation of the presence and accuracy of the required information as defined in these Standards.

**Late Effect:* A health problem that occurs months or years after a disease is diagnosed or after treatment has been administered. Late effects may be caused by the primary disease or its treatment, and may include physical, mental, or social problems and/or secondary cancers.

Licensed health care professional: An individual who has completed a prescribed program of health-care related study and has been certified, registered, or licensed by the applicable authority in the jurisdiction in which he or she is performing services to perform duties within the scope of practice of that certificate, registration, or license.

Manipulation: An ex vivo procedure(s) that selectively removes, enriches, expands, or functionally alters the cellular therapy product.

Minimally Manipulated: Processing that does not alter the relevant biological characteristics of cells or tissues. For structural tissue, processing that does not alter the original relevant characteristics of the tissue relating to the tissue's utility for reconstruction, repair, or replacement.

More than minimally manipulated: Processing that does alter the relevant biological characteristics of cells or tissues. For structural tissue, processing that does alter the original relevant characteristics of the tissue relating to the tissue's utility for reconstruction, repair, or replacement. Products that are more than minimally manipulated are referred to as Advanced Therapy Medicinal Products in the European Union.

Unmanipulated: A cellular therapy product as obtained at collection and not subjected to any form of processing.

Manufacturing: Activity that includes, but is not limited to, any or all steps in the recovery, processing, packaging, labeling, storage, or distribution of any human cellular or tissue-based product, and/or the screening and testing of a cell or tissue donor.

Marrow collection: Harvest of bone marrow for transplantation to achieve hematopoietic reconstitution in the recipient or for further cellular therapy product manufacture. This does not include marrow aspirations intended for diagnostic purposes.

Materials management: An integrated process for planning and controlling all steps in the acquisition and use of goods or supply items (materials) used for the collection or processing of cellular therapy products to determine whether these materials are of adequate quality and quantity and available when needed. The materials management system combines and integrates the material selection, vendor evaluation, purchasing, expediting, storage, distribution, and disposition of materials.

Microbial: Related to infectious agents including bacterial and fungal organisms.

Negative selection: The manipulation of a cellular therapy product such that a specific cell population(s) is reduced.

New patient: An individual undergoing the specified type of transplantation (allogeneic, autologous, or syngeneic) for the first time in the Clinical Program, whether or not that patient was previously treated by that Clinical Program.

Orientation: An introduction to guide one in adjusting to new surroundings, employment, or activity.

Outcome analysis: The process by which the results of a therapeutic procedure are formally assessed.

Partial label: The minimum essential elements that must be affixed to all cellular therapy product containers at all times.

Physician-in-training: A physician in one of the postgraduate years of clinical training. Can be referred to as resident, fellow, registrar, or other designation, depending on the setting. The length of training varies according to the specialty.

Policy: A document that defines the scope of an organization, explains how the goals of the organization will be achieved, and/or serves as a means by which authority can be delegated.

Positive selection: The manipulation of a cellular therapy product such that a specific cell population(s) is enriched.

Potency: The therapeutic activity of a product as indicated by appropriate laboratory tests or adequately developed and controlled clinical data.

Preparative (conditioning) regimen: The treatment(s) used to prepare a patient for stem cell transplantation (e.g., chemotherapy, monoclonal antibody therapy, radiation therapy).

Preventive action: Action taken to eliminate the root cause and prevent occurrence of a potential discrepancy or other undesirable situation.

Procedure: A document that describes in detail the process or chronological steps taken to accomplish a specific task; work instructions; a procedure is more specific than a policy.

Process: A goal-directed, interrelated series of actions, events, or steps.

Process control: The standardization of processes in order to produce predictable output.

Process development: The series of procedures performed in order to develop a final process that achieves the required results.

Processing: All aspects of manipulation, cryopreservation, packaging, and labeling of cellular therapy products regardless of source, including microbial testing, preparation for administration or storage, and removal from storage. Processing does not include collection, donor screening, donor testing, storage, or distribution.

Processing Facility: A location where cellular therapy product processing activities are performed in support of the Clinical Program. A Processing Facility may be part of the same institution as the Clinical Program or may be part of another institution and perform these functions through contractual agreement.

Product identity: Unique title that identifies the cellular composition of the product in a way that can be directly tied back to a manufacturing entity or process (e.g., a protocol number, a commercial product title, or a site-defined unique identifier).

Product sample: A representative quantity of product removed from the cellular therapy product; an aliquot.

***Products:* The ISBT 128 Cellular Therapy Class product database name and definition (format: type of cells, comma, source of cells) for products collected from marrow, peripheral blood, and cord blood are as follows:

Subcategory 1: At collection the product code will describe the composition of the cell therapy products. It can be HPC, NC, or MNC. These products can be collected for direct infusion without further manipulation. HPCs may be further manipulated, but would retain the class name HPC if they are used as a source of hematopoietic progenitor cells. If these products undergo modification such as cryopreservation and thawing, the class will not change but the modification is added into the product description as an attribute.

CONCURRENT PLASMA, APHERESIS: Plasma collected from the donor as part of an apheresis cell collection procedure.

HPC, APHERESIS: A cell product containing hematopoietic progenitor cells obtained by apheresis.

HPC, CORD BLOOD: A cell product containing hematopoietic progenitor cells obtained from cord blood.

HPC, MARROW: A cell product containing hematopoietic progenitor cells obtained from bone marrow.

HPC, WHOLE BLOOD: A cell product containing hematopoietic progenitor cells obtained from whole blood.

MNC, APHERESIS: A cell product containing mononuclear cells obtained by apheresis.

MNC, UMBILICAL CORD TISSUE: A cell product containing mononuclear cells derived from umbilical cord tissue.

NC, CORD BLOOD: A cell product containing nucleated cells obtained from cord blood.

NC, MARROW: A cell product containing nucleated cells obtained from bone marrow.

NC, WHOLE BLOOD: A cell product containing nucleated cells obtained from whole blood.

Subcategory 2: After enumeration or manufacture/processing of the collected products, the product may be identified by the target cell population. These class names are based on desired cell population thought to be present in the product.

DC, APHERESIS: A cell product containing dendritic cells obtained by apheresis.

DC, CORD BLOOD: A cell product containing dendritic cells obtained from cord blood.

DC, MARROW: A cell product containing dendritic cells obtained from bone marrow.

DC, WHOLE BLOOD: A cell product containing dendritic cells obtained from whole blood.

INVESTIGATIONAL PRODUCT: A product for an investigational study that is accompanied by appropriate identifying study information. This class may be used for a specific product that may be part of a blinded comparison study. Products labeled as Investigational Product may include different doses or may include an active product or a placebo.

MALIGNANT CELLS, APHERESIS: A cell product containing malignant cells obtained by apheresis.

MALIGNANT CELLS, MARROW: A cell product containing malignant cells obtained from marrow.

MALIGNANT CELLS, WHOLE BLOOD: A cell product containing malignant cells obtained from whole blood.

MSC, CORD BLOOD: A cell product containing mesenchymal stromal cells derived from cord blood.

MSC, MARROW: A cell product containing mesenchymal stromal cells derived from bone marrow.

MSC, WHARTON'S JELLY: A cell product containing mesenchymal stromal cells derived from Wharton's jelly.

NK CELLS, APHERESIS: A cell product containing natural killer cells obtained by apheresis.

NK CELLS, CORD BLOOD: A cell product containing natural killer cells obtained from cord blood.

NK CELLS, MARROW: A cell product containing natural killer cells obtained from bone marrow.

NK CELLS, WHOLE BLOOD: A cell product containing natural killer cells obtained from whole blood.

T CELLS, APHERESIS: A cell product containing T cells obtained by apheresis.

T CELLS, CORD BLOOD: A cell product containing T cells obtained from cord blood.

T CELLS, MARROW: A cell product containing T cells obtained from bone marrow.

T CELLS, WHOLE BLOOD: A cell product containing T cells obtained from whole blood.

Proficiency test: A test to evaluate the adequacy of testing methods and equipment and the competency of personnel performing testing.

Protocol: A written document describing steps of a treatment or procedure in sufficient detail such that the treatment or procedure can be reproduced repeatedly without variation.

Purity: Relative freedom from extraneous matter in the finished product, whether or not harmful to the recipient or deleterious to the product.

Qualification: The establishment of confidence that equipment, supplies, and reagents function consistently within established limits.

Qualified person: A person who has received training, is experienced, and has documented competence in the task assigned.

Quality: Conformance of a product or process with pre-established specifications or standards.

Quality assurance: The actions, planned and performed, to provide confidence that all systems and elements that influence the quality of the product or service are working as expected or exceed expectations individually and collectively.

Quality assessment: The actions, planned and performed, to evaluate all systems and elements that influence the quality of the product or service.

Quality audit: A documented, independent inspection and review of a facility's quality management activities to verify, by examination and evaluation of objective evidence, the degree of compliance with those aspects of the quality program under review.

Quality control: A component of a quality management program that includes the activities and controls used to determine the accuracy and reliability of the establishment's personnel, equipment, reagents, and operations in the manufacturing of cellular therapy products, including testing and product release.

Quality improvement: The actions, planned and performed, to implement changes designed to improve the quality of a product or process.

Quality management: The integration of quality assessment, assurance, control, and improvement in cellular therapy activities.

Quality management plan: A written document that describes the systems in place to implement the quality management program.

Quality management program: An organization's comprehensive system of quality assessment, assurance, control, and improvement. A quality management program is designed to prevent, detect, and correct deficiencies that may adversely affect the quality of the cellular therapy product or increase the risk of communicable disease introduction or transmission. May also be referred to by other terms.

Quality Unit: The personnel responsible for Quality Management. Under good manufacturing practices, the quality unit must be independent from manufacturing, facility, and medical oversight and have final authority and oversight for the release of cellular therapy products.

Quarantine: The identification or storage of a cellular therapy product in a physically separate area clearly identified for such use, or through use of other procedures such as automated designation to prevent improper release of that product. Also refers to segregated storage of products known to contain infectious disease agents to reduce the likelihood of cross-contamination.

Record: Documented evidence that activities have been performed or results have been achieved. A record does not exist until the activity has been performed.

Release: Removal of a product from quarantine or in-process status when it meets specified criteria.

Release criteria: The requirements that must have been met before a cellular therapy product may leave the control of the Collection or Processing Facility.

Safety: Relative freedom from harmful effects to persons or products.

Shipping: The physical act of transferring a cellular therapy product within or between facilities. During shipping the product leaves the control of trained personnel at the distributing or receiving facility.

Standard Operating Procedures (SOP) Manual: A compilation of policies and procedures with written detailed instructions required to perform procedures. The SOP Manual may be in electronic or paper format.

Standards: The current edition of the *FACT-JACIE International Standards for Hematopoietic Cellular Therapy Product Collection, Processing, and Administration*, which may be referred to herein as "Standards" or "FACT-JACIE Standards."

Storage: Holding a cellular therapy product for future processing, distribution, or administration.

Suitable: Donor or recipient suitability refers to issues that relate to the general health or medical fitness of the donor or recipient to undergo the collection procedure or therapy.

Syngeneic: The biologic relationship between identical twins.

Target cell population: A cell population that is expected to be affected by an action or that is believed to be mainly responsible for a given activity.

Time of collection: The time of day at the end of the cellular therapy product collection procedure.

Trace: To follow the history of a process, product, or service by review of documents.

Track: To follow a process or product from beginning to end.

Transplantation: The infusion of allogeneic, autologous, or syngeneic HPC with the intent of providing transient or permanent engraftment in support of therapy of disease.

Transport: The physical act of transferring a cellular therapy product within or between facilities. During transportation the product does not leave the control of trained personnel at the transporting or receiving facility.

Unique: Being the only one of its kind or having only one use or purpose.

Unique identifier: A numeric or alphanumeric sequence used to designate a given cellular therapy product with reasonable confidence that it will not be used for another purpose.

Unplanned deviation: The action of departing from an established course or accepted standard without intent.

Urgent medical need: A situation in which no comparable cellular therapy product is available and the recipient is likely to suffer death or serious morbidity without the cellular therapy product.

Validation: Confirmation by examination and provision of objective evidence that particular requirements can consistently be fulfilled. A process is validated by establishing, by objective evidence, that the process consistently produces a cellular therapy product meeting its predetermined specifications.

Variance: A planned deviation from recommended practice or standard operating procedure approved as the best course of action when adherence to the established course or accepted standard was not feasible or possible .

Verification: The confirmation of the accuracy of something or that specified requirements have been fulfilled.

Verification typing: HLA typing performed on an independently collected sample with the purpose of verifying concordance of that typing assignment with the initial HLA typing assignment. Concordance does not require identical levels of resolution for the two sets of typing but requires the two assignments be consistent with one another.

Viability: Living cells as defined by dye exclusion, flow cytometry, or progenitor cell culture.

Written: Documentation in human readable form.

**A portion of the definition that can be located in the National Cancer Institute at the National Institutes of Health's NCI Dictionary of Cancer Terms: <http://www.cancer.gov/dictionary?Cdrid=390292>.*

***These definitions are as of the date of publication and use the current terminology as found in ISBT 128 Standard Terminology for Blood, Cellular Therapy, and Tissue Product Descriptions. Available at: www.iccbba.org > Subject Area > Cellular Therapy > Standard Terminology.*

CLINICAL PROGRAM STANDARDS**PART B**

- B1 General
- B2 Clinical Unit
- B3 Personnel
- B4 Quality Management
- B5 Policies and Procedures
- B6 Allogeneic and Autologous Donor Selection,
Evaluation, and Management
- B7 Recipient Care
- B8 Clinical Research
- B9 Data Management
- B10 Records

PART B: CLINICAL PROGRAM STANDARDS**B1: GENERAL**

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- B1.1 The Clinical Program shall consist of an integrated medical team that includes a Clinical Program Director(s) housed in a defined location(s).
- B1.1.1 The Clinical Program shall demonstrate common staff training, protocols, procedures, quality management systems, clinical outcome analysis, and regular interaction among all clinical sites.
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- B1.2 The Clinical Program shall use cell collection and processing facilities that meet FACT-JACIE Standards with respect to their interactions with the Clinical Program.
- B1.2.1 If cellular therapy products are received directly by the Clinical Program from a third-party provider, the following responsibilities at a minimum shall be defined in a written agreement:
- B1.2.1.1 Traceability and chain of custody of cellular therapy products.
- B1.2.1.2 Cellular therapy product storage and distribution.
- B1.2.1.3 Verification of cellular therapy product identity.
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- B1.3 The Clinical Program shall abide by all applicable laws and regulations.
- B1.3.1 The Clinical Program shall be licensed, registered, or accredited as required by the appropriate governmental authorities for the activities performed.
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- B1.4 The Clinical Program shall have a designated transplant team that includes a Clinical Program Director, a Quality Manager, and a minimum of one (1) additional attending transplant physician. The designated transplant team shall have been in place for at least twelve (12) months preceding initial accreditation.
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- B1.5 The Clinical Program shall comply with the Minimum Number of New Patients for Accreditation table in Appendix I.
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B2: CLINICAL UNIT

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- B2.1 There shall be a designated inpatient unit of appropriate location and adequate space and design that minimizes airborne microbial contamination.
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- B2.2 There shall be a designated outpatient care area that protects the patient from transmission of infectious agents and allows, as necessary, for appropriate patient isolation; confidential examination and evaluation; and administration of intravenous fluids, medications, or blood products.
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- B2.3 When the preparative regimen, cellular therapy product administration, or initial post-transplant care is provided in an ambulatory setting, there shall be a designated area with appropriate location and adequate space and design to minimize the risk of airborne microbial contamination.
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- B2.4 Facilities used by the Clinical Program shall be maintained in a clean, sanitary, and orderly manner.
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- B2.5 There shall be provisions for prompt evaluation and treatment by a transplant attending physician available on a 24-hour basis.
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- B2.6 There shall be written guidelines for communication, patient monitoring, and prompt transfer of patients to an intensive care unit, emergency department, or equivalent when appropriate.
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- B2.7 There shall be attending physician oversight if general medical physicians, physicians in training, or APPs provide care to transplant patients. The scope of responsibility of general medical physicians or APPs shall be defined.
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- B2.8 There shall be a pharmacy providing 24-hour availability of medications needed for the care of transplant patients.
- B2.8.1 Pharmacies shall have access to medications adequate to treat expected complications of immune effector cell administration, including cytokine release syndrome.
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- B2.9 There shall be access to renal support under the direction of nephrologists and trained personnel.
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- B2.10 There shall be 24-hour availability of CMV-appropriate and irradiated blood products needed for the care of transplant recipients.
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- B2.11 Clinical Programs performing allogeneic transplantation shall use HLA testing laboratories that are capable of carrying out DNA-based intermediate and high resolution HLA-typing and are appropriately accredited by the American Society for Histocompatibility and Immunogenetics (ASHI), European Federation for Immunogenetics (EFI), or other accrediting organizations providing histocompatibility services appropriate for hematopoietic cellular therapy transplant patients.
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- B2.12 Chimerism testing shall be performed in laboratories accredited for the techniques used.
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- B2.13 There shall be an intensive care unit or equivalent coverage available.
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- B2.14 The Clinical Program shall be operated in a manner designed to minimize risks to the health and safety of employees, patients, donors, visitors, and volunteers.
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- B2.15 The Clinical Program shall have a written safety manual that includes instructions for action in case of exposure, as applicable, to liquid nitrogen; communicable disease; and to chemical, biological, or radiological hazards.
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B3: PERSONNEL

B3.1 CLINICAL PROGRAM DIRECTOR

- B3.1.1 The Clinical Program Director shall be a physician appropriately licensed or certified to practice medicine in the jurisdiction in which the Clinical Program is located and shall have achieved specialist certification in one or more of the following specialties: Hematology, Medical Oncology, Pediatric Immunology, or Pediatric Hematology/Oncology. A physician trained prior to requirements for specialty training may serve as the Clinical Program Director if he/she has documented experience in the field of HPC transplantation extending over ten (10) years.

- B3.1.2 The Clinical Program Director shall have two (2) years of experience as an attending physician responsible for the direct clinical management of HPC transplant patients in the inpatient and outpatient settings.
- B3.1.3 The Clinical Program Director shall be responsible for administrative and clinical operations, including compliance with these Standards and applicable laws and regulations.
- B3.1.4 The Clinical Program Director shall be responsible for all elements of the design of the Clinical Program including quality management, the selection and care of patients and donors, and cell collection and processing, whether internal or contracted services.
- B3.1.5 The Clinical Program Director shall have oversight of the medical care provided by all members of the Clinical Program.
 - B3.1.5.1 The Clinical Program Director or designee shall be responsible for verifying the knowledge and skills of members of the Clinical Program once per accreditation cycle, at minimum.
- B3.1.6 The Clinical Program Director shall participate in ten (10) hours of educational activities related to cellular therapy annually at a minimum.
 - B3.1.6.1 Continuing education shall include, but is not limited to, activities related to the field of HPC transplantation.

B3.2 ATTENDING PHYSICIANS

- B3.2.1 Attending physicians shall be appropriately licensed to practice medicine in the jurisdiction of the Clinical Program and should be specialist certified or trained in one of the following specialties: Hematology, Medical Oncology, Immunology, or Pediatric Hematology/Oncology.
 - B3.2.1.1 Clinical Programs performing adult transplantation shall have at least one attending physician who has achieved specialist certification in Hematology, Medical Oncology, or Immunology.
 - B3.2.1.2 Clinical Programs performing pediatric transplantation shall have at least one attending physician who has achieved specialist certification in Pediatric Hematology/Oncology or Pediatric Immunology.
- B3.2.2 Attending physicians shall participate in ten (10) hours of educational activities related to cellular therapy annually at a minimum.
 - B3.2.2.1 Continuing education shall include, but is not limited to, activities related to the field of HPC transplantation.

B3.3 TRAINING FOR CLINICAL PROGRAM DIRECTORS AND ATTENDING PHYSICIANS

- B3.3.1 Attending physicians shall each have had a minimum total of one year of supervised training in the management of transplant patients in both inpatient and outpatient settings.
- B3.3.2 Clinical training and competency shall include the management of autologous and/or allogeneic transplant recipients, as applicable.
- B3.3.3 Clinical Program Directors and attending physicians shall have received specific training and maintain competency in each of the following areas as applicable to the Clinical Program's services:
 - B3.3.3.1 Indications for HPC transplantation.
 - B3.3.3.2 Selection of suitable recipients and appropriate preparative regimens.
 - B3.3.3.3 Allogeneic and autologous donor selection, evaluation, and management.
 - B3.3.3.4 Donor and recipient informed consent.
 - B3.3.3.5 Administration of ABO incompatible cellular therapy products.
 - B3.3.3.6 Administration of preparative regimens.
 - B3.3.3.7 Administration of growth factors for HPC mobilization and for post-transplant hematopoietic cell reconstitution.
 - B3.3.3.8 HPC product infusion and patient management.
 - B3.3.3.9 Management of neutropenic fever.
 - B3.3.3.10 Diagnosis and management of infectious and non-infectious pulmonary complications of transplantation.
 - B3.3.3.11 Diagnosis and management of fungal disease.
 - B3.3.3.12 Diagnosis and management of veno-occlusive disease of the liver and other causes of hepatic dysfunction.
 - B3.3.3.13 Management of thrombocytopenia and bleeding, including recognition of disseminated intravascular coagulation.
 - B3.3.3.14 Management of hemorrhagic cystitis.
 - B3.3.3.15 Management of mucositis, nausea, and vomiting.
 - B3.3.3.16 Monitoring and management of pain.
 - B3.3.3.17 Graft versus host disease.
 - B3.3.3.18 Cytokine release syndrome.

- B3.3.3.19 Tumor lysis syndrome.
- B3.3.3.20 Macrophage activation syndrome.
- B3.3.3.21 Cardiac dysfunction.
- B3.3.3.22 Renal dysfunction.
- B3.3.3.23 Respiratory distress.
- B3.3.3.24 Neurologic toxicity.
- B3.3.3.25 Anaphylaxis.
- B3.3.3.26 Infectious and noninfectious processes.
- B3.3.3.27 Diagnosis and management of HPC graft failure.
- B3.3.3.28 Evaluation of post-transplant cellular therapy outcomes.
- B3.3.3.29 Evaluation of late effects of allogeneic and autologous transplants, including cellular, pharmacologic, and radiation therapy.
- B3.3.3.30 Documentation and reporting for patients on investigational protocols.
- B3.3.3.31 Applicable regulations and reporting responsibilities for adverse events.
- B3.3.3.32 Palliative and end of life care.
- B3.3.4 Additional specific clinical training and competency required for physicians in Clinical Programs requesting accreditation for allogeneic HPC transplantation shall include:
 - B3.3.4.1 Identification, evaluation, and selection of HPC source, including use of donor registries.
 - B3.3.4.2 Donor eligibility determination.
 - B3.3.4.3 Methodology and implications of human leukocyte antigen (HLA) typing.
 - B3.3.4.4 Management of patients receiving ABO incompatible HPC products.
 - B3.3.4.5 Diagnosis and management of immunodeficiencies and opportunistic infections.
 - B3.3.4.6 Diagnosis and management of acute graft versus host disease.
 - B3.3.4.7 Diagnosis and management of chronic graft versus host disease.
- B3.3.5 The attending physicians shall be knowledgeable in the following procedures:
 - B3.3.5.1 HPC processing.

- B3.3.5.2 HPC cryopreservation.
- B3.3.5.3 Bone marrow harvest procedures.
- B3.3.5.4 Apheresis collection procedures.
- B3.3.5.5 Extracorporeal photopheresis for GVHD.
- B3.3.5.6 Washing and diluting of cellular therapy products.
- B3.3.5.7 Cellular therapy product administration.

B3.4 PHYSICIANS-IN-TRAINING

- B3.4.1 Physicians-in-training shall be licensed to practice in the jurisdiction of the Clinical Program and shall be limited to a scope of practice within the parameters of their training and licensure and shall be appropriately supervised.
- B3.4.2 Physicians-in-training shall receive specific training and develop competency in transplant-related skills, including but not limited to those listed in B3.3.3 and B3.3.4.

B3.5 ADVANCED PRACTICE PROVIDERS/PROFESSIONALS

- B3.5.1 APPs shall be licensed to practice in the jurisdiction of the Clinical Program and shall be limited to a scope of practice within the parameters of their training and licenses.
- B3.5.2 APPs shall have received specific training and maintain competency in the transplant-related skills that they routinely practice including but not limited to those listed in B3.3.3 and B3.3.4.
- B3.5.3 APPs shall participate in ten (10) hours of educational activities related to cellular therapy annually at a minimum.
 - B3.5.3.1 Continuing education shall include, but is not limited to, activities related to the field of HPC transplantation.

B3.6 CLINICAL TRANSPLANT TEAM

- B3.6.1 Clinical Programs performing pediatric transplantation shall have a transplant team trained in the management of pediatric patients.
- B3.6.2 The Clinical Program shall have access to licensed physicians who are trained and competent in marrow collection and utilize a marrow collection facility that meets these Standards.

- B3.6.3 The Clinical Program shall have access to personnel who are trained and competent in cellular therapy product collection by apheresis and utilize an apheresis collection facility that meets these Standards.

B3.7 NURSES

- B3.7.1 The Clinical Program shall have nurses formally trained and experienced in the management of patients receiving cellular therapy.
- B3.7.2 Clinical Programs treating pediatric patients shall have nurses formally trained and experienced in the management of pediatric patients receiving cellular therapy.
- B3.7.3 Training and competency shall include:
- B3.7.3.1 Hematology/oncology patient care, including an overview of the cellular therapy process.
 - B3.7.3.2 Administration of preparative regimens.
 - B3.7.3.3 Administration of blood products, growth factors, cellular therapy products, and other supportive therapies.
 - B3.7.3.4 Care interventions to manage cellular therapy complications, including, but not limited to, cytokine release syndrome, tumor lysis syndrome, cardiac dysfunction, respiratory distress, neurologic toxicity, renal and hepatic failure, disseminated intravascular coagulation, anaphylaxis, neutropenic fever, infectious and noninfectious processes, mucositis, nausea and vomiting, and pain management.
 - B3.7.3.5 Recognition of cellular therapy complications and emergencies requiring rapid notification of the transplant team.
 - B3.7.3.6 Palliative and end of life care.
- B3.7.4 There shall be written policies for all relevant nursing procedures, including, but not limited to:
- B3.7.4.1 Care of immunocompromised patients.
 - B3.7.4.2 Administration of preparative regimens.
 - B3.7.4.3 Administration of cellular therapy products.
 - B3.7.4.4 Central venous access device care.
 - B3.7.4.5 Administration of blood products.
 - B3.7.4.6 Detection and management of immune effector cellular therapy complications including, but not limited to, those listed in B3.7.3.4.

- B3.7.5 There shall be an adequate number of nurses experienced in the care of transplant patients.
- B3.7.6 There shall be a nurse/patient ratio satisfactory to manage the severity of the patients' clinical status.

B3.8 PHARMACISTS

- B3.8.1 Pharmacists shall be licensed to practice in the jurisdiction of the Clinical Program and shall be limited to a scope of practice within the parameters of their training and licensure.
- B3.8.2 Training shall include:
 - B3.8.2.1 An overview of hematology/oncology patient care, including the cellular therapy process, cytokine release syndrome, and neurological toxicities.
 - B3.8.2.2 Therapeutic drug monitoring, including, but not limited to, anti-infective agents, immunosuppressive therapy, anti-seizure medications, and anticoagulation.
 - B3.8.2.3 Monitoring for and recognition of drug/drug and drug/food interactions and necessary dose modifications.
 - B3.8.2.4 Recognition of medications that require adjustment for organ dysfunction.
- B3.8.3 Pharmacists shall be involved in the development and implementation of guidelines or SOPs related to the pharmaceutical management of cellular therapy recipients.
- B3.8.4 Designated transplant pharmacists shall participate in ten (10) hours of educational activities related to cellular therapy annually at a minimum.
 - B3.8.4.1 Continuing education shall include, but is not limited to, activities related to the field of HPC transplantation and cytokine release syndrome and neurological toxicities resulting from cellular therapies.

B3.9 CONSULTING SPECIALISTS

- B3.9.1 The Clinical Program shall have access to certified or trained consulting specialists and/or specialist groups from key disciplines who are capable of assisting in the management of patients requiring medical care, including, but not limited to:
 - B3.9.1.1 Surgery.
 - B3.9.1.2 Pulmonary medicine.
 - B3.9.1.3 Intensive care.

- B3.9.1.4 Gastroenterology.
- B3.9.1.5 Nephrology.
- B3.9.1.6 Infectious disease.
- B3.9.1.7 Cardiology.
- B3.9.1.8 Pathology.
- B3.9.1.9 Psychiatry.
- B3.9.1.10 Radiology.
- B3.9.1.11 Radiation oncology with experience in large-field (e.g., total body or total lymphoid) irradiation treatment protocols, if radiation therapy is administered.
- B3.9.1.12 Transfusion medicine.
- B3.9.1.13 Neurology.
- B3.9.1.14 Ophthalmology.
- B3.9.1.15 Obstetrics/Gynecology.
- B3.9.1.16 Dermatology.
- B3.9.1.17 Palliative and end of life care.

B3.9.2 A Clinical Program treating pediatric patients shall have consultants, as defined in B3.9.1, qualified to manage pediatric patients.

B3.10 QUALITY MANAGER

- B3.10.1 There shall be a Clinical Program Quality Manager to establish and maintain systems to review, modify, and approve all policies and procedures intended to monitor compliance with these Standards and/or the performance of the Clinical Program.
- B3.10.2 The Clinical Program Quality Manager should have a reporting structure independent of cellular therapy product manufacturing.
- B3.10.3 The Clinical Program Quality Manager shall participate in ten (10) hours of educational activities related to cellular therapy and/or quality management annually at a minimum.
 - B3.10.3.1 Continuing education shall include, but is not limited to, activities related to the field of HPC transplantation.

B3.11 SUPPORT SERVICES STAFF

B3.11.1 The Clinical Program shall have one or more designated staff with appropriate training and education to assist in the provision of pre-transplant patient evaluation, treatment, and post-transplant follow-up and care. Designated staff shall include:

B3.11.1.1 Dietary staff capable of providing dietary consultation regarding the nutritional needs of the recipient, including enteral and parenteral support, and appropriate dietary advice to avoid food-borne illness.

B3.11.1.2 Social Services staff.

B3.11.1.3 Psychology Services staff.

B3.11.1.4 Physical Therapy staff.

B3.11.1.5 Data Management staff sufficient to comply with B9.

B4: QUALITY MANAGEMENT

B4.1 There shall be an overall Quality Management Program that incorporates key performance data from clinical, collection, and processing facility quality management.

B4.1.1 The Clinical Program Director or designee shall have authority over and responsibility for ensuring that the Quality Management Program is effectively established and maintained.

B4.1.2 The Clinical Program Director shall annually review the effectiveness of the Quality Management Program.

B4.2 The Clinical Program shall establish and maintain a written Quality Management Plan.

B4.2.1 The Clinical Program Director or designee shall be responsible for the Quality Management Plan.

B4.2.2 The Clinical Program Director or designee shall review and report to staff quality management activities, at a minimum, quarterly.

B4.2.3 The Clinical Program Director or designee shall not have oversight of his/her own work if this person also performs other tasks in the Clinical Program.

B4.3 The Quality Management Plan shall include, or summarize and reference, an organizational chart of key positions and functions within the cellular therapy program, including clinical, collection, and processing.

B4.3.1 The Quality Management Plan shall include a description of how these key positions interact to implement the quality management activities.

B4.4 The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures addressing personnel requirements for each key position in the Clinical Program. Personnel requirements shall include at a minimum:

B4.4.1 A current job description for all staff.

B4.4.2 A system to document the following for all staff:

B4.4.2.1 Initial qualifications.

B4.4.2.2 New employee orientation.

B4.4.2.3 Initial training and retraining when appropriate for all procedures performed.

B4.4.2.4 Competency for each critical function performed.

B4.4.2.5 Continued competency at least annually.

B4.4.2.6 Continuing education.

B4.5 The Quality Management Plan shall include, or summarize and reference, a comprehensive system for document control and management.

B4.5.1 There shall be policies and procedures for development, approval, implementation, review, revision, and archival of all critical documents.

B4.5.2 There shall be a current listing of all active critical documents that shall comply with the document control system requirements. Controlled documents shall include at a minimum:

B4.5.2.1 Policies, protocols, and Standard Operating Procedures.

B4.5.2.2 Worksheets.

B4.5.2.3 Forms.

B4.5.2.4 Labels.

B4.5.3 The document control policy shall include:

B4.5.3.1 A standardized format for policies, procedures, worksheets, and forms.

- B4.5.3.2 Assignment of numeric or alphanumeric identifier and title to each document and document version regulated within the system.
 - B4.5.3.3 A procedure for document approval, including the approval date, signature of approving individual(s), and the effective date.
 - B4.5.3.4 A system to protect controlled documents from accidental or unauthorized modification.
 - B4.5.3.5 A system for document change control that includes a description of the change, the signature of approving individual(s), approval date(s), effective date, and archival date.
 - B4.5.3.6 Archived policies and procedures, the inclusive dates of use, and their historical sequence shall be maintained for a minimum of ten (10) years from archival or according to governmental or institutional policy, whichever is longer.
 - B4.5.3.7 A system for the retraction of obsolete documents to prevent unintended use.
 - B4.5.3.8 A system for record creation, assembly, review, storage, archival, and retrieval.
 - B4.5.4 There shall be a process for the regular review and assessment of records to identify recurring problems, potential points of failure, or need for process improvement.
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- B4.6 The Quality Management Plan shall include, or summarize and reference, policies and procedures for establishment and maintenance of written agreements with third parties whose services impact the clinical care of the recipient and/or donor.
 - B4.6.1 Agreements shall include the responsibility of the third-party facility performing any step in collection, processing, or testing to comply with applicable laws and regulations and these Standards.
 - B4.6.2 Agreements shall be dated and reviewed on a regular basis.
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- B4.7 The Quality Management Plan shall include, or summarize and reference, policies and procedures for documentation and review of outcome analysis and cellular therapy product efficacy to verify that the procedures in use consistently provide a safe and effective product.
 - B4.7.1 Criteria for cellular therapy product safety, product efficacy, and/or the clinical outcome shall be determined and shall be reviewed at regular time intervals.
 - B4.7.2 Both individual cellular therapy product data and aggregate data for each type of cellular therapy product and/or recipient type shall be evaluated.

- B4.7.3 Review of outcome analysis and/or product efficacy shall include at a minimum:
- B4.7.3.1 For HPC products intended for hematopoietic reconstitution, time to engraftment following product administration.
 - B4.7.3.2 For immune effector cells, an endpoint of clinical function as approved by the Clinical Program Director.
 - B4.7.3.3 Overall and treatment-related morbidity and mortality at thirty (30) days, one hundred (100) days, and one (1) year after cellular therapy product administration.
 - B4.7.3.4 Acute GVHD grade within one hundred (100) days after allogeneic transplantation.
 - B4.7.3.5 Chronic GVHD grade within one (1) year after allogeneic transplantation.
 - B4.7.3.6 Central venous catheter infection.
- B4.7.4 Data on outcome analysis and cellular therapy product efficacy, including adverse events related to the recipient, donor, and/or product, shall be provided in a timely manner to entities involved in the collection, processing, and/or distribution of the cellular therapy product.
- B4.7.5 The Clinical Program should achieve one-year survival outcome within or above the expected range when compared to national or international outcome data.
- B4.7.5.1 If expected one-year survival outcome is not met, the Clinical Program shall submit a corrective action plan.
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- B4.8 The Quality Management Plan shall include, or summarize and reference, policies, procedures, and a schedule for conducting, reviewing, and reporting audits of the Clinical Program's activities to verify compliance with elements of the Quality Management Program and operational policies and procedures.
- B4.8.1 Audits shall be conducted on a regular basis by an individual with sufficient expertise to identify problems, but who is not solely responsible for the process being audited.
 - B4.8.2 The results of audits shall be used to recognize problems, detect trends, identify improvement opportunities, implement corrective and preventive actions when necessary, and follow up on the effectiveness of these actions in a timely manner.
 - B4.8.3 Audits shall include, at a minimum:
 - B4.8.3.1 Periodic audit of the accuracy of clinical data.
 - B4.8.3.2 Annual audit of safety endpoints and immune effector cellular therapy toxicity management.

- B4.8.3.3 Periodic audit of the accuracy of data contained in the Transplant Essential Data Forms of the CIBMTR or the Minimum Essential Data-A Forms of the EBMT.
- B4.8.3.4 Annual audit of donor screening and testing.
- B4.8.3.5 Annual audit of verification of chemotherapy drug and dose against the prescription ordering system and the protocol.
- B4.8.3.6 Annual audit of management of cellular therapy products with positive microbial culture results.

B4.9 The Quality Management Plan shall include, or summarize and reference, policies and procedures on the management of cellular therapy products with positive microbial culture results that address at a minimum:

- B4.9.1 Notification of the recipient.
- B4.9.2 Recipient follow-up and outcome analysis.
- B4.9.3 Follow-up of the donor, if relevant.
- B4.9.4 Reporting to regulatory agencies if appropriate.
- B4.9.5 Criteria for the administration of cellular therapy products with positive microbial culture results.

B4.10 The Quality Management Plan shall include, or summarize and reference, policies and procedures for errors, accidents, biological product deviations, serious adverse events, and complaints, including the following activities at a minimum:

- B4.10.1 Detection.
- B4.10.2 Investigation.
 - B4.10.2.1 A thorough investigation shall be conducted by the Clinical Program in collaboration with the Collection Facility, Processing Facility, and other entities involved in the manufacture of the cellular therapy product, as appropriate.
 - B4.10.2.2 Investigations shall identify the root cause and a plan for short- and long-term corrective actions as warranted.
- B4.10.3 Documentation.

- B4.10.3.1 Documentation shall include a description of the event, the involved individuals and/or cellular therapy products, when the event occurred, when and to whom the event was reported, and the immediate actions taken.
 - B4.10.3.2 All investigation reports shall be reviewed in a timely manner by the Clinical Program Director or designee and the Quality Manager.
 - B4.10.3.3 Cumulative files of errors, accidents, biological product deviations, serious adverse events, and complaints shall be maintained.
 - B4.10.3.4 Cumulative files shall include written investigation reports containing conclusions, follow-up, corrective actions, and a link to the record(s) of the involved cellular therapy products, if applicable.
 - B4.10.4 Reporting.
 - B4.10.4.1 When it is determined that a cellular therapy product was responsible for an adverse reaction, the reaction and results of the investigation shall be reported to the recipient's physician, other facilities participating in the manufacturing of the cellular therapy product, registries, and governmental agencies as required by applicable laws and regulations.
 - B4.10.4.2 Errors, accidents, biological product deviations, and complaints shall be reported to other facilities performing cellular therapy product functions on the affected cellular therapy product and to the appropriate regulatory and accrediting agencies, registries, grant agencies, and IRBs or Ethics Committees.
 - B4.10.5 Corrective and preventive action.
 - B4.10.5.1 Appropriate corrective action shall be implemented if indicated, including both short-term action to address the immediate problem and long-term action to prevent the problem from recurring.
 - B4.10.5.2 Follow-up audits of the effectiveness of corrective actions shall be performed in a timeframe as indicated in the investigative report.
 - B4.10.6 There shall be a defined process to obtain feedback from patients or legally authorized representatives.
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- B4.11 The Quality Management Plan shall include, or summarize and reference, policies and procedures for cellular therapy product tracking and tracing that allow tracking from the donor to the recipient or final disposition and tracing from the recipient or final disposition to the donor.
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- B4.12 The Quality Management Plan shall include, or summarize and reference, policies and procedures for actions to take in the event the Clinical Program's operations are interrupted.

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- B4.13 The Quality Management Plan shall include, or summarize and reference, policies and procedures for qualification of supplies and validation and/or verification of the procedure for marrow collection to achieve the expected end-points, including viability of cells and cellular therapy product characteristics.
- B4.13.1 Critical reagents, supplies, equipment, and facilities used for the marrow collection procedure shall be qualified.
- B4.13.1.1 Qualification plans shall be reviewed and approved by the Clinical Program Director or designee.
- B4.13.2 The marrow collection procedure validation shall include:
- B4.13.2.1 An approved validation plan, including conditions to be validated.
- B4.13.2.2 Acceptance criteria.
- B4.13.2.3 Data collection.
- B4.13.2.4 Evaluation of data.
- B4.13.2.5 Summary of results.
- B4.13.2.6 Review and approval of the validation plan, results, and conclusion by the Marrow Collection Facility Director or designee and the Quality Manager or designee.
- B4.13.3 Changes to a process with the potential to affect the potency, viability, or purity of the cellular therapy product shall include evaluation of risk that the change might create an adverse impact anywhere in the operation and shall be validated or verified as appropriate.
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B5: POLICIES AND PROCEDURES

- B5.1 The Clinical Program shall establish and maintain policies and/or procedures addressing critical aspects of operations and management in addition to those required in B4. These documents shall include all elements required by these Standards and shall address at a minimum:
- B5.1.1 Recipient evaluation, selection, and treatment.
- B5.1.2 Donor and recipient confidentiality.
- B5.1.3 Donor and recipient consent.
- B5.1.4 Donor screening, testing, eligibility determination, selection, and management.

B5.1.5	Management of donors who require central venous access.
B5.1.6	Administration of the preparative regimen.
B5.1.7	Administration of blood products.
B5.1.8	Administration of HPC and other cellular therapy products, including products under exceptional release.
B5.1.9	Administration of ABO-incompatible products to include a description of the indication for and processing methods to be used for red cell or plasma reduction.
B5.1.10	Management of toxicities of immune effector cellular therapies, including cytokine release syndrome and central nervous system complications.
B5.1.11	Duration and conditions of cellular therapy product storage and indications for disposal.
B5.1.12	Hygiene and use of personal protective equipment.
B5.1.13	Disposal of medical and biohazard waste.
B5.1.14	Emergency and disaster plan, including the Clinical Program response.
B5.2	The Clinical Program shall maintain a detailed Standard Operating Procedures Manual that includes a listing of all current Standard Operating Procedures, including title, identifier, and version.
B5.3	Standard Operating Procedures shall be sufficiently detailed and unambiguous to allow qualified staff to follow and complete the procedures successfully. Each individual procedure shall include:
B5.3.1	A clearly written description of the objectives.
B5.3.2	A description of equipment and supplies used.
B5.3.3	Acceptable end-points and the range of expected results.
B5.3.4	A stepwise description of the procedure.
B5.3.5	Reference to other Standard Operating Procedures or policies required to perform the procedure.
B5.3.6	Age-specific issues where relevant.
B5.3.7	A reference section listing appropriate literature.

B5.3.8	Documented approval of each procedure by the Clinical Program Director or designated physician prior to implementation and every two years thereafter.
B5.3.9	Documented approval of each procedural modification by the Clinical Program Director or designated physician prior to implementation.
B5.3.10	Reference to a current version of orders, worksheets, reports, labels, and forms.
B5.4	Standard Operating Procedures relevant to processes being performed shall be readily available to the facility staff.
B5.5	Staff training and, if appropriate, competency shall be documented before performing a new or revised procedure.
B5.6	All personnel shall follow the Standard Operating Procedures related to their positions.
B5.7	Variances shall be pre-approved by the Clinical Program Director and reviewed by the Quality Manager.

B6: ALLOGENEIC AND AUTOLOGOUS DONOR SELECTION, EVALUATION, AND MANAGEMENT

B6.1	There shall be written criteria for allogeneic and autologous donor selection, evaluation, and management by trained medical personnel.
B6.1.1	Written criteria shall include criteria for the selection of allogeneic donors who are minors or elderly.
B6.1.2	Written criteria shall include criteria for the selection of allogeneic donors when more than one donor is available and suitable.
B6.1.3	Information regarding the donation process should be provided to the potential allogeneic donor prior to HLA typing.
B6.2	ALLOGENEIC AND AUTOLOGOUS DONOR INFORMATION AND CONSENT TO DONATE
B6.2.1	The collection procedure shall be explained in terms the donor can understand, and shall include the following information at a minimum:
B6.2.1.1	The risks and benefits of the procedure.

- B6.2.1.2 Tests and procedures performed on the donor to protect the health of the donor and the recipient.
 - B6.2.1.3 The rights of the donor or legally authorized representative to review the results of such tests according to applicable laws and regulations.
 - B6.2.1.4 Alternative collection methods.
 - B6.2.1.5 Protection of medical information and confidentiality.
 - B6.2.2 Interpretation and translation shall be performed by individuals qualified to provide these services in the clinical setting.
 - B6.2.3 Family members and legally authorized representatives should not serve as interpreters or translators.
 - B6.2.4 The donor shall have an opportunity to ask questions.
 - B6.2.5 The donor shall have the right to refuse to donate.
 - B6.2.5.1 The allogeneic donor shall be informed of the potential consequences to recipient of such refusal.
 - B6.2.6 Donor informed consent for the cellular therapy product donation shall be obtained and documented by a licensed health care professional familiar with the collection procedure.
 - B6.2.6.1 Informed consent from the allogeneic donor shall be obtained by a licensed health care professional who is not the primary health care professional overseeing care of the recipient.
 - B6.2.7 In the case of a minor donor, informed consent shall be obtained from the donor's legally authorized representative in accordance with applicable laws and regulations and shall be documented.
 - B6.2.8 The allogeneic donor shall give informed consent and authorization prior to release of the donor's health or other information to the recipient's physician and/or the recipient.
 - B6.2.9 The donor shall be informed of the policy for cellular therapy product discard or disposal, including actions taken when an intended recipient no longer requires the cellular therapy product.
 - B6.2.10 Documentation of consent shall be available to the Collection Facility staff prior to the collection procedure.
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- B6.3 ALLOGENEIC AND AUTOLOGOUS DONOR SUITABILITY FOR CELLULAR THERAPY PRODUCT COLLECTION
- B6.3.1 There shall be criteria and evaluation policies and procedures in place to protect the safety of donors during the process of cellular therapy product collection.

- B6.3.1.1 Any abnormal finding shall be reported to the prospective donor with documentation in the donor record of recommendations made for follow-up care.
- B6.3.1.2 Allogeneic donor suitability shall be evaluated by a licensed health care professional who is not the primary health care professional overseeing care of the recipient.
- B6.3.1.3 Autologous donors shall be tested as required by applicable laws and regulations.
- B6.3.2 The risks of donation shall be evaluated and documented, including:
 - B6.3.2.1 Possible need for central venous access.
 - B6.3.2.2 Mobilization therapy for collection of HPC, Apheresis.
 - B6.3.2.3 Anesthesia for collection of HPC, Marrow.
- B6.3.3 The donor should be evaluated for the risk of hemoglobinopathy prior to administration of the mobilization regimen.
- B6.3.4 A pregnancy test shall be performed for all female donors with childbearing potential within seven (7) days prior to starting the donor mobilization regimen and, as applicable, within seven (7) days prior to the initiation of the recipient's preparative regimen.
- B6.3.5 Laboratory testing of all donors shall be performed by a laboratory that is accredited, registered, or licensed in accordance with applicable laws and regulations.
- B6.3.6 The Clinical Program shall inform the Collection Facility and Processing Facility of donor test results or if any testing was not performed.
- B6.3.7 There shall be a written order from a physician specifying, at a minimum, timing and goals of collection and processing.
- B6.3.8 Issues of donor health that pertain to the safety of the collection procedure shall be communicated in writing to the Collection Facility staff prior to collection.
- B6.3.9 Collection from a donor who does not meet Clinical Program collection safety criteria shall require documentation of the rationale for his/her selection by the recipient's physician.
- B6.3.10 There shall be a policy for follow-up of donors that includes routine management and the management of collection-associated adverse events.

B6.4 ADDITIONAL REQUIREMENTS FOR ALLOGENEIC DONORS

- B6.4.1 A donor advocate shall be available to represent allogeneic donors who are minors or who are mentally incapacitated, as those terms as defined by applicable laws.
- B6.4.2 Allogeneic donor infectious disease testing shall be performed using donor screening tests approved or cleared by the governmental authority.
- B6.4.3 Allogeneic donors and allogeneic recipients shall be tested for ABO group and Rh type using two independently collected samples. Discrepancies shall be resolved and documented prior to issue of the cellular therapy product.
- B6.4.4 A red cell antibody screen shall be performed on allogeneic recipients.
- B6.4.5 Allogeneic donors shall be evaluated for risk factors that might result in disease transmission from the cellular therapy product by medical history, physical examination, examination of relevant medical records, and laboratory testing.
- B6.4.6 The medical history for allogeneic donors shall include at least the following:
 - B6.4.6.1 Vaccination history.
 - B6.4.6.2 Travel history.
 - B6.4.6.3 Blood transfusion history.
 - B6.4.6.4 Questions to identify persons at high risk for transmission of communicable disease as defined by the applicable governmental authority.
 - B6.4.6.5 Questions to identify persons at risk of transmitting inherited conditions.
 - B6.4.6.6 Questions to identify persons at risk of transmitting a hematological or immunological disease.
 - B6.4.6.7 Questions to identify a past history of malignant disease.
 - B6.4.6.8 The allogeneic donor shall confirm that all the information provided is true to the best of his/her knowledge.
- B6.4.7 Allogeneic donors shall be tested for evidence of clinically relevant infection by the following communicable disease agents using tests required by applicable laws and regulations:
 - B6.4.7.1 Human immunodeficiency virus, type 1.
 - B6.4.7.2 Human immunodeficiency virus, type 2.
 - B6.4.7.3 Hepatitis B virus.
 - B6.4.7.4 Hepatitis C virus.
 - B6.4.7.5 *Treponema pallidum* (syphilis).

- B6.4.8 If required by applicable laws and regulations, allogeneic donors shall also be tested for evidence of clinically relevant infection by the following disease agents:
- B6.4.8.1 Human T cell lymphotropic virus I.
 - B6.4.8.2 Human T cell lymphotropic virus II.
 - B6.4.8.3 West Nile Virus.
 - B6.4.8.4 *Trypanosoma cruzi* (Chagas Disease).
- B6.4.9 Blood samples for testing for evidence of clinically relevant infection shall be drawn and tested within timeframes required by applicable laws and regulations.
- B6.4.9.1 Blood samples for communicable disease testing from allogeneic HPC donors shall be obtained within thirty (30) days prior to collection.
 - B6.4.9.2 For viable, lymphocyte rich cells, including mononuclear cells and other cellular therapy products, blood samples from allogeneic donors shall be obtained within seven (7) days prior to or after collection in the U.S. or 30 days prior to collection in European Union member states.
- B6.4.10 Allogeneic donors shall be tested for CMV (unless previously documented to be positive).
- B6.4.11 Additional tests shall be performed as required to assess the possibility of transmission of other infectious and non-infectious diseases.
- B6.4.12 Allogeneic donors and recipients shall be tested for HLA antigens by a laboratory accredited by ASHI, EFI, or other appropriate organization. Typing shall include at a minimum HLA-A, B, and DRB1 type for all allogeneic donors and also HLA-C type for unrelated allogeneic donors and related allogeneic donors other than siblings.
- B6.4.12.1 DNA high resolution molecular typing shall be used for DRB1 typing.
 - B6.4.12.2 Verification typing shall be performed on the selected allogeneic donor using an independently collected sample. Results shall be confirmed prior to administration of the preparative regimen.
 - B6.4.12.3 There shall be a procedure to confirm the identity of cord blood units if verification typing cannot be performed on attached segments.
 - B6.4.12.4 There shall be a policy for anti-HLA antibody testing for mismatched donors and recipients.
- B6.4.13 Allogeneic donor eligibility, as defined by applicable laws and regulations, shall be determined by a physician after history, exam, medical record review, and testing. The donor eligibility determination shall be documented in the recipient's medical record before the recipient's preparative regimen is initiated and before the allogeneic donor begins the mobilization regimen.
- B6.4.14 Records required for donor eligibility determination shall be in English or translated into English when crossing international borders.

- B6.4.15 The use of an ineligible allogeneic donor, or an allogeneic donor for whom donor eligibility determination is incomplete, shall require documentation of the rationale for his/her selection by the transplant physician, urgent medical need documentation, and the informed consent of the donor and the recipient.
- B6.4.16 Allogeneic donor eligibility shall be communicated in writing to the Collection and Processing Facilities.
- B6.4.17 There shall be a policy covering the creation and retention of allogeneic donor records.
 - B6.4.17.1 Allogeneic donor records shall include donor eligibility determination, including the name of the responsible person who made the determination and the date of the determination.

B7: RECIPIENT CARE

- B7.1 Recipient informed consent for the cellular therapy shall be obtained and documented by a licensed health care professional familiar with the proposed therapy.
 - B7.1.1 The Clinical Program shall provide information regarding the risks and benefits of the proposed cellular therapy.
- B7.2 The attending physician shall verify the availability and suitability of a donor or cellular therapy product prior to initiating the recipient's preparative regimen.
 - B7.2.1 The Clinical Program shall notify the Processing Facility prior to requesting a cellular therapy product from a cord blood bank, registry, or other facility.
- B7.3 Records shall be made concurrently with each step of recipient care in such a way that all steps may be accurately traced.
 - B7.3.1 Records shall identify the person immediately responsible for each significant step, including dates and times (where appropriate) of various steps.
- B7.4 There shall be a policy addressing safe administration of the preparative regimen.
 - B7.4.1 The treatment orders shall include the patient height and weight, specific dates of administration, daily doses (if appropriate), and route of administration of each agent.

- B7.4.2 Preprinted orders or electronic equivalent shall be used for protocols and standardized regimens. These orders shall be verified and documented by an attending physician.
- B7.4.3 The pharmacist preparing the drug shall verify and document the doses against the protocol or standardized regimen listed on the orders.
- B7.4.4 Prior to administration of the preparative regimen, one (1) qualified person using a validated process or two (2) qualified people shall verify and document the drug and dose in the bag or pill against the orders and the protocol, and the identity of the patient to receive the therapy.
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- B7.5 There shall be a policy addressing safe administration of radiation therapy.
- B7.5.1 There shall be a consultation with a radiation oncologist prior to initiation of therapy if radiation treatment is used in the preparative regimen.
- B7.5.2 The patient's diagnosis, relevant medical history including pre-existing co-morbid conditions, and proposed preparative regimen shall be made available to the consulting radiation oncologist in writing.
- B7.5.3 A documented consultation by a radiation oncologist shall address any prior radiation treatment the patient may have received, any other factors that may increase the toxicity of the radiation, and include a plan for delivery of radiation therapy.
- B7.5.4 Prior to administration of each dose of radiation therapy, the dose shall be verified and documented as per radiation therapy standards.
- B7.5.5 A final report of the details of the radiation therapy administered shall be documented in the patient medical record.
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- B7.6 There shall be a policy addressing safe administration of cellular therapy products.
- B7.6.1 There shall be a policy for determining the appropriate volume and the appropriate dose of red blood cells, cryoprotectants, and other additives.
- B7.6.2 There shall be a policy for volume of ABO-incompatible red cells in allogeneic cellular therapy products.
- B7.6.3 There shall be consultation with the Processing Facility regarding cord blood preparation for administration.
- B7.6.3.1 Cord blood units that have not been red cell reduced prior to cryopreservation shall be washed prior to administration.
- B7.6.3.2 Cord blood units that have been red cell reduced prior to cryopreservation should be diluted or washed prior to administration.

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- B7.6.4 Two (2) qualified persons shall verify the identity of the recipient and the product and the order for administration prior to the administration of the cellular therapy product.
- B7.6.5 For transplants utilizing cellular therapy products from more than one donor, the first cellular therapy product shall be administered safely prior to administration of the second cellular therapy product.
- B7.6.6 There shall be documentation in the recipient's medical record of the administered cellular therapy product unique identifier, initiation and completion times of administration, and any adverse events related to administration.
- B7.6.7 A circular of information for cellular therapy products shall be available to staff.
- B7.6.8 There should be policies and procedures in place for monitoring by appropriate specialists of recipients for post-transplant late effects, including at a minimum endocrine and reproductive function, osteoporosis, cardiovascular risk factors, respiratory function, chronic renal impairment, secondary cancers, and the growth and development of pediatric patients.
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- B7.7 ADDITIONAL REQUIREMENTS FOR ALLOGENEIC TRANSPLANTATION
- B7.7.1 Allogeneic recipients should be assessed regularly for evidence of acute GVHD using an established staging and grading system.
- B7.7.2 Allogeneic recipients should be assessed regularly for evidence of chronic GVHD using an established staging and grading system.
- B7.7.3 There should be policies and procedures in place for allogeneic recipient post-transplant vaccination schedules and indications.
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- B7.8 The Clinical Program shall refer planned discharges and post-transplant care to facilities and health care professionals adequate for post-transplant care.
- B7.8.1 The Clinical Program shall provide or secure oversight of care that meets applicable standards.
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- B7.9 There shall be a policy addressing indications for and safe administration of ECP if utilized by the Clinical Program.
- B7.9.1 There shall be a consultation with the facility or physician that performs ECP prior to initiation of therapy.
- B7.9.2 Before ECP is undertaken, there shall be a written therapy plan from an attending physician specifying the patient's diagnosis and GVHD grade, involved organs, timing of the procedure, and any other factors that may affect the safe administration of ECP.
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- B7.9.3 A report of the details of ECP administered, including an assessment of the response, shall be documented in the recipient's medical record.
- B7.9.4 The facility performing ECP shall follow written procedures appropriate for the clinical condition of the patient.
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- B7.10 There shall be policies and procedures addressing the administration of immune effector cells and management of complications.
- B7.10.1 There shall be a consultation with the referring physician prior to initiation of immune effector cellular therapy to review the goal and plan of the treatment.
- B7.10.2 There shall be regular assessment of the recipient to detect complications, including cytokine release syndrome and neurologic dysfunction.
- B7.10.3 There shall be a written plan for rapid escalation of care, increased intensity of monitoring, and relevant workup to address complications.
- B7.10.4 Communication to the clinical staff, intensive care unit, emergency department, and pharmacy shall be timely.
- B7.10.5 The Clinical Program shall have written guidelines for management of complications, including the use of cytokine-blocking agents and corticosteroid administration.
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B8: CLINICAL RESEARCH

- B8.1 Clinical Programs shall have formal review of investigational treatment protocols and patient consent forms by a process that is approved under institutional policies and applicable laws and regulations.
- B8.1.1 Those Clinical Programs utilizing investigational treatment protocols shall have in place a pharmacy equipped for research activities, including a process for tracking, inventory, and secured storage of investigational drugs.
- B8.1.2 There shall be a process to manage investigational cellular therapy products.
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- B8.2 Documentation for all research protocols performed by the Clinical Program shall be maintained in accordance with institutional policies and applicable laws and regulations, including audits; approvals by the Institutional Review Board, Ethics Committee, or equivalent; correspondence with regulatory agencies; and any adverse events.
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- B8.3 For clinical research, informed consent shall be obtained from each research subject or legally authorized representative, in language he or she can understand, and under circumstances that minimize the possibility of coercion or undue influence.
- B8.3.1 The research subject or legally authorized representative shall be given the opportunity to ask questions and to have his/her questions answered to his/her satisfaction, and to withdraw from the research without prejudice.
- B8.3.2 Informed consent for a research subject shall contain the following elements at a minimum and comply with applicable laws and regulations:
- B8.3.2.1 An explanation of the research purposes, a description of the procedures to be followed, and the identification of investigational procedures.
- B8.3.2.2 The expected duration of the subject's participation.
- B8.3.2.3 A description of the reasonably expected risks, discomforts, benefits to the subject and others, and alternative procedures.
- B8.3.2.4 A statement of the extent to which confidentiality will be maintained.
- B8.3.2.5 An explanation of the extent of compensation for injury.
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- B8.4 There shall be a process in place to address the disclosure of any issues that may represent a conflict of interest in clinical research.
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B9: DATA MANAGEMENT

- B9.1 The Clinical Program shall collect all the data necessary to complete the Transplant Essential Data Forms of the CIBMTR or the Minimum Essential Data-A forms of the EBMT.
- B9.1.1 Clinical Programs shall submit the data specified in B9.1 to a national or international database if required by applicable laws and regulations.
- B9.1.2 Clinical Programs should submit the data specified in B9.1 for allogeneic and autologous transplants to a national or international database.
- B9.1.3 Clinical Programs should collect the data specified in B9.1 for all patients for at least one year following administration of the cellular therapy product.
- B9.2 The Clinical Program should collect all the data elements included in the applicable CIBMTR Cellular Therapy forms or EBMT forms.
- B9.3 The Clinical Program shall define staff responsible for collecting data and, as appropriate, reporting data to institutional repositories and CIBMTR or EBMT.

B10: RECORDS

B10.1 Clinical Program records related to quality control, personnel training and competency, facility maintenance, facility management, complaints, or other general facility issues shall be retained for a minimum of ten (10) years by the Clinical Program, or longer in accordance with applicable laws and regulations, or by a defined program or institutional policy.

B10.1.1 Employee records shall be maintained in a confidential manner and as required by applicable laws and regulations.

B10.2 Patient and donor records including, but not limited to, consents and records of care, shall be maintained in a confidential manner as required by applicable laws and regulations for a minimum of ten (10) years after the administration of the cellular therapy product, or, if not known, ten (10) years after the date of the distribution, disposition, or expiration, whichever requires the longest maintenance period.

B10.3 Research records shall be maintained in a confidential manner as required by applicable laws and regulations for a minimum of ten (10) years after the administration, distribution, disposition, or expiration of the cellular therapy product, whichever is latest.

B10.4 RECORDS IN CASE OF DIVIDED RESPONSIBILITY

B10.4.1 If two (2) or more facilities participate in the collection, processing, or administration of the cellular therapy product, the records of each facility shall show plainly the extent of its responsibility.

B10.4.2 The Clinical Program shall furnish outcome data, in so far as they concern the safety, purity, or potency of the cellular therapy product involved, to other facilities involved in the collection or processing of the cellular therapy product.

MARROW COLLECTION FACILITY STANDARDS**PART CM**

CM1	General
CM2	Marrow Collection Facility
CM3	Personnel
CM4	Quality Management
CM5	Policies and Procedures
CM6	Allogeneic and Autologous Donor Evaluation and Management
CM7	Coding and Labeling of Cellular Therapy Products
CM8	Process Controls
CM9	Cellular Therapy Product Storage
CM10	Cellular Therapy Product Transportation and Shipping
CM11	Records
CM12	Direct Distribution to Clinical Program

PART CM: MARROW COLLECTION FACILITY STANDARDS**CM1: GENERAL**

CM1.1 These Standards apply to the Marrow Collection Facility for collection activities of all cellular therapy products collected from living donors.

CM1.2 The Marrow Collection Facility shall use cell processing facilities that meet FACT-JACIE Standards with respect to their interactions with the Marrow Collection Facility.

CM1.3 The Marrow Collection Facility shall abide by all applicable laws and regulations.

CM1.3.1 The Marrow Collection Facility shall be licensed, registered, or accredited as required by the appropriate governmental authorities for the activities performed.

CM1.4 The Marrow Collection Facility shall have a Marrow Collection Facility Medical Director, a Quality Manager, and at least one (1) additional designated staff member. This team shall have been in place and performing cellular therapy product collections for at least twelve (12) months preceding initial accreditation.

CM1.5 A minimum of one (1) marrow collection procedure shall have been performed in the twelve (12) month period immediately preceding facility accreditation, and a minimum average of one (1) marrow collection procedure per year shall be performed within the accreditation cycle.

CM2: MARROW COLLECTION FACILITY

CM2.1 There shall be appropriate designated areas for collection of cellular therapy products, for collected products, and for storage of supplies, reagents, and equipment.

CM2.1.1 The Marrow Collection Facility shall be divided into defined areas of adequate size to prevent improper labeling, mix-ups, contamination, or cross-contamination of cellular therapy products.

CM2.1.2 There shall be a process to control storage areas to prevent mix-ups, contamination, and cross-contamination of all cellular therapy products prior to release or distribution.

CM2.1.3 There shall be a process for confidential donor examination and evaluation.

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- CM2.2 The Marrow Collection Facility shall provide adequate lighting, ventilation, and access to sinks to prevent the introduction, transmission, or spread of communicable disease.
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- CM2.3 Critical Marrow Collection Facility parameters that may affect cellular therapy product viability, integrity, contamination, sterility, or cross-contamination during collection, including temperature and humidity at a minimum, shall be assessed for risk to the cellular therapy product.
- CM2.3.1 Critical facility parameters identified to be a risk to the cellular therapy product shall be controlled, monitored, and recorded.
-
- CM2.4 Marrow Collection Facility parameters and environmental conditions shall be controlled to protect the safety and comfort of patients, donors, and personnel.
-
- CM2.5 The Marrow Collection Facility shall document facility cleaning and sanitation and maintain order sufficient to achieve adequate conditions for operations.
-
- CM2.6 There shall be adequate equipment and materials for the procedures performed.
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- CM2.7 There shall be access to an intensive care unit and/or emergency services.
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- CM2.8 The Marrow Collection Facility shall be operated in a manner designed to minimize risks to the health and safety of employees, patients, donors, visitors, and volunteers.
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- CM2.9 The Marrow Collection Facility shall have a written safety manual that includes instructions for action in case of exposure, as applicable, to communicable disease and to chemical, biological, or radiological hazards.
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CM3: PERSONNEL

CM3.1 MARROW COLLECTION FACILITY MEDICAL DIRECTOR

- CM3.1.1 There shall be a Marrow Collection Facility Medical Director who is a licensed physician with postgraduate training in cell collection and/or transplantation.
- CM3.1.2 The Marrow Collection Facility Medical Director or designee shall be responsible for the following elements:
 - CM3.1.2.1 All technical procedures.
 - CM3.1.2.2 Performance of the marrow collection procedure.
 - CM3.1.2.3 Supervision of staff.
 - CM3.1.2.4 Administrative operations.
 - CM3.1.2.5 The medical care of allogeneic and/or autologous donors undergoing marrow collection.
 - CM3.1.2.6 Pre-collection evaluation of allogeneic and/or autologous donors at the time of donation.
 - CM3.1.2.7 Care of any complications resulting from the collection procedure.
 - CM3.1.2.8 The Quality Management Program, including compliance with these Standards and other applicable laws and regulations.
- CM3.1.3 The Marrow Collection Facility Medical Director shall have at least one year experience in cellular therapy product collection procedures.
- CM3.1.4 The Marrow Collection Facility Medical Director shall have performed or supervised at least ten (10) marrow collection procedures within his/her career.
- CM3.1.5 The Marrow Collection Facility Medical Director shall participate in ten (10) hours of educational activities related to cellular therapy annually at a minimum.
 - CM3.1.5.1 Continuing education shall include, but is not limited to, activities related to the field of HPC transplantation and marrow collection.

CM3.2 QUALITY MANAGER

- CM3.2.1 There shall be a Marrow Collection Facility Quality Manager to establish and maintain systems to review, modify, and approve all policies and procedures intended to monitor compliance with these Standards and/or the performance of the Marrow Collection Facility.

CM3.2.2 The Marrow Collection Facility Quality Manager shall participate in ten (10) hours of educational activities related to cellular therapy, cell collection, and/or quality management annually at a minimum.

CM3.2.2.1 Continuing education shall include, but is not limited to, activities related to the field of HPC transplantation.

CM3.3 STAFF

CM3.3.1 The Marrow Collection Facility shall have access to licensed health care professionals who are trained and competent in marrow collection.

CM3.3.2 The number of trained collection personnel shall be adequate for the number of procedures performed and shall include a minimum of one designated trained individual with an identified trained backup to maintain sufficient coverage.

CM3.3.3 For Marrow Collection Facilities collecting cellular therapy products from pediatric donors, physicians and collection staff shall have documented training and experience in performing these procedures.

CM4: QUALITY MANAGEMENT

CM4.1 The Marrow Collection Facility shall comply with B4 if it operates independently of a Clinical Program.

CM5: POLICIES AND PROCEDURES

CM5.1 The Marrow Collection Facility shall establish and maintain policies and/or procedures addressing critical aspects of operations and management in addition to those required in CM4. These documents shall include all elements required by these Standards and shall address at a minimum:

CM5.1.1 Donor and recipient confidentiality.

CM5.1.2 Donor consent.

CM5.1.3 Donor screening, testing, eligibility determination, and management.

CM5.1.4 Cellular therapy product collection.

CM5.1.5 Prevention of mix-ups and cross-contamination.

CM5.1.6 Labeling (including associated forms and samples).

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- CM5.1.7 Cellular therapy product expiration dates.
 - CM5.1.8 Cellular therapy product storage.
 - CM5.1.9 Release and exceptional release.
 - CM5.1.10 Transportation and shipping, including methods and conditions to be used for distribution to external facilities.
 - CM5.1.11 Critical equipment, reagent, and supply management including recalls and corrective actions in the event of failure.
 - CM5.1.12 Hygiene and use of personal protective attire.
 - CM5.1.13 Emergency and disaster plan related to the marrow collection procedure.
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- CM5.2 The Marrow Collection Facility shall comply with B5.2 if it operates independently of a Clinical Program.
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- CM5.3 Standard Operating Procedures required in CM5.1 shall be sufficiently detailed and unambiguous to allow qualified staff to follow and complete the procedures successfully. Each individual procedure shall include:
- CM5.3.1 A clearly written description of the objectives.
 - CM5.3.2 A description of equipment and supplies used.
 - CM5.3.3 Acceptable end-points and the range of expected results.
 - CM5.3.4 A stepwise description of the procedure.
 - CM5.3.5 Age-specific issues where relevant.
 - CM5.3.6 Reference to other Standard Operating Procedures or policies required to perform the procedure.
 - CM5.3.7 A reference section listing appropriate literature.
 - CM5.3.8 Documented approval of each procedure by the Marrow Collection Facility Medical Director prior to implementation and every two years thereafter.
 - CM5.3.9 Documented approval of each procedural modification by the Marrow Collection Facility Medical Director or designated physician prior to implementation.
 - CM5.3.10 Reference to a current version of orders, worksheets, reports, labels, and forms.
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- CM5.4 Standard Operating Procedures relevant to processes being performed shall be readily available to the facility staff.
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- CM5.5 Staff training and, if appropriate, competency shall be documented before performing a new or revised procedure.
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- CM5.6 All personnel shall follow the Standard Operating Procedures related to their positions.
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- CM5.7 Variances shall be pre-approved by the Marrow Collection Facility Medical Director, and reviewed by the Quality Manager.
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CM6: ALLOGENEIC AND AUTOLOGOUS DONOR EVALUATION AND MANAGEMENT

- CM6.1 There shall be written criteria for allogeneic and autologous donor evaluation and management by trained medical personnel.
-
- CM6.2 ALLOGENEIC AND AUTOLOGOUS DONOR INFORMATION AND CONSENT FOR COLLECTION
- CM6.2.1 The collection procedure shall be explained in terms the donor can understand, and shall include the following information at a minimum:
- CM6.2.1.1 The risks and benefits of the procedure.
- CM6.2.1.2 Tests and procedures performed on the donor to protect the health of the donor and the recipient.
- CM6.2.1.3 The rights of the donor or legally authorized representative to review the results of such tests according to applicable laws and regulations.
- CM6.2.1.4 Protection of medical information and confidentiality.
- CM6.2.2 Interpretation and translation shall be performed by individuals qualified to provide these services in the clinical setting.
- CM6.2.3 Family members and legally authorized representatives should not serve as interpreters or translators.
- CM6.2.4 The donor shall have an opportunity to ask questions.
- CM6.2.5 The donor shall have the right to refuse to donate.
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- CM6.2.5.1 The allogeneic donor shall be informed of the potential consequences to recipient of such refusal.
- CM6.2.6 Donor informed consent for the cellular therapy product collection shall be obtained and documented by a licensed health care professional familiar with the collection procedure.
- CM6.2.6.1 Informed consent from the allogeneic donor shall be obtained by a licensed health care professional who is not the primary health care professional overseeing care of the recipient.
- CM6.2.7 In the case of a minor donor, informed consent shall be obtained from the donor's legally authorized representative in accordance with applicable laws and regulations and shall be documented.
- CM6.2.8 The allogeneic donor shall give informed consent and authorization prior to release of the donor's health or other information to the recipient's physician and/or the recipient.
- CM6.2.9 Documentation of consent shall be available to the Marrow Collection Facility staff prior to the collection procedure.
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- CM6.3 ALLOGENEIC AND AUTOLOGOUS DONOR SUITABILITY FOR CELLULAR THERAPY PRODUCT COLLECTION
- CM6.3.1 There shall be criteria and evaluation policies and procedures in place to protect the safety of donors during the process of cellular therapy product collection.
- CM6.3.1.1 The Marrow Collection Facility shall confirm that any abnormal findings are reported to the prospective donor with documentation in the donor record of recommendations made for follow-up care.
- CM6.3.1.2 Allogeneic donor suitability shall be evaluated by a licensed health care professional who is not the primary health care professional overseeing care of the recipient.
- CM6.3.1.3 Autologous donors shall be tested as required by applicable laws and regulations.
- CM6.3.2 The risks of donation shall be evaluated and documented, including anesthesia for marrow collection.
- CM6.3.3 A pregnancy test shall be performed for all female donors with childbearing potential within seven (7) days prior to starting the donor mobilization regimen and, as applicable, within seven (7) days prior to the initiation of the recipient's preparative regimen.
- CM6.3.4 Laboratory testing of all donors shall be performed by a laboratory that is accredited, registered, or licensed in accordance with applicable laws and regulations.

- CM6.3.5 The Clinical Program shall inform the Collection Facility and Processing Facility of donor test results or if any testing was not performed.
- CM6.3.6 There shall be a written order from a physician specifying, at a minimum, timing and goals of collection.
- CM6.3.7 Collection from a donor who does not meet Clinical Program collection safety criteria shall require documentation of the rationale for his/her selection by the transplant physician. Collection staff shall document review of these donor safety issues.
- CM6.3.8 There shall be written documentation of issues of donor health that pertain to the safety of the collection procedure available to the Marrow Collection Facility staff. Collection staff shall document review of these issues prior to collection.
- CM6.3.9 There shall be a policy for follow-up of donors that includes routine management and the management of collection-associated adverse events.

CM6.4 ADDITIONAL REQUIREMENTS FOR ALLOGENEIC DONORS

- CM6.4.1 A donor advocate shall be available to represent allogeneic donors who are minors or who are mentally incapacitated.
- CM6.4.2 Allogeneic donor infectious disease testing shall be performed using donor screening tests approved or cleared by the governmental authority.

CM7: CODING AND LABELING OF CELLULAR THERAPY PRODUCTS

CM7.1 ISBT 128 CODING AND LABELING

- CM7.1.1 Cellular therapy products shall be identified according to the proper name of the product, including appropriate attributes, as defined in ISBT 128 Standard Terminology for Blood, Cellular Therapy, and Tissue Product Descriptions.
- CM7.1.2 If coding and labeling technologies have not yet been implemented, the Marrow Collection Facility shall be actively implementing ISBT 128.

CM7.2 LABELING OPERATIONS

- CM7.2.1 Labeling operations shall be conducted in a manner adequate to prevent mislabeling or misidentification of cellular therapy products, product samples, and associated records.
 - CM7.2.1.1 Stocks of unused labels representing different products shall be stored in a controlled manner to prevent errors.

- CM7.2.1.2 Obsolete labels shall be restricted from use.
- CM7.2.2 Pre-printed labels shall be held upon receipt from the manufacturer pending review and proofing against a copy or template approved by the Marrow Collection Facility Medical Director or designee to confirm accuracy regarding identity, content, and conformity.
- CM7.2.3 Print-on-demand label systems shall be validated to confirm accuracy regarding identity, content, and conformity of labels to templates approved by the Marrow Collection Facility Medical Director or designee.
- CM7.2.4 A system for label version control shall be employed.
- CM7.2.4.1 Representative obsolete labels shall be archived minimally for ten (10) years after the last cellular therapy product was distributed with inclusive dates of use or as defined by applicable laws and regulations, whichever is longer.
- CM7.2.5 A system of checks in labeling procedures shall be used to prevent errors in transferring information to labels.
- CM7.2.5.1 Cellular therapy products that are subsequently re-packaged into new containers shall be labeled with new labels before they are detached from the original container.
- CM7.2.5.2 A controlled labeling procedure consistent with applicable law shall be defined and followed if container label information is transmitted electronically during a labeling process. This procedure shall include a verification step.
- CM7.2.6 When the label has been affixed to the container, a sufficient area of the container shall remain uncovered to permit inspection of the contents.
- CM7.2.7 The information entered on a container label shall be verified by one (1) qualified staff member using a validated process to verify the information or two (2) qualified staff members.
- CM7.2.8 Labeling elements required by applicable laws and regulations shall be present.
- CM7.2.9 All data fields on labels shall be completed.
- CM7.2.10 All labeling shall be clear, legible, and completed using ink that is indelible to all relevant agents.
- CM7.2.11 Labels affixed directly to a cellular therapy product bag shall be applied using appropriate materials as defined by the applicable regulatory authority.
- CM7.2.12 The label shall be validated as reliable for storage under the conditions in use.

CM7.3 PRODUCT IDENTIFICATION

- CM7.3.1 Each cellular therapy product collection shall be assigned a unique numeric or alphanumeric identifier by which it will be possible to trace any cellular therapy product to its donor, its recipient or final disposition, and all records.
- CM7.3.1.1 The cellular therapy product, product samples, and concurrently collected samples shall be labeled with the same identifier.
- CM7.3.1.2 If a single cellular therapy product is stored in more than one container, there shall be a system to identify each container.
- CM7.3.1.3 Supplementary identifiers shall not obscure the original identifier.
- CM7.3.1.4 The facility associated with each identifier shall be noted on the label.

CM7.4 LABEL CONTENT

- CM7.4.1 At the end of the cellular therapy product collection, the cellular therapy product label on the primary product container shall bear the information in the Cellular Therapy Product Labeling table in Appendix II.
- CM7.4.2 Each label shall bear the appropriate biohazard and warning labels as found in the Circular of Information (COI) for the Use of Cellular Therapy Products, "Table 2. Biohazard and Warning Labels on Cellular Therapy Products Collected, Processed, and/or Administered in the United States."
- CM7.4.3 Labeling at the end of collection shall occur before the cellular therapy product bag is removed from the proximity of the donor.
- CM7.4.4 Cellular therapy products collected in or designated for use in the U.S. shall be accompanied by the elements listed in the Accompanying Documents at Distribution table in Appendix IV at the time of distribution.
- CM7.4.5 For cellular therapy products distributed before completion of donor eligibility determination, there shall be documentation that donor eligibility determination was completed during or after the use of the product.
- CM7.4.6 Cellular therapy products distributed for nonclinical purposes shall be labeled with the statement, "For Nonclinical Use Only."

CM8: PROCESS CONTROLS

- CM8.1 Collection of cellular therapy products shall be performed according to written collection procedures.

- CM8.2 There shall be a process for inventory control that encompasses equipment, reagents, supplies, and labels.
- CM8.2.1 There shall be a system to uniquely identify and track and trace all critical equipment, reagents, supplies, and labels used in the collection of cellular therapy products.
- CM8.2.2 Each supply and reagent used to collect cellular therapy products shall be visually examined at receipt and prior to use for damage or evidence of contamination.
- CM8.2.3 Supplies and reagents coming into contact with cellular therapy products during collection shall be sterile and of the appropriate grade for the intended use.
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- CM8.3 Equipment for the marrow collection procedure shall conform to applicable laws and regulations.
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- CM8.4 Autologous and/or CMV-appropriate and irradiated blood components shall be available during the marrow collection procedure for all donors.
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- CM8.5 Before cell collection is undertaken, there shall be a written order from a physician specifying, at a minimum, timing and goals of collection.
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- CM8.6 There shall be peripheral blood count criteria to proceed with collection.
-
- CM8.7 There shall be written documentation of an assessment of donor suitability for the collection procedure performed by a qualified person immediately prior to each collection procedure.
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- CM8.8 General or regional anesthesia, if required, shall be performed or supervised by a licensed, specialist-certified anesthesiologist.
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- CM8.9 Administration of mobilization agents shall be under the supervision of a licensed health care professional experienced in their administration and management of complications in persons receiving these agents.
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CM8.10 The Marrow Collection Facility shall utilize a process for assessing the quality of cellular therapy products to confirm product safety, viability, and integrity and to document that products meet predetermined release specifications. Results of all such assessments shall become part of the permanent record of the product collected.

CM8.10.1 Methods for collection shall include a process for controlling and monitoring the collection of cellular therapy products to confirm products meet predetermined release specifications.

CM8.10.2 Methods for collection shall employ procedures validated to result in acceptable cell viability and recovery.

CM8.11 Collection methods shall employ aseptic technique so that cellular therapy products do not become contaminated during collection.

CM8.12 Collection methods for pediatric donors shall employ appropriate age and size adjustments to the procedures.

CM8.13 Cellular therapy products shall be packaged in a closed sterile transfer pack appropriate for blood or marrow products.

CM8.14 HPC, Marrow products shall be filtered to remove particulate material prior to final packaging, distribution, or administration using filters that are non-reactive with blood.

CM8.15 Records shall be made concurrently with each step of collection of each cellular therapy product in such a way that all steps may be accurately traced.

CM8.15.1 Records shall identify the person immediately responsible for each significant step, including dates and times, where appropriate.

CM9: CELLULAR THERAPY PRODUCT STORAGE

CM9.1 Marrow Collection Facilities shall control storage areas to prevent mix-ups, deterioration, contamination, cross-contamination, and improper release or distribution of products.

CM9.2 Marrow Collection Facilities shall establish policies for the duration and conditions of short-term storage prior to distribution to a Processing Facility or Clinical Program.

CM10: CELLULAR THERAPY PRODUCT TRANSPORTATION AND SHIPPING

CM10.1 Procedures for transportation and shipping of the cellular therapy product shall be designed to protect the integrity of the product and the health and safety of individuals in the immediate area.

CM10.2 The primary cellular therapy product container shall be placed in a secondary container that is sealed to prevent leakage.

CM10.3 The cellular therapy product shall be transported and/or shipped to the Processing Facility in a validated container at a temperature defined in a Standard Operating Procedure.

CM10.3.1 Cellular therapy products that are transported and/or shipped from the collection site to the Processing Facility shall be transported and/or shipped in an outer container made of material adequate to withstand leakage of contents, impact shocks, pressure changes, temperature changes, puncture, and other conditions incident to ordinary handling.

CM10.3.2 If the intended recipient has received high-dose therapy, the cellular therapy product shall be transported.

CM10.4 The cellular therapy product shall be transported and/or shipped with required accompanying records as defined in the transportation and shipping procedure and in compliance with CM7.4.4 and CM7.4.5.

CM10.5 There shall be a record of the date and time of cellular therapy product distribution.

CM11: RECORDS

CM11.1 The Marrow Collection Facility shall comply with B10 if it operates independently of a Clinical Program.

CM12: DIRECT DISTRIBUTION TO CLINICAL PROGRAM

- CM12.1 Where cellular therapy products are distributed directly from the Marrow Collection Facility to the Clinical Program for administration or subsequent processing, the Standards related to labeling, documentation, distribution, transportation, and recordkeeping in Sections D7, D10, D11, D13, and the Appendices apply.

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APHERESIS COLLECTION FACILITY STANDARDS**PART C**

- C1 General
- C2 Apheresis Collection Facility
- C3 Personnel
- C4 Quality Management
- C5 Policies and Procedures
- C6 Allogeneic and Autologous Donor Evaluation and Management
- C7 Coding and Labeling of Cellular Therapy Products
- C8 Process Controls
- C9 Cellular Therapy Product Storage
- C10 Cellular Therapy Product Transportation and Shipping
- C11 Records
- C12 Direct Distribution to Clinical Program

PART C: APHERESIS COLLECTION FACILITY STANDARDS**C1: GENERAL**

-
- C1.1 These Standards apply to the Apheresis Collection Facility for collection activities of all cellular therapy products collected from living donors.
-
- C1.2 The Apheresis Collection Facility shall use cell processing facilities that meet FACT-JACIE Standards with respect to their interactions with the Apheresis Collection Facility.
-
- C1.3 The Apheresis Collection Facility shall abide by all applicable laws and regulations.
- C1.3.1 The Apheresis Collection Facility shall be licensed, registered, or accredited as required by the appropriate governmental authorities for the activities performed.
-
- C1.4 The Apheresis Collection Facility shall have an Apheresis Collection Facility Director, an Apheresis Collection Facility Medical Director, a Quality Manager, and at least one (1) additional designated staff member. This team shall have been in place and performing cellular therapy product collections for at least twelve (12) months preceding initial accreditation.
-
- C1.5 A minimum of ten (10) cellular therapy products shall have been collected by apheresis in the twelve (12) month period immediately preceding facility accreditation, and a minimum average of ten (10) cellular therapy products shall have been collected by apheresis per year within the accreditation cycle.
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C2: APHERESIS COLLECTION FACILITY

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- C2.1 There shall be appropriate designated areas for collection of cellular therapy products, for collected products, and for storage of supplies, reagents, and equipment.
- C2.1.1 The Apheresis Collection Facility shall be divided into defined areas of adequate size to prevent improper labeling, mix-ups, contamination, or cross-contamination of cellular therapy products.
- C2.1.2 There shall be a designated area with appropriate location and adequate space and design to minimize the risk of airborne microbial contamination in outpatient units where collection is performed.
-

- C2.1.3 There shall be a process to control storage areas to prevent mix-ups, contamination, and cross-contamination of all cellular therapy products prior to release or distribution.
- C2.1.4 There shall be suitable space for confidential donor examination and evaluation.
-
- C2.2 The Apheresis Collection Facility shall provide adequate lighting, ventilation, and access to sinks to prevent the introduction, transmission, or spread of communicable disease.
-
- C2.3 Apheresis Collection Facility parameters and environmental conditions shall be controlled to protect the safety and comfort of patients, donors, and personnel.
-
- C2.4 Critical Apheresis Collection Facility parameters that may affect cellular therapy product viability, integrity, contamination, sterility, or cross-contamination during collection, including temperature and humidity at a minimum, shall be assessed for risk to the cellular therapy product.
- C2.4.1 Critical facility parameters identified to be a risk to the cellular therapy product shall be controlled, monitored, and recorded.
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- C2.5 When using collection methods that may result in contamination or cross-contamination of cellular therapy products, critical environmental conditions shall be controlled, monitored, and recorded, where appropriate, for air quality and surface contaminants.
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- C2.6 The Apheresis Collection Facility shall document facility cleaning and sanitation and maintain order sufficient to achieve adequate conditions for operations.
-
- C2.7 There shall be adequate equipment and materials for the procedures performed.
-
- C2.8 There shall be access to an intensive care unit and/or emergency services.
-
- C2.9 The Apheresis Collection Facility shall be operated in a manner designed to minimize risks to the health and safety of employees, patients, donors, visitors, and volunteers.
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- C2.10 The Apheresis Collection Facility shall have a written safety manual that includes instructions for action in case of exposure to communicable disease and to chemical, biological, or radiological hazards.

C3: PERSONNEL

C3.1 APHERESIS COLLECTION FACILITY DIRECTOR

- C3.1.1 There shall be an Apheresis Collection Facility Director with a medical degree or degree in a relevant science, qualified by postgraduate training or experience for the scope of activities carried out in the Apheresis Collection Facility. The Apheresis Collection Facility Director may also serve as the Apheresis Collection Facility Medical Director, if appropriately credentialed.
- C3.1.2 The Apheresis Collection Facility Director shall be responsible for all technical procedures, performance of the collection procedure, supervision of staff, administrative operations, and the Quality Management Program, including compliance with these Standards and other applicable laws and regulations.
- C3.1.3 The Apheresis Collection Facility Director shall have at least one year experience in cellular therapy product collection procedures.
- C3.1.4 The Apheresis Collection Facility Director shall have performed or supervised a minimum of five (5) cellular therapy product apheresis collection procedures in the twelve (12) months preceding accreditation and a minimum average of five (5) cellular therapy product apheresis collection procedures per year within the accreditation cycle.
- C3.1.5 The Apheresis Collection Facility Director shall participate in ten (10) hours of educational activities related to cellular therapy annually at a minimum.
- C3.1.5.1 Continuing education shall include, but is not limited to, activities related to the field of HPC transplantation and apheresis.

C3.2 APHERESIS COLLECTION FACILITY MEDICAL DIRECTOR

- C3.2.1 There shall be an Apheresis Collection Facility Medical Director who is a licensed or certified physician with postgraduate training in cell collection and/or transplantation.
- C3.2.2 The Apheresis Collection Facility Medical Director or designee shall be responsible for the medical care of donors undergoing apheresis, including the pre-collection evaluation of the donor at the time of donation and care of any complications resulting from the collection procedure.

- C3.2.3 The Apheresis Collection Facility Medical Director shall have at least one year experience in performing and/or supervising cellular therapy product collection procedures.
- C3.2.4 The Apheresis Collection Facility Medical Director shall have performed or supervised a minimum of five (5) cellular therapy product apheresis collection procedures in the twelve (12) months preceding accreditation and a minimum average of five (5) cellular therapy product apheresis collection procedures per year within the accreditation cycle.
- C3.2.5 The Apheresis Collection Facility Medical Director shall participate in ten (10) hours of educational activities related to cellular therapy annually at a minimum.
- C3.2.5.1 Continuing education shall include, but is not limited to, activities related to the field of HPC transplantation and apheresis.

C3.3 QUALITY MANAGER

- C3.3.1 There shall be an Apheresis Collection Facility Quality Manager to establish and maintain systems to review, modify, and approve all policies and procedures intended to monitor compliance with these Standards and/or the performance of the Apheresis Collection Facility.
- C3.3.2 The Quality Manager should have a reporting structure independent of cellular therapy product manufacturing.
- C3.3.3 The Apheresis Collection Facility Quality Manager shall participate in ten (10) hours of educational activities related to cellular therapy, cell collection, and/or quality management annually at a minimum.
- C3.3.3.1 Continuing education shall include, but is not limited to, activities related to the field of HPC transplantation.

C3.4 STAFF

- C3.4.1 The number of trained collection personnel shall be adequate for the number of procedures performed and shall include a minimum of one designated trained individual with an identified trained backup to maintain sufficient coverage.
- C3.4.2 For Apheresis Collection Facilities collecting cellular therapy products from pediatric donors, physicians and collection staff shall have documented training and experience in performing these procedures.

C4: QUALITY MANAGEMENT

C4.1 The Apheresis Collection Facility Director or designee shall have authority over and responsibility for ensuring that the Quality Management Program is effectively established and maintained.

C4.1.1 The Apheresis Collection Facility Director or designee shall annually review the effectiveness of the Quality Management Program. Documentation of the review findings shall be provided to the Clinical Program Director.

C4.2 The Apheresis Collection Facility shall establish and maintain a written Quality Management Plan.

C4.2.1 The Apheresis Collection Facility Director or designee shall be responsible for the Quality Management Plan as it pertains to the Apheresis Collection Facility.

C4.2.2 The Apheresis Collection Facility Director or designee shall review and report to staff quality management activities, at a minimum, quarterly.

C4.2.3 The Apheresis Collection Facility Director or designee shall not have oversight of his/her own work if this person also performs other tasks in the Apheresis Collection Facility.

C4.3 The Quality Management Plan shall include, or summarize and reference, an organizational chart of key positions and functions within the Apheresis Collection Facility.

C4.3.1 The Quality Management Plan shall include a description of how these key positions interact to implement the quality management activities.

C4.4 The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures addressing personnel requirements for each key position in the Apheresis Collection Facility. Personnel requirements shall include at a minimum:

C4.4.1 A current job description for all staff.

C4.4.2 A system to document the following for all staff:

C4.4.2.1 Initial qualifications.

C4.4.2.2 New employee orientation.

C4.4.2.3 Initial training and retraining when appropriate for all procedures performed.

C4.4.2.4 Competency for each critical function performed.

C4.4.2.5 Continued competency at least annually.

C4.4.2.6 Continuing education.

C4.5 The Quality Management Plan shall include, or summarize and reference, a comprehensive system for document control and management.

C4.5.1 There shall be policies and procedures for development, approval, implementation, review, revision, and archival of all critical documents.

C4.5.2 There shall be a current listing of all active critical documents that shall comply with the document control system requirements. Controlled documents shall include at a minimum:

C4.5.2.1 Policies and Standard Operating Procedures.

C4.5.2.2 Worksheets.

C4.5.2.3 Forms.

C4.5.2.4 Labels.

C4.5.3 The document control policy shall include:

C4.5.3.1 A standardized format for policies, procedures, worksheets, forms, and labels.

C4.5.3.2 Assignment of numeric or alphanumeric identifier and title to each document and document version regulated within the system.

C4.5.3.3 A procedure for document approval, including the approval date, signature of approving individual(s), and the effective date.

C4.5.3.4 A system to protect controlled documents from accidental or unauthorized modification.

C4.5.3.5 A system for document change control that includes a description of the change, the signature of the approving individual(s), approval date, effective date, and archival date.

C4.5.3.6 Archived policies and procedures, the inclusive dates of use, and their historical sequence shall be maintained for a minimum of ten (10) years from archival or according to governmental or institutional policy, whichever is longer.

C4.5.3.7 A system for the retraction of obsolete documents to prevent unintended use.

C4.5.3.8 A system for record creation, assembly, review, storage, archival, and retrieval.

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- C4.6 The Quality Management Plan shall include, or summarize and reference, policies and procedures for establishment and maintenance of written agreements with third parties whose services impact the cellular therapy product or clinical care of the donor.
- C4.6.1 Agreements shall include the responsibility of the facility performing any step in collection, processing, or testing to comply with applicable laws and regulations and these Standards.
- C4.6.2 Agreements shall be dated and reviewed on a regular basis.
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- C4.7 The Quality Management Plan shall include, or summarize and reference, policies and procedures for documentation and review of outcome analysis and cellular therapy product efficacy to verify that the procedures in use consistently provide a safe and effective product.
- C4.7.1 Criteria for cellular therapy product safety, product efficacy, and/or the clinical outcome shall be determined and shall be reviewed at regular time intervals.
- C4.7.2 Both individual cellular therapy product data and aggregate data for each type of cellular therapy product shall be evaluated.
- C4.7.3 For HPC products intended for hematopoietic reconstitution, time to engraftment following product administration measured by ANC and platelet count shall be analyzed.
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- C4.8 The Quality Management Plan shall include, or summarize and reference, policies, procedures, and a schedule for conducting, reviewing, and reporting audits of the Apheresis Collection Facility's activities to verify compliance with elements of the Quality Management Program and operational policies and procedures.
- C4.8.1 Audits shall be conducted on a regular basis by an individual with sufficient expertise to identify problems, but who is not solely responsible for the process being audited.
- C4.8.2 The results of audits shall be used to recognize problems, detect trends, identify improvement opportunities, implement corrective and preventive actions when necessary, and follow up on the effectiveness of these actions in a timely manner.
- C4.8.3 Audits shall include the following annually at a minimum:
- C4.8.3.1 Documentation of proper donor eligibility determination prior to start of the collection procedure.
- C4.8.3.2 Documentation that external facilities performing critical contracted services have met the requirements of the written agreements.
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- C4.9 The Quality Management Plan shall include, or summarize and reference, policies and procedures on the management of cellular therapy products with positive microbial culture results that address at a minimum:
- C4.9.1 Notification of the recipient's physician.
 - C4.9.2 Investigation of cause.
 - C4.9.3 Follow-up of the donor, if relevant.
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- C4.10 The Quality Management Plan shall include, or summarize and reference, policies and procedures for errors, accidents, biological product deviations, serious adverse events, and complaints, including the following activities at a minimum:
- C4.10.1 Detection.
 - C4.10.2 Investigation.
 - C4.10.2.1 A thorough investigation shall be conducted by the Apheresis Collection Facility in collaboration with the Processing Facility and Clinical Program, as appropriate.
 - C4.10.2.2 Investigations shall identify the root cause and a plan for short- and long-term corrective actions as warranted.
 - C4.10.3 Documentation.
 - C4.10.3.1 Documentation shall include a description of the event, the involved individuals and/or cellular therapy products, when the event occurred, when and to whom the event was reported, and the immediate actions taken.
 - C4.10.3.2 All investigation reports shall be reviewed in a timely manner by the Apheresis Collection Facility Director, Medical Director, or designee and the Quality Manager.
 - C4.10.3.3 Cumulative files of errors, accidents, biological product deviations, serious adverse events, and complaints shall be maintained.
 - C4.10.3.4 Cumulative files shall include written investigation reports containing conclusions, follow-up, corrective actions, and a link to the record(s) of the involved cellular therapy products
 - C4.10.4 Reporting.
 - C4.10.4.1 When it is determined that a cellular therapy product was responsible for an adverse reaction, the reaction and results of the investigation shall be reported to the recipient's physician, other facilities participating in the manufacturing of the cellular therapy product, registries, and governmental agencies as required by applicable laws.

C4.10.4.2 Errors, accidents, biological product deviations, and complaints shall be reported to other facilities performing cellular therapy product functions on the affected cellular therapy product and to the appropriate regulatory and accrediting agencies, registries, grant agencies, and IRBs or Ethics Committees.

C4.10.5 Corrective and preventive action.

C4.10.5.1 Appropriate corrective action shall be implemented if indicated, including both short-term action to address the immediate problem and long-term action to prevent the problem from recurring.

C4.10.5.2 Follow-up audits of the effectiveness of corrective actions shall be performed in a timeframe as indicated in the investigative report.

C4.11 The Quality Management Plan shall include, or summarize and reference, policies and procedures for cellular therapy product tracking and tracing that allow tracking from the donor to the recipient or final disposition and tracing from the recipient or final disposition to the donor.

C4.12 The Quality Management Plan shall include, or summarize and reference, policies and procedures for actions to take in the event the Apheresis Collection Facility's operations are interrupted.

C4.13 The Quality Management Plan shall include, or summarize and reference, policies and procedures for qualification of critical reagents, supplies, equipment, and facilities.

C4.13.1 Qualification plans shall be reviewed and approved by the Apheresis Collection Facility Director or designee.

C4.14 The Quality Management Plan shall include, or summarize and reference, policies and procedures for validation and/or verification of critical procedures to achieve the expected end-points, including viability of cells and cellular therapy product characteristics.

C4.14.1 Critical procedures shall include at least the following: collection procedures, labeling, storage, and distribution.

C4.14.2 Each validation shall include:

C4.14.2.1 An approved validation plan, including conditions to be validated.

C4.14.2.2 Acceptance criteria.

C4.14.2.3 Data collection.

- C4.14.2.4 Evaluation of data.
- C4.14.2.5 Summary of results.
- C4.14.2.6 Review and approval of the validation plan, results, and conclusion by the Apheresis Collection Facility Director or designee and the Quality Manager or designee.
- C4.14.3 Changes to a process shall include evaluation of risk to confirm that they do not create an adverse impact anywhere in the operation and shall be validated or verified as appropriate.

C5: POLICIES AND PROCEDURES

- C5.1 The Apheresis Collection Facility shall establish and maintain policies and/or procedures addressing critical aspects of operations and management in addition to those required in C4. These documents shall include all elements required by these Standards and shall address at a minimum:
 - C5.1.1 Donor and recipient confidentiality.
 - C5.1.2 Donor consent.
 - C5.1.3 Donor screening, testing, eligibility determination, and management.
 - C5.1.4 Management of donors who require central venous access.
 - C5.1.5 Cellular therapy product collection.
 - C5.1.6 Administration of blood products.
 - C5.1.7 Prevention of mix-ups and cross-contamination.
 - C5.1.8 Labeling (including associated forms and samples).
 - C5.1.9 Cellular therapy product expiration dates.
 - C5.1.10 Cellular therapy product storage.
 - C5.1.11 Release and exceptional release.
 - C5.1.12 Transportation and shipping, including methods and conditions to be used for distribution to external facilities.
 - C5.1.13 Critical reagent and supply management.
 - C5.1.14 Equipment operation, maintenance, and monitoring including corrective actions in the event of failure.

- C5.1.15 Recalls of equipment, supplies, and reagents.
 - C5.1.16 Cleaning and sanitation procedures including identification of the individuals responsible for the activities.
 - C5.1.17 Hygiene and use of personal protective attire.
 - C5.1.18 Disposal of medical and biohazard waste.
 - C5.1.19 Emergency and disaster plan, including the Apheresis Collection Facility response.
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- C5.2 The Apheresis Collection Facility shall maintain a detailed Standard Operating Procedures Manual that includes a listing of all current Standard Operating Procedures, including title, identifier, and version.
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- C5.3 Standard Operating Procedures shall be sufficiently detailed and unambiguous to allow qualified staff to follow and complete the procedures successfully. Each individual procedure shall include:
- C5.3.1 A clearly written description of the objectives.
 - C5.3.2 A description of equipment and supplies used.
 - C5.3.3 Acceptable end-points and the range of expected results.
 - C5.3.4 A stepwise description of the procedure.
 - C5.3.5 Age-specific issues where relevant.
 - C5.3.6 Reference to other Standard Operating Procedures or policies required to perform the procedure.
 - C5.3.7 A reference section listing appropriate literature.
 - C5.3.8 Documented approval of each procedure by the Apheresis Collection Facility Director or Medical Director, as appropriate, prior to implementation and every two years thereafter.
 - C5.3.9 Documented approval of each procedural modification by the Apheresis Collection Facility Director or Medical Director, as appropriate, prior to implementation.
 - C5.3.10 Reference to a current version of orders, worksheets, reports, labels, and forms.
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- C5.4 Standard Operating Procedures relevant to processes being performed shall be readily available to the facility staff.

C5.5 Staff training and, if appropriate, competency shall be documented before performing a new or revised procedure.

C5.6 All personnel shall follow the Standard Operating Procedures related to their positions.

C5.7 Variances shall be pre-approved by the Apheresis Collection Facility Director and/or Medical Director, and reviewed by the Quality Manager.

C6: ALLOGENEIC AND AUTOLOGOUS DONOR EVALUATION AND MANAGEMENT

C6.1 There shall be written criteria for allogeneic and autologous donor evaluation and management by trained medical personnel.

C6.2 ALLOGENEIC AND AUTOLOGOUS DONOR INFORMATION AND CONSENT FOR COLLECTION

C6.2.1 The collection procedure shall be explained in terms the donor can understand, and shall include the following information at a minimum:

C6.2.1.1 The risks and benefits of the procedure.

C6.2.1.2 Tests and procedures performed on the donor to protect the health of the donor and the recipient.

C6.2.1.3 The rights of the donor or legally authorized representative to review the results of such tests according to applicable laws and regulations.

C6.2.1.4 Protection of medical information and confidentiality.

C6.2.2 Interpretation and translation shall be performed by individuals qualified to provide these services in the clinical setting.

C6.2.3 Family members and legally authorized representatives should not serve as interpreters or translators.

C6.2.4 The donor shall have an opportunity to ask questions.

C6.2.5 The donor shall have the right to refuse to donate.

C6.2.5.1 The allogeneic donor shall be informed of the potential consequences to the recipient of such refusal.

- C6.2.6 Donor informed consent for the cellular therapy product collection shall be obtained and documented by a licensed health care professional familiar with the collection procedure.
- C6.2.6.1 Informed consent from the allogeneic donor shall be obtained by a licensed health care professional who is not the primary health care professional overseeing care of the recipient.
- C6.2.7 In the case of a donor who is a minor, informed consent shall be obtained from the donor's legally authorized representative in accordance with applicable laws and regulations and shall be documented.
- C6.2.8 The allogeneic donor shall give informed consent and authorization prior to release of the donor's health or other information to the recipient's physician and/or the recipient.
- C6.2.9 Documentation of consent shall be available to the Apheresis Collection Facility staff prior to the collection procedure.
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- C6.3 ALLOGENEIC AND AUTOLOGOUS DONOR SUITABILITY FOR CELLULAR THERAPY PRODUCT COLLECTION
- C6.3.1 There shall be criteria and evaluation policies and procedures in place to protect the safety of donors during the process of cellular therapy product collection.
- C6.3.1.1 The Apheresis Collection Facility shall confirm that any abnormal findings are reported to the prospective donor with documentation in the donor record of recommendations made for follow-up care.
- C6.3.1.2 Allogeneic donor suitability shall be evaluated by a licensed health care professional who is not the primary health care professional overseeing care of the recipient.
- C6.3.1.3 Autologous donors shall be tested as required by applicable laws and regulations.
- C6.3.2 The risks of donation shall be evaluated and documented, including:
- C6.3.2.1 Possible need for central venous access.
- C6.3.2.2 Mobilization therapy for collection of HPC, Apheresis.
- C6.3.3 The donor should be evaluated for the risk of hemoglobinopathy prior to administration of the mobilization regimen.
- C6.3.4 A pregnancy test shall be performed for all female donors with childbearing potential within seven (7) days prior to starting the donor mobilization regimen and, as applicable, within seven (7) days prior to the initiation of the recipient's preparative regimen.

- C6.3.5 Laboratory testing of all donors shall be performed by a laboratory that is accredited, registered, or licensed in accordance with applicable laws and regulations.
- C6.3.6 The Clinical Program shall inform the Collection Facility and Processing Facility of donor test results or if any testing was not performed.
- C6.3.7 Collection from a donor who does not meet Clinical Program collection safety criteria shall require documentation of the rationale for his/her selection by the transplant physician. Collection staff shall document review of these donor safety issues.
- C6.3.8 There shall be written documentation of issues of donor health that pertain to the safety of the collection procedure available to the Apheresis Collection Facility staff. Collection staff shall document review of these issues prior to collection.
- C6.3.9 There shall be a policy for follow-up of donors that includes routine management and the management of collection-associated adverse events.

C6.4 ADDITIONAL REQUIREMENTS FOR ALLOGENEIC DONORS

- C6.4.1 A donor advocate shall be available to represent allogeneic donors who are minors or who are mentally incapacitated.
- C6.4.2 Allogeneic donor infectious disease testing shall be performed using donor screening tests approved or cleared by the governmental authority.
- C6.4.3 The Apheresis Collection Facility shall comply with B6.4.6 through B6.4.6.8 when primarily responsible for donor screening for transmissible disease.
- C6.4.4 The Apheresis Collection Facility shall comply with B6.4.7 through B6.4.11 when primarily responsible for infectious and non-infectious disease testing of HPC donors.
- C6.4.5 The Apheresis Collection Facility shall comply with B6.4.3, B6.4.4, and B6.4.12 through B6.4.12.4 when primarily responsible for testing for the selection of allogeneic donors.
- C6.4.6 The Apheresis Collection Facility shall confirm that allogeneic donor eligibility, as defined by applicable laws and regulations, is determined by a physician after history, exam, medical record review, and testing before the donor begins the mobilization regimen.
- C6.4.7 Records required for donor eligibility determination shall be in English or translated into English when crossing international borders.
- C6.4.8 Collection of a cellular therapy product from an ineligible allogeneic donor, or from an allogeneic donor for whom donor eligibility determination is incomplete, shall require documentation of urgent medical need that includes the rationale for the selection and documentation of the informed consent of the donor and the recipient.

- C6.4.9 Allogeneic donor eligibility shall be communicated in writing to the Processing Facility.

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- C6.5 There shall be a policy covering the creation and retention of donor records including at a minimum:

- C6.5.1 Donor identification including at least name and date of birth.
 - C6.5.2 Age, gender, and medical history, and, for allogeneic donors, behavioral history.
 - C6.5.3 Consent to donate.
 - C6.5.4 Results of laboratory testing.
 - C6.5.5 Allogeneic donor eligibility determination, including the name of the responsible person who made the determination and the date of the determination.
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C7: CODING AND LABELING OF CELLULAR THERAPY PRODUCTS

C7.1 ISBT 128 CODING AND LABELING

- C7.1.1 Cellular therapy products shall be identified according to the proper name of the product, including appropriate attributes, as defined in ISBT 128 Standard Terminology for Blood, Cellular Therapy, and Tissue Product Descriptions.
 - C7.1.2 If coding and labeling technologies have not yet been implemented, the Apheresis Collection Facility shall be actively implementing ISBT 128.
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C7.2 LABELING OPERATIONS

- C7.2.1 Labeling operations shall be conducted in a manner adequate to prevent mislabeling or misidentification of cellular therapy products, product samples, and associated records.
 - C7.2.1.1 Stocks of unused labels representing different products shall be stored in a controlled manner to prevent errors.
 - C7.2.1.2 Obsolete labels shall be restricted from use.
 - C7.2.2 Pre-printed labels shall be held upon receipt from the manufacturer pending review and proofing against a copy or template approved by the Apheresis Collection Facility Director or designee to confirm accuracy regarding identity, content, and conformity.
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- C7.2.3 Print-on-demand label systems shall be validated to confirm accuracy regarding identity, content, and conformity of labels to templates approved by the Apheresis Collection Facility Director or designee.
- C7.2.4 A system for label version control shall be employed.
 - C7.2.4.1 Representative obsolete labels shall be archived minimally for ten (10) years after the last cellular therapy product was distributed with inclusive dates of use or as defined by applicable laws and regulations, whichever is longer.
- C7.2.5 A system of checks in labeling procedures shall be used to prevent errors in transferring information to labels.
 - C7.2.5.1 Cellular therapy products that are subsequently re-packaged into new containers shall be labeled with new labels before they are detached from the original container.
 - C7.2.5.2 A controlled labeling procedure consistent with applicable law shall be defined and followed if container label information is transmitted electronically during a labeling process. This procedure shall include a verification step.
- C7.2.6 When the label has been affixed to the container, a sufficient area of the container shall remain uncovered to permit inspection of the contents.
- C7.2.7 The information entered on a container label shall be verified by one (1) qualified staff member using a validated process to verify the information or two (2) qualified staff members.
- C7.2.8 Labeling elements required by applicable laws and regulations shall be present.
- C7.2.9 All data fields on labels shall be completed.
- C7.2.10 All labeling shall be clear, legible, and completed using ink that is indelible to all relevant agents.
- C7.2.11 Labels affixed directly to a cellular therapy product bag shall be applied using appropriate materials as defined by the applicable regulatory authority.
- C7.2.12 The label shall be validated as reliable for storage under the conditions in use.

C7.3 PRODUCT IDENTIFICATION

- C7.3.1 Each cellular therapy product collection shall be assigned a unique numeric or alphanumeric identifier by which it will be possible to trace any cellular therapy product to its donor, its recipient or final disposition, and all records.
 - C7.3.1.1 The cellular therapy product, product samples, concurrent plasma, and concurrently collected samples shall be labeled with the same identifier.

- C7.3.1.2 If a single cellular therapy product is stored in more than one container, there shall be a system to identify each container.
- C7.3.1.3 If cellular therapy products from the same donor are pooled, the pool identifier shall allow tracing to the original products.
- C7.3.1.4 Supplementary identifiers shall not obscure the original identifier.
- C7.3.1.5 The facility associated with each identifier shall be noted on the label.

C7.4 LABEL CONTENT

- C7.4.1 At the end of the cellular therapy product collection, the cellular therapy product label on the primary product container and concurrent plasma container shall bear the information in the Cellular Therapy Product Labeling table in Appendix II.
- C7.4.2 Each label shall bear the appropriate biohazard and warning labels as found in the Circular of Information (COI) for the Use of Cellular Therapy Products, "Table 2. Biohazard and Warning Labels on Cellular Therapy Products Collected, Processed, and/or Administered in the United States."
- C7.4.3 Labeling at the end of collection shall occur before the cellular therapy product bag is disconnected from the donor.
- C7.4.4 Cellular therapy products collected in or designated for use in the U.S. shall be accompanied by the elements listed in the Accompanying Documents at Distribution table in Appendix IV at the time of distribution.
- C7.4.5 For cellular therapy products distributed before completion of donor eligibility determination, there shall be documentation that donor eligibility determination was completed during or after the use of the product.
- C7.4.6 Cellular therapy products distributed for nonclinical purposes shall be labeled with the statement, "For Nonclinical Use Only."

C8: PROCESS CONTROLS

- C8.1 Collection of cellular therapy products shall be performed according to written procedures in the Apheresis Collection Facility's Standard Operating Procedures Manual.
- C8.2 There shall be a process for inventory control that encompasses equipment, reagents, supplies, and labels.

- C8.2.1 There shall be a system to uniquely identify and track and trace all critical equipment, reagents, supplies, and labels used in the collection of cellular therapy products.
- C8.2.2 Each supply and reagent used to collect cellular therapy products shall be visually examined at receipt and prior to use for damage or evidence of contamination.
- C8.2.3 Supplies and reagents coming into contact with cellular therapy products during collection shall be sterile and of the appropriate grade for the intended use.
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- C8.3 Equipment shall be inspected for cleanliness prior to each use and verified to be in compliance with the maintenance schedule daily prior to use. Equipment shall also be standardized and calibrated on a regularly scheduled basis and after a critical repair or move as described in Standard Operating Procedures and in accordance with the manufacturer's recommendations.
- C8.3.1 All equipment with a critical measuring function shall be calibrated against a traceable standard, if available. Where no traceable standard is available, the basis for calibration shall be described and documented.
- C8.3.2 When equipment is found to be out of calibration or specification, there shall be a defined process for action required for cellular therapy products collected since the last calibration.
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- C8.4 Equipment shall conform to applicable laws and regulations.
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- C8.5 Autologous and/or CMV-appropriate and irradiated blood components shall be available during the apheresis collection procedure for all donors.
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- C8.6 Before cell collection is undertaken, there shall be a written order from a physician specifying, at a minimum, timing and goals of collection.
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- C8.7 A complete blood count, including platelet count, shall be performed within 24 hours prior to each subsequent cellular therapy product collection by apheresis.
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- C8.8 There shall be peripheral blood count criteria to proceed with collection.
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- C8.9 There shall be written documentation of an assessment of donor suitability for the collection procedure performed by a qualified person immediately prior to each collection procedure.
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- C8.10 If required, central venous catheters shall be placed by a licensed health care professional qualified to perform the procedure.
- C8.10.1 Adequacy of central line placement shall be verified by the Apheresis Collection Facility prior to initiating the collection procedure.
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- C8.11 Administration of mobilization agents shall be under the supervision of a licensed health care professional experienced in their administration and management of complications in persons receiving these agents.
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- C8.12 The Apheresis Collection Facility shall utilize a process for assessing the quality of cellular therapy products to confirm product safety, viability, and integrity and to document that products meet predetermined release specifications. Results of all such assessments shall become part of the permanent record of the product collected.
- C8.12.1 Methods for collection shall include a process for controlling and monitoring the collection of cellular therapy products to confirm products meet predetermined release specifications.
- C8.12.2 Methods for collection shall employ procedures validated to result in acceptable cell viability and recovery.
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- C8.13 Collection methods shall employ aseptic technique so that cellular therapy products do not become contaminated during collection.
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- C8.14 Collection methods for pediatric donors shall employ appropriate age and size adjustments to the procedures.
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- C8.15 Cellular therapy products shall be packaged in a closed sterile transfer pack appropriate for blood products.
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- C8.16 Records shall be made concurrently with each step of collection of each cellular therapy product in such a way that all steps may be accurately traced.
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- C8.16.1 Records shall identify the person immediately responsible for each significant step, including dates and times, where appropriate.

C8.17 There shall be a policy addressing safe administration of ECP.

- C8.17.1 Before ECP is undertaken, there shall be a written therapy plan from a physician specifying the patient's diagnosis and GVHD grade, involved organs, indication, timing of the procedure, proposed regimen, and any other factors that may affect the safe administration of ECP.
- C8.17.2 The ECP procedure shall be performed according to written standard operating procedures of the facility performing the procedure appropriate for the clinical condition of the patient.
- C8.17.3 A final report of the details of ECP administered shall be documented in the patient's medical record.

C9: CELLULAR THERAPY PRODUCT STORAGE

- C9.1 Apheresis Collection Facilities shall control storage areas to prevent mix-ups, deterioration, contamination, cross-contamination, and improper release or distribution of products.

- C9.2 Apheresis Collection Facilities shall establish policies for the duration and conditions of short-term storage prior to distribution to a Processing Facility or Clinical Program.

C10: CELLULAR THERAPY PRODUCT TRANSPORTATION AND SHIPPING

- C10.1 Procedures for transportation and shipping of the cellular therapy product shall be designed to protect the integrity of the product and the health and safety of individuals in the immediate area.

- C10.2 The primary cellular therapy product container shall be placed in a secondary container that is sealed to prevent leakage.

- C10.3 The cellular therapy product shall be transported and/or shipped to the Processing Facility in a validated container at a temperature defined in a Standard Operating Procedure.

- C10.3.1 Cellular therapy products that are transported and/or shipped from the collection site to the Processing Facility shall be transported and/or shipped in an outer container made of material adequate to withstand leakage of contents, impact shocks, pressure changes, temperature changes, puncture, and other conditions incident to ordinary handling.
- C10.3.2 If the intended recipient has received high-dose therapy, the cellular therapy product shall be transported.

C10.4 The cellular therapy product shall be transported and/or shipped with required accompanying records as defined in the transportation and shipping procedure and in compliance with C7.4.4 and C7.4.5.

C10.5 There shall be a record of the date and time of cellular therapy product distribution.

C11: RECORDS

C11.1 GENERAL REQUIREMENTS

- C11.1.1 A records management system shall be established and maintained to facilitate the review of records.
- C11.1.1.1 The records management system shall facilitate tracking of the cellular therapy product from the donor to the recipient or final disposition and tracing from the recipient or final disposition to the donor.
- C11.1.1.2 For cellular therapy products that are to be distributed for use at another institution, the Apheresis Collection Facility shall inform the receiving institution of the tracking system and requirement for tracking the product in writing or electronic format at or before the time of product distribution.
- C11.1.2 Records shall be maintained in such a way as to preserve their integrity, preservation, and retrieval.
- C11.1.3 Records shall be accurate, legible, and indelible.
- C11.1.4 Safeguards to secure the confidentiality of all records and communications between the collection, processing, and clinical facilities, and their recipients and donors, shall be established and followed in compliance with applicable laws and regulations.
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C11.2 Apheresis Collection Facility records related to quality control, personnel training and competency, facility maintenance, facility management, complaints, or other general facility issues shall be retained for a minimum of ten (10) years by the Collection Facility, or longer in accordance with applicable laws and regulations, or a defined program or institution policy.

C11.2.1 Employee records shall be maintained in a confidential manner, as required by applicable laws and regulations.

C11.3 Records to allow tracking and tracing of cellular therapy products shall be maintained for a minimum of ten (10) years after final distribution of the product, or as required by applicable laws and regulations. These records shall include product identity, unique numeric or alphanumeric identifier, and collection date and time; and donor and recipient identification as far as known.

C11.4 Patient and donor records including, but not limited to, consents and records of care shall be maintained in a confidential manner as required by applicable laws and regulations for a minimum of ten (10) years after the administration of the cellular therapy product, or, if not known, ten (10) years after the date of the distribution, disposition, or expiration of the product, whichever requires the longest maintenance period.

C11.5 Research records shall be maintained in a confidential manner as required by applicable laws and regulations for a minimum of ten (10) years after the administration, distribution, disposition, or expiration of the cellular therapy product, whichever is latest.

C11.6 ELECTRONIC RECORDS

C11.6.1 The Apheresis Collection Facility shall maintain a current listing of all critical electronic record systems. Critical electronic record systems shall include at a minimum systems under the control of the Apheresis Collection Facility that are used as a substitute for paper, to make decisions, to perform calculations, or to create or store information used in critical procedures.

C11.6.2 For all critical electronic record systems, there shall be policies, procedures, and system elements to maintain the accuracy, integrity, identity, and confidentiality of all records.

C11.6.3 There shall be a means by which access to electronic records is limited to authorized individuals.

C11.6.4 The critical electronic record system shall maintain unique identifiers.

C11.6.5 There shall be protection of the records to enable their accurate and ready retrieval throughout the period of record retention.

- C11.6.6 For all critical electronic record systems, there shall be an alternative system for all electronic records to allow for continuous operation in the event that critical electronic record systems are not available. The alternative system shall be validated and Apheresis Collection Facility staff shall be trained in its use.
- C11.6.7 For all critical electronic record systems, there shall be written procedures for record entry, verification, and revision.
- C11.6.7.1 A method shall be established or the system shall provide for review of data before final acceptance.
- C11.6.7.2 A method shall be established or the system shall provide for the unambiguous identification of the individual responsible for each record entry.
- C11.6.8 For all critical electronic record systems, there shall be the ability to generate true copies of the records in both human readable and electronic format suitable for inspection and review.
- C11.6.9 For all critical electronic record systems, there shall be validated procedures for and documentation of:
- C11.6.9.1 Training and continued competency of personnel in systems use.
- C11.6.9.2 Monitoring of data integrity.
- C11.6.9.3 Back-up of the electronic records system on a regular schedule.
- C11.6.9.4 System assignment of unique identifiers.

C11.7 RECORDS IN CASE OF DIVIDED RESPONSIBILITY

- C11.7.1 The Apheresis Collection Facility shall furnish to the facility of final disposition a copy of all records relating to the collection procedures performed in so far as they concern the safety, purity, or potency of the cellular therapy product involved.
- C11.7.2 If two (2) or more facilities participate in the collection, processing, or administration of the cellular therapy product, the records of each facility shall show plainly the extent of its responsibility.

C12: DIRECT DISTRIBUTION TO CLINICAL PROGRAM

- C12.1 Where cellular therapy products are distributed directly from the Apheresis Collection Facility to the Clinical Program for administration or for subsequent processing, the Standards related to labeling, documentation, distribution, transportation, and recordkeeping in Sections D7, D10, D11, D13, and the Appendices apply.

PROCESSING FACILITY STANDARDS**PART D**

- D1 General
- D2 Processing Facility
- D3 Personnel
- D4 Quality Management
- D5 Policies and Procedures
- D6 Equipment, Supplies, and Reagents
- D7 Coding and Labeling of Cellular Therapy Products
- D8 Process Controls
- D9 Cellular Therapy Product Storage
- D10 Cellular Therapy Product Transportation and Shipping
- D11 Distribution and Receipt
- D12 Disposal
- D13 Records

PART D: PROCESSING FACILITY STANDARDS**D1: GENERAL**

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- D1.1 These Standards apply to all processing, storage, and distribution activities performed in the Processing Facility on cellular therapy products obtained from living donors.
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- D1.2 The Processing Facility shall abide by all applicable laws and regulations.
- D1.2.1 The Processing Facility shall be licensed, registered, or accredited as required by the appropriate governmental authorities for the activities performed.
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- D1.3 The Processing Facility shall have a Processing Facility Director, a Processing Facility Medical Director, a Quality Manager, and at least one designated staff member actively performing cellular therapy product processing. This team shall have been in place for at least twelve (12) months preceding initial accreditation.
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D2: PROCESSING FACILITY

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- D2.1 The Processing Facility shall be of adequate space, design, and location, for the intended procedures.
- D2.1.1 The Processing Facility shall provide adequate lighting, ventilation, and access to sinks to prevent the introduction, transmission, or spread of communicable disease.
- D2.1.2 Oxygen sensors shall be appropriately placed and utilized in areas where liquid nitrogen is present.
- D2.1.3 The Processing Facility shall be secure to prevent the entrance of unauthorized personnel.
- D2.1.4 The Processing Facility shall be divided into defined areas of adequate size to prevent improper labeling, mix-ups, contamination, or cross-contamination of cellular therapy products.
- D2.1.5 There shall be a process to control storage areas to prevent mix-ups, contamination, and cross-contamination of all cellular therapy products prior to release or distribution.
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- D2.2 Processing Facility parameters and environmental conditions shall be controlled to protect the safety and comfort of personnel.
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- D2.3 Critical facility parameters that may affect processing, storage, or distribution, including temperature and humidity at a minimum, shall be assessed for risk to the cellular therapy product.
- D2.3.1 Critical facility parameters identified to be a risk to the cellular therapy product shall be controlled, monitored, and recorded.
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- D2.4 When using procedures that may result in contamination or cross-contamination of cellular therapy products or when performing more than minimal manipulation, critical environmental conditions shall be controlled, monitored, and recorded where appropriate for air quality and surface contaminants.
- D2.4.1 The Processing Facility shall qualify environmental control systems and validate cleaning and sanitation procedures appropriate for the environmental classification and degree of manipulation performed.
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- D2.5 The Processing Facility shall document facility cleaning and sanitation and maintain order sufficient to achieve adequate conditions for operations.
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- D2.6 There shall be adequate equipment and materials for the procedures performed.
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- D2.7 The Processing Facility shall be operated in a manner designed to minimize risks to the health and safety of employees, patients, donors, visitors, and volunteers.
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- D2.8 The Processing Facility shall have a written safety manual that includes instructions for action in case of exposure, as applicable, to liquid nitrogen; communicable disease; and to chemical, biological, or radiological hazards.
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- D2.9 All waste generated by the Processing Facility activities shall be disposed of in a manner that minimizes any hazard to facility personnel and to the environment in accordance with applicable laws and regulations.
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- D2.10 Gloves and protective clothing shall be worn while handling biological specimens. Such protective clothing shall not be worn outside the work area.
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D3: PERSONNEL

D3.1 PROCESSING FACILITY DIRECTOR

- D3.1.1 There shall be a Processing Facility Director with a medical degree, doctoral degree, or equivalent degree in a relevant science, qualified by a minimum of two (2) years training and experience for the scope of activities carried out in the Processing Facility.
 - D3.1.2 The Processing Facility Director shall be responsible for all procedures, administrative operations, and the Quality Management Program of the Processing Facility, including compliance with these Standards and other applicable laws and regulations.
 - D3.1.3 The Processing Facility Director shall participate in ten (10) hours of educational activities related to cellular therapy annually at a minimum.
 - D3.1.3.1 Continuing education shall include, but is not limited to, activities related to the field of HPC transplantation and processing.
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D3.2 PROCESSING FACILITY MEDICAL DIRECTOR

- D3.2.1 There shall be a Processing Facility Medical Director who is a licensed or certified physician with a minimum of two (2) years postgraduate training and practical and relevant experience for the scope of activities carried out in the preparation and clinical use of cellular therapy products.
 - D3.2.2 The Processing Facility Medical Director or designee shall be directly responsible for all medical aspects related to the Processing Facility.
 - D3.2.3 The Processing Facility Medical Director shall participate in ten (10) hours of educational activities related to cellular therapy annually at a minimum.
 - D3.2.3.1 Continuing education shall include, but is not limited to, activities related to the field of HPC transplantation and processing.
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D3.3 QUALITY MANAGER

- D3.3.1 There shall be a Processing Facility Quality Manager to establish and maintain systems to review, modify, and approve all policies and procedures intended to monitor compliance with these Standards and/or the performance of the Processing Facility.

- D3.3.2 The Processing Facility Quality Manager should have a reporting structure independent of cellular therapy product manufacturing.
- D3.3.3 The Processing Facility Quality Manager shall participate in ten (10) hours of educational activities related to cellular therapy processing and/or quality management annually at a minimum.
- D3.3.3.1 Continuing education shall include, but is not limited to, activities related to the field of HPC transplantation.

D3.4 STAFF

- D3.4.1 The number of trained processing personnel shall be adequate for the number of procedures performed and shall include a minimum of one designated trained individual with an identified trained backup to maintain sufficient coverage.

D4: QUALITY MANAGEMENT

- D4.1 The Processing Facility Director or designee shall have authority over and responsibility for ensuring that the Quality Management Program is effectively established and maintained.
- D4.1.1 The Processing Facility Director or designee shall annually review the effectiveness of the Quality Management Program. Documentation of the review findings shall be provided to the Clinical Program Director.
- D4.2 The Processing Facility shall establish and maintain a written Quality Management Plan.
- D4.2.1 The Processing Facility Director or designee shall be responsible for the Quality Management Plan as it pertains to the Processing Facility.
- D4.2.2 The Processing Facility Director or designee shall review and report to staff quality management activities, at a minimum, quarterly.
- D4.2.3 The Processing Facility Director or designee shall not have oversight of his/her own work if this person also performs other tasks in the Processing Facility.
- D4.3 The Quality Management Plan shall include, or summarize and reference, an organizational chart of key positions and functions within the Processing Facility.
- D4.3.1 The Quality Management Plan shall include a description of how these key positions interact to implement the quality management activities.

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- D4.4 The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures addressing personnel requirements for each key position in the Processing Facility. Personnel requirements shall include at a minimum:
- D4.4.1 A current job description for all staff.
 - D4.4.2 A system to document the following for all staff:
 - D4.4.2.1 Initial qualifications.
 - D4.4.2.2 New employee orientation.
 - D4.4.2.3 Initial training and retraining when appropriate for all procedures performed.
 - D4.4.2.4 Competency for each critical function performed.
 - D4.4.2.5 Continued competency at least annually.
 - D4.4.2.6 Continuing education.
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- D4.5 The Quality Management Plan shall include, or summarize and reference, a comprehensive system for document control and management.
- D4.5.1 There shall be policies and procedures for development, approval, implementation, review, revision, and archival of all critical documents.
 - D4.5.2 There shall be a current listing of all active critical documents that shall comply with the document control system requirements. Controlled documents shall include at a minimum:
 - D4.5.2.1 Policies and Standard Operating Procedures.
 - D4.5.2.2 Worksheets.
 - D4.5.2.3 Forms.
 - D4.5.2.4 Labels.
 - D4.5.3 The document control policy shall include:
 - D4.5.3.1 A standardized format for policies, procedures, worksheets, forms, and labels.
 - D4.5.3.2 Assignment of a numeric or alphanumeric identifier and title to each document and document version regulated within the system.
 - D4.5.3.3 A procedure for document approval, including the approval date, signature of approving individual(s), and the effective date.
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- D4.5.3.4 A system to protect controlled documents from accidental or unauthorized modification.
- D4.5.3.5 A system for document change control that includes a description of the change, the signature of approving individual(s), approval date(s), effective date, and archival date.
- D4.5.3.6 Archived policies and procedures, the inclusive dates of use, and their historical sequence shall be maintained for a minimum of ten (10) years from archival or according to governmental or institutional policy, whichever is longer.
- D4.5.3.7 A system for the retraction of obsolete documents to prevent unintended use.
- D4.5.3.8 A system for record creation, assembly, review, storage, archival, and retrieval.

D4.6 The Quality Management Plan shall include, or summarize and reference, policies and procedures for establishment and maintenance of written agreements with third parties whose services impact the cellular therapy product.

D4.6.1 Agreements shall include the responsibility of the facility performing any step in processing, testing, or storage to comply with applicable laws and regulations and these Standards.

D4.6.2 Agreements shall be dated and reviewed on a regular basis.

D4.7 The Quality Management Plan shall include, or summarize and reference, policies and procedures for review of outcome analysis and cellular therapy product efficacy to verify that the procedures in use consistently provide a safe and effective product.

D4.7.1 Criteria for cellular therapy product safety, product efficacy, and/or the clinical outcome shall be determined and shall be reviewed at regular time intervals.

D4.7.2 Both individual cellular therapy product data and aggregate data for each type of cellular therapy product shall be evaluated.

D4.7.3 For HPC products intended for hematopoietic reconstitution, time to engraftment following cellular therapy product administration measured by ANC and platelet count shall be analyzed.

D4.8 The Quality Management Plan shall include, or summarize and reference, policies, procedures, and a schedule for conducting, reviewing, and reporting audits of the Processing Facility's activities to verify compliance with elements of the Quality Management Program and operational policies and procedures.

- D4.8.1 Audits shall be conducted on a regular basis by an individual with sufficient expertise to identify problems, but who is not solely responsible for the process being audited.
 - D4.8.2 The results of audits shall be used to recognize problems, detect trends, identify improvement opportunities, implement corrective and preventive actions when necessary, and follow-up on the effectiveness of these actions in a timely manner.
 - D4.8.3 Documentation that external facilities performing critical contracted services have met the requirements of the written agreements shall be audited annually.
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- D4.9 The Quality Management Plan shall include, or summarize and reference, policies and procedures on the management of cellular therapy products with positive microbial culture results that address at a minimum:
 - D4.9.1 Documentation and product labeling.
 - D4.9.2 Product quarantine.
 - D4.9.3 Criteria for product release.
 - D4.9.4 Identification of individuals authorized to approve release, including the Processing Facility Medical Director at a minimum.
 - D4.9.5 Investigation of cause.
 - D4.9.6 Notification of the recipient's physician, collection facility, and/or any other facility in receipt of the cellular therapy product.
 - D4.9.7 Reporting to regulatory agencies if appropriate.
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- D4.10 The Quality Management Plan shall include, or summarize and reference, policies and procedures for errors, accidents, biological product deviations, serious adverse events, and complaints, including the following activities at a minimum:
 - D4.10.1 Detection.
 - D4.10.2 Investigation.
 - D4.10.2.1 A thorough investigation shall be conducted by the Processing Facility in collaboration with the Collection Facility and Clinical Program, as appropriate.
 - D4.10.2.2 Investigations shall identify the root cause and a plan for short- and long-term corrective actions as warranted.
 - D4.10.3 Documentation.

- D4.10.3.1 Documentation shall include a description of the event, the involved individuals and/or cellular therapy products, when the event occurred, when and to whom the event was reported, and the immediate actions taken.
- D4.10.3.2 All investigation reports shall be reviewed in a timely manner by the Processing Facility Director, Medical Director, or designee and the Quality Manager.
- D4.10.3.3 Cumulative files of errors, accidents, biological product deviations, serious adverse events, and complaints shall be maintained.
- D4.10.3.4 Cumulative files shall include written investigation reports containing conclusions, follow-up, corrective actions, and a link to the record(s) of the involved cellular therapy products.

D4.10.4 Reporting.

- D4.10.4.1 When it is determined that a cellular therapy product was responsible for a serious adverse reaction, the reaction report and results of the investigation shall be made available to the recipient's physician, other facilities participating in the manufacturing of the cellular therapy product, registries, and governmental agencies as required by applicable laws.
- D4.10.4.2 Errors, accidents, biological product deviations, and complaints shall be reported to other facilities performing cellular therapy product functions on the affected cellular therapy product and to the appropriate regulatory and accrediting agencies, registries, grant agencies, and IRBs or Ethics Committees.

D4.10.5 Corrective and preventive action.

- D4.10.5.1 Appropriate corrective action shall be implemented if indicated, including both short-term action to address the immediate problem and long-term action to prevent the problem from recurring.
- D4.10.5.2 Follow-up audits of the effectiveness of corrective actions shall be performed in a timeframe as indicated in the investigative report.

D4.11 The Quality Management Plan shall include, or summarize and reference, policies and procedures for cellular therapy product tracking and tracing that allow tracking from the donor to the recipient or final disposition and tracing from the recipient or final disposition to the donor.

D4.12 The Quality Management Plan shall include, or summarize and reference, policies and procedures for actions to take in the event the Processing Facility's operations are interrupted.

- D4.13 The Quality Management Plan shall include, or summarize and reference, policies and procedures for qualification of critical supplies, manufacturers, vendors, reagents, equipment, and facilities.
- D4.13.1 Qualification plans shall be reviewed and approved by the Processing Facility Director or designee.
 - D4.13.2 Reagents that are not the appropriate grade shall undergo qualification for the intended use.
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- D4.14 The Quality Management Plan shall include, or summarize and reference, policies and procedures for validation and/or verification of critical procedures to achieve the expected end-points, including viability of cells and cellular therapy product characteristics.
- D4.14.1 Critical procedures to be validated or verified shall include at least the following: processing techniques, cryopreservation procedures, labeling, storage, and distribution.
 - D4.14.2 Each validation shall include:
 - D4.14.2.1 An approved validation plan, including conditions to be validated.
 - D4.14.2.2 Acceptance criteria.
 - D4.14.2.3 Data collection.
 - D4.14.2.4 Evaluation of data.
 - D4.14.2.5 Summary of results.
 - D4.14.2.6 Review and approval of the validation plan, results, and conclusion by the Processing Facility Director or designee and the Quality Manager or designee.
 - D4.14.3 Changes to a process shall include evaluation of risk to confirm that they do not create an adverse impact anywhere in the operation and shall be validated or verified as appropriate.
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D5: POLICIES AND PROCEDURES

- D5.1 The Processing Facility shall establish and maintain policies and/or procedures addressing critical aspects of operations and management in addition to those required in D4. These documents shall include all elements required by these Standards and shall address at a minimum:
- D5.1.1 Donor and recipient confidentiality.

D5.1.2	Cellular therapy product receipt.
D5.1.3	Processing and process control.
D5.1.4	Processing of ABO-incompatible cellular therapy products to include a description of the indication for and processing methods to be used for red cell and plasma depletion.
D5.1.5	Prevention of mix-ups and cross-contamination.
D5.1.6	Labeling (including associated forms and samples).
D5.1.7	Cryopreservation and thawing.
D5.1.8	Cellular therapy product expiration dates.
D5.1.9	Cellular therapy product storage to include alternative storage if the primary storage device fails.
D5.1.10	Release and exceptional release.
D5.1.11	Transportation and shipping, including methods and conditions within the Processing Facility and to and from external facilities.
D5.1.12	Cellular therapy product recall, to include a description of responsibilities and actions to be taken, and notification of appropriate regulatory agencies.
D5.1.13	Cellular therapy product disposal.
D5.1.14	Critical reagent and supply management.
D5.1.15	Equipment operation, maintenance, and monitoring including corrective actions in the event of failure.
D5.1.16	Recalls of equipment, supplies, and reagents.
D5.1.17	Cleaning and sanitation procedures including identification of the individuals responsible for the activities.
D5.1.18	Environmental control to include a description of the environmental monitoring plan.
D5.1.19	Hygiene and use of personal protective equipment.
D5.1.20	Disposal of medical and biohazard waste.
D5.1.21	Emergency and disaster plan, including the Processing Facility response.
D5.2	The Processing Facility shall maintain a detailed Standard Operating Procedures Manual that includes a listing of all current Standard Operating Procedures, including title, identifier, and version.

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- D5.3 Standard Operating Procedures shall be sufficiently detailed and unambiguous to allow qualified staff to follow and complete the procedures successfully. Each individual procedure shall include:
- D5.3.1 A clearly written description of the objectives.
 - D5.3.2 A description of equipment and supplies used.
 - D5.3.3 Acceptable end-points and the range of expected results.
 - D5.3.4 A stepwise description of the procedure.
 - D5.3.5 Reference to other Standard Operating Procedures or policies required to perform the procedure.
 - D5.3.6 A reference section listing appropriate literature.
 - D5.3.7 Documented approval of each procedure by the Processing Facility Director or Medical Director, as appropriate, prior to implementation and every two years thereafter.
 - D5.3.8 Documented approval of each procedural modification by the Processing Facility Director or Medical Director, as appropriate, prior to implementation.
 - D5.3.9 Reference to a current version of orders, worksheets, reports, labels, and forms.
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- D5.4 Standard Operating Procedures relevant to processes being performed shall be readily available to the facility staff.
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- D5.5 Staff training and, if appropriate, competency shall be documented before performing a new or revised procedure.
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- D5.6 All personnel shall follow the Standard Operating Procedures related to their positions.
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- D5.7 Variances shall be pre-approved by the Processing Facility Director and/or Medical Director, and reviewed by the Quality Manager.
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D6: EQUIPMENT, SUPPLIES, AND REAGENTS

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- D6.1 Equipment, supplies, and reagents used to process cellular therapy products shall be used in a manner that maintains product function and integrity and prevents product mix-ups, contamination, and cross-contamination.
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- D6.2 Supplies and reagents used in processing, testing, cryopreservation, and storage shall be controlled by a materials management system that includes requirements for the following, at a minimum:
- D6.2.1 Visual examination of each supply and reagent used to manufacture cellular therapy products for damage or evidence of contamination upon receipt and acceptance into inventory.
 - D6.2.2 Records of receipt that shall include the supply or reagent type, quantity, manufacturer, lot number, date of receipt, acceptability, and expiration date.
 - D6.2.3 Storage of materials under the appropriate environmental conditions in a secure, sanitary, and orderly manner to prevent mix up or unintended use.
 - D6.2.4 Use of supplies and reagents coming into contact with cellular therapy products during processing, storage, and/or administration that are sterile and of the appropriate grade for the intended use.
 - D6.2.5 Cleaning and sterilizing of non-disposable supplies or instruments using a procedure verified to remove infectious agents and other contaminants.
 - D6.2.6 Use of supplies and reagents in a manner consistent with manufacturer instructions.
 - D6.2.7 Process to prevent the use of expired reagents and supplies.
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- D6.3 There shall be a system to uniquely identify and track all critical equipment used in the processing of cellular therapy products. The system shall identify each cellular therapy product for which the equipment was used.
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- D6.4 Equipment used in cellular therapy product processing, testing, cryopreservation, storage, and distribution shall be maintained in a clean and orderly manner and located to facilitate cleaning, sanitation, calibration, and maintenance according to established schedules.
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- D6.5 The equipment shall be inspected for cleanliness prior to each use and verified to be in compliance with the maintenance schedule daily prior to use.
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- D6.6 The equipment shall be standardized and calibrated on a regularly scheduled basis and after a critical repair or move as described in Standard Operating Procedures and in accordance with the manufacturer's recommendations.
- D6.6.1 All equipment with a critical measuring function shall be calibrated against a traceable standard, if available. Where no traceable standard is available, the basis for calibration shall be described and documented.
- D6.6.2 When equipment is found to be out of calibration or specification, there shall be a defined process for action required for cellular therapy products manufactured since the last calibration.
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- D6.7 There shall be a procedure that addresses the actions to take in the event of equipment malfunction or failure.
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- D6.8 Equipment shall conform to applicable laws and regulations.
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- D6.9 Lot numbers, expiration dates, and manufacturers of critical reagents and supplies and identification of key equipment used in each procedure shall be documented.
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- D6.10 The Processing Facility shall use an inventory control system to document the availability and identity of critical reagents and supplies. This shall include at a minimum:
- D6.10.1 A system to uniquely identify and track all critical reagents and supplies used to manufacture cellular therapy products.
- D6.10.2 A system to identify each cellular therapy product for which each critical reagent or supply was used.
- D6.10.3 A system to maintain adequate stocks of reagents and supplies for the procedures to be performed.
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D7: CODING AND LABELING OF CELLULAR THERAPY PRODUCTS

- D7.1 ISBT 128 CODING AND LABELING
- D7.1.1 Cellular therapy products shall be identified according to the proper name of the product, including appropriate attributes, as defined in ISBT 128 Standard Terminology for Blood, Cellular Therapy, and Tissue Product Descriptions.
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- D7.1.2 If coding and labeling technologies have not yet been implemented, the Processing Facility shall be actively implementing ISBT 128.

D7.2 LABELING OPERATIONS

- D7.2.1 Labeling operations shall be conducted in a manner adequate to prevent mislabeling or misidentification of cellular therapy products, product samples, and associated records.
- D7.2.1.1 Stocks of unused labels representing different cellular therapy products shall be stored in a controlled manner to prevent errors.
- D7.2.1.2 Obsolete labels shall be restricted from use.
- D7.2.2 Pre-printed labels shall be held upon receipt from the manufacturer pending review and proofing against a copy or template approved by the Processing Facility Director or designee to confirm accuracy regarding identity, content, and conformity.
- D7.2.3 Print-on-demand label systems shall be validated to confirm accuracy regarding identity, content, and conformity of labels to templates approved by the Processing Facility Director or designee.
- D7.2.4 A system for label version control shall be employed.
- D7.2.4.1 Representative obsolete labels shall be archived minimally for ten (10) years after the last cellular therapy product was distributed with inclusive dates of use or as defined by applicable laws and regulations, whichever is longer.
- D7.2.5 A system of checks in labeling procedures shall be used to prevent errors in transferring information to labels.
- D7.2.5.1 Cellular therapy products that are subsequently re-packaged into new containers shall be labeled with new labels before they are detached from the original container.
- D7.2.5.2 A controlled labeling procedure consistent with applicable law shall be defined and followed if container label information is transmitted electronically during a labeling process. This procedure shall include a verification step.
- D7.2.6 When the label has been affixed to the container, a sufficient area of the container shall remain uncovered to permit inspection of the contents.
- D7.2.7 The information entered on a container label shall be verified by one (1) qualified staff member using a validated process to verify the information or two (2) qualified staff members prior to distribution of the cellular therapy product.
- D7.2.8 Labeling elements required by applicable laws and regulations shall be present.
- D7.2.9 All data fields on labels shall be completed.

- D7.2.10 All labeling shall be clear, legible, and completed using ink that is indelible to all relevant agents.
- D7.2.11 Labels affixed directly to a cellular therapy product bag shall be applied using appropriate materials as defined by the applicable regulatory authority.
- D7.2.12 The label shall be validated as reliable for storage under the conditions in use.

D7.3 PRODUCT IDENTIFICATION

- D7.3.1 Each cellular therapy product shall be assigned a unique numeric or alphanumeric identifier by which it will be possible to trace any cellular therapy product to its donor, its recipient or final disposition, and all records.
 - D7.3.1.1 The cellular therapy product, product samples, concurrent plasma, and concurrently collected samples shall be labeled with the same identifier.
 - D7.3.1.2 If a single cellular therapy product is stored in more than one container, there shall be a system to identify each container.
 - D7.3.1.3 If cellular therapy products from the same donor are pooled, the pool identifier shall allow tracing to the original products.
 - D7.3.1.4 Supplementary identifiers shall not obscure the original identifier.
 - D7.3.1.5 The facility associated with each identifier shall be noted on the label.
 - D7.3.1.6 If the original identifier is replaced, documentation shall link the new identifier to the original.

D7.4 LABEL CONTENT

- D7.4.1 At the completion of processing and at distribution for administration, the cellular therapy product label on the primary product container and concurrent plasma container shall bear the information in the Cellular Therapy Product Labeling table in Appendix II.
- D7.4.2 Each label shall bear the appropriate biohazard and warning labels as found in the Circular of Information for the Use of Cellular Therapy Products, "Table 2. Biohazard and Warning Labels on Cellular Therapy Products Collected, Processed, and/or Administered in the United States."
- D7.4.3 Any container bearing a partial label shall be accompanied by the information required by the Cellular Therapy Product Labeling table in Appendix II. Such information shall be attached securely to the cellular therapy product on a tie tag or enclosed in a sealed package to accompany the product.

- D7.4.4 The name and address of the facility that determines that the cellular therapy product meets release criteria and the name and address of the facility that makes the product available for distribution shall either appear on the product label or accompany the product at distribution.
- D7.4.5 Cellular therapy products collected in or designated for use in the U.S. shall have the elements in the Accompanying Documents at Distribution table in Appendix IV accompany the cellular therapy product when it leaves the Processing Facility.
- D7.4.6 For cellular therapy products distributed before completion of donor eligibility determination, there shall be documentation that donor eligibility determination was completed during or after distribution of the cellular therapy product and that the physician using the product was informed of the results of that determination.
- D7.4.7 Cellular therapy products distributed for nonclinical purposes shall be labeled with the statement, "For Nonclinical Use Only."

D8: PROCESS CONTROLS

- D8.1 There shall be a process for controlling and monitoring the manufacturing of cellular therapy products so that products meet predetermined release specifications.
 - D8.1.1 The Processing Facility Director shall define tests and procedures for measuring and assaying cellular therapy products to assure their safety, viability, and integrity and to document that products meet predetermined release specifications. Results of all such tests and procedures shall become part of the permanent record of the product processed.
 - D8.1.2 There shall be a documented system for the identification and handling of test samples so that they are accurately related to the corresponding cellular therapy product, donor, or recipient.
 - D8.1.2.1 There shall be a mechanism to identify the individual obtaining the sample, the sample source, the date, and the time, if appropriate.
 - D8.1.2.2 Samples obtained for testing shall be representative of the cellular therapy product to be evaluated.
 - D8.1.3 There shall be the establishment of appropriate and validated assays and test procedures for the evaluation of cellular therapy products.
 - D8.1.3.1 For all cellular therapy products, a total nucleated cell count and viability measurement shall be performed.
 - D8.1.3.2 For HPC products intended for restoration of hematopoiesis, an assay measuring viable CD34 shall be performed.

- D8.1.3.3 For cellular therapy products undergoing manipulation that alters the final cell population, a relevant and validated assay, where available, shall be employed for evaluation of the viable target cell population before and after the processing procedures.
- D8.1.4 For tests required by these Standards performed within the Processing Facility:
- D8.1.4.1 There shall be a process for monitoring the reliability, accuracy, precision, and performance of laboratory test procedures and instruments.
 - D8.1.4.2 New reagent lots shall be verified to provide comparable results to current lots or to give results in agreement with suitable reference material before or concurrently with being placed into service.
 - D8.1.4.3 Where available, controls shall be used each day of testing and shown to give results within the defined range established for that material.
 - D8.1.4.4 Function checks shall be performed for testing instruments prior to testing donor, recipient, or cellular therapy product samples.
 - D8.1.4.5 For tests performed within the Processing Facility, there shall be documentation of ongoing proficiency testing as designated by the Processing Facility Director. The results shall be reviewed by the Processing Facility Director or designee and outcomes reviewed with the staff.
- D8.1.5 Tests required by these Standards, not performed by the Processing Facility, shall be performed by a laboratory that is certified, licensed, or accredited by the appropriate laboratory regulatory agency.
- D8.1.6 Infectious disease testing required by these Standards shall be performed using screening tests approved or cleared by the governmental authority for cellular therapy product donors.
- D8.1.7 Cellular therapy products that do not meet allogeneic donor eligibility requirements, or for which allogeneic donor eligibility determination is not yet complete, shall be distributed only if there is documented urgent medical need for the product. Documentation shall include, at a minimum, the approval of the recipient's physician and the Processing Facility Medical Director or other designated physician.
- D8.1.8 Notification of the recipient's physician of nonconforming cellular therapy products and approval for their release shall be documented.
-
- D8.2 Before a cellular therapy product is processed, shipped, or otherwise prepared for administration, there shall be a written request from the recipient's physician specifying the cellular therapy product type, recipient and donor identifiers, the type of processing that is to be performed, and the anticipated date of processing.
-

- D8.3 For allogeneic cellular therapy products, information required by the Processing Facility prior to distribution of the product shall include:
- D8.3.1 A statement of donor eligibility.
 - D8.3.2 For ineligible donors, the reason for their ineligibility.
 - D8.3.3 For ineligible donors or donors for whom eligibility determination is incomplete, documentation of urgent medical need and physician approval for use.
-
- D8.4 Processing procedures shall be validated in the Processing Facility and documented to result in acceptable target cell viability and recovery.
- D8.4.1 Published validated processes shall be verified within the Processing Facility prior to implementation.
 - D8.4.2 The Processing Facility shall use validated methods for preparation of cellular therapy products for administration.
 - D8.4.3 Cord blood units that have not been red cell reduced prior to cryopreservation shall be washed prior to administration.
 - D8.4.4 Cord blood units that have been red cell reduced prior to cryopreservation should be diluted or washed prior to administration.
 - D8.4.5 If the Processing Facility lacks experience with the type of cellular therapy product requested for a recipient, personnel shall obtain the manufacturer's instructions and follow these instructions to the extent possible.
 - D8.4.5.1 The Processing Facility should verify the processing procedures utilizing practice units similar to the cellular therapy product intended for administration when feasible.
-
- D8.5 Critical control points and associated assays shall be identified and performed on each cellular therapy product as defined in Standard Operating Procedures.
-
- D8.6 Methods for processing shall employ aseptic technique and cellular therapy products shall be processed in a manner that minimizes the risk of cross-contamination.
- D8.6.1 Where processing of tissues and cells involves exposure to the environment, processing shall take place in an environment with specified air quality and cleanliness.
 - D8.6.2 The effectiveness of measures to avoid contamination and cross-contamination shall be verified and monitored.
-

- D8.7 The Processing Facility shall monitor and document microbial contamination of cellular therapy products after processing as specified in Standard Operating Procedures.
- D8.7.1 The results of microbial cultures shall be reviewed by the Processing Facility Director or designee in a timely manner.
- D8.7.2 The recipient's physician shall be notified in a timely manner of any positive microbial cultures.
-
- D8.8 Records shall be made concurrently with each step of the processing, testing, cryopreservation, storage, and administration or disposal/disposition/distribution of each cellular therapy product in such a way that all steps may be accurately traced.
- D8.8.1 Records shall identify the person immediately responsible for each significant step, including dates and times, where appropriate.
- D8.8.2 Records shall show the test results and the interpretation of each result, where appropriate.
-
- D8.9 The Processing Facility Director or designee shall review the processing record for each cellular therapy product prior to release or distribution.
-
- D8.10 There shall be documented notification to the recipient's physician and the Processing Facility Medical Director of clinically relevant processing end-points not met and remedial actions taken.
-
- D8.11 Processing using more-than-minimal manipulation shall only be performed with Institutional Review Board or Ethics Committee approval, with the written informed consent of the donor, if applicable, and the recipient of the cellular therapy product, and in compliance with applicable laws and regulations.
- D8.11.1 The Processing Facility shall adhere to good manufacturing practices (GMP) appropriate for the degree of cellular therapy product manipulation.
-
- D8.12 For allogeneic cellular therapy products containing red blood cells at the time of administration:
- D8.12.1 Results for ABO group and Rh type testing shall be available from two (2) independently collected samples. Discrepancies shall be resolved and documented prior to issue of the cellular therapy product.
- D8.12.2 Results for a red cell antibody screen on the recipient shall be available.

D8.13 There shall be a procedure to confirm the identity of cord blood units if verification typing cannot be performed on attached segments.

D8.14 One or more samples representing the cryopreserved cellular therapy product shall be stored.

D8.14.1 Sample(s) from cryopreserved cellular therapy products shall be stored under conditions that achieve a valid representation of the clinical product.

D8.14.2 Cryopreserved samples shall be retained according to institutional Standard Operating Procedures.

D9: CELLULAR THERAPY PRODUCT STORAGE

D9.1 Processing Facilities shall control storage areas to prevent mix-ups, deterioration, contamination, cross-contamination, and improper distribution of cellular therapy products.

D9.2 STORAGE DURATION

D9.2.1 Processing Facilities processing, storing, and/or releasing cellular therapy products for administration shall assign an expiration date and time for non-cryopreserved products and for products thawed after cryopreservation.

D9.2.2 There shall be a written stability program that evaluates the viability and potency of cryopreserved cellular therapy products, minimally annually.

D9.3 TEMPERATURE

D9.3.1 Storage temperatures shall be defined in Standard Operating Procedures.

D9.3.2 Noncryopreserved cellular therapy products shall be maintained within a specific temperature range to maintain viability and function, to inhibit infectious agents, and for a period of time not to exceed that specified in Standard Operating Procedures.

D9.3.3 Cryopreserved cellular therapy products shall be stored within a temperature range, as defined in Standard Operating Procedures, that is appropriate for the product and cryoprotectant solution used.

- D9.3.4 Prior to receipt of a cellular therapy product from an external facility, there shall be confirmation that the product can be appropriately stored.

D9.4 PRODUCT SAFETY

- D9.4.1 Materials that may adversely affect cellular therapy products shall not be stored in the same refrigerators or freezers as the cellular therapy products.
- D9.4.2 For cellular therapy products immersed in liquid nitrogen, procedures to minimize the risk of cross-contamination of products shall be employed.
- D9.4.3 Processes for storing cellular therapy products in quarantine shall be defined in Standard Operating Procedures.
- D9.4.3.1 Quarantined cellular therapy products shall be easily distinguishable and stored in a manner that minimizes the risks of cross-contamination and inappropriate distribution.
- D9.4.3.2 All cellular therapy products with positive infectious disease test results for relevant communicable disease agents and/or positive microbial cultures shall be quarantined.
- D9.4.3.3 Processing Facilities storing cellular therapy products shall quarantine each product until completion of the donor eligibility determination as required by applicable laws and regulations.

D9.5 STORAGE MONITORING

- D9.5.1 Refrigerators and freezers used for storage where cellular therapy products are not fully immersed in liquid nitrogen shall have a system to monitor the temperature continuously and to record the temperature at least every four (4) hours.
- D9.5.2 There shall be a mechanism to confirm that levels of liquid nitrogen in liquid nitrogen freezers are consistently maintained to assure that cellular therapy products remain within the specified temperature range.

D9.6 ALARM SYSTEMS

- D9.6.1 Storage devices for cellular therapy products or reagents for cellular therapy product processing shall have alarm systems that are continuously active.
- D9.6.2 Alarm systems shall have audible and visible signals or other effective notification methods.
- D9.6.3 Alarm systems shall be checked periodically for function.

- D9.6.4 If trained personnel are not always present in the immediate area of the storage device, a system shall be in place that alerts responsible personnel of alarm conditions on a 24-hour basis.
- D9.6.5 Alarms shall be set to activate at a temperature or level of liquid nitrogen that will allow time to salvage products.
- D9.6.6 Written instructions to be followed if the storage device fails shall be displayed in the immediate area of the storage device and at each remote alarm location.
- D9.6.6.1 Instructions shall include a procedure for notifying processing personnel.
- D9.6.7 Storage devices of appropriate temperature shall be available for cellular therapy product storage if the primary storage device fails.
-
- D9.7 The storage device shall be located in a secure area and accessible only to authorized personnel.
-
- D9.8 The Processing Facility shall use an inventory control system to identify the location of each cellular therapy product and associated samples. The inventory control system records shall include:
- D9.8.1 Cellular therapy product unique identifier.
- D9.8.2 Recipient name or unique identifier.
- D9.8.3 Storage device identifier.
- D9.8.4 Location within the storage device.
-

D10: CELLULAR THERAPY PRODUCT TRANSPORTATION AND SHIPPING

- D10.1 Procedures for transportation and shipping of cellular therapy products shall be designed to protect the integrity of the product and the health and safety of individuals in the immediate area.
-
- D10.2 The primary product container for non-frozen cellular therapy products shall be placed in a secondary container and sealed to prevent leakage.
-

- D10.3 Cellular therapy products that require a temperature-controlled environment and that are transported or shipped over an extended period of time shall be transported or shipped in a container validated to maintain the appropriate temperature range.
-
- D10.4 Conditions shall be established and maintained to preserve the integrity and safety of cellular therapy products during transport or shipping.
-
- D10.5 Cellular therapy products that are shipped to another facility or transported on public roads shall be packaged in an outer container.
- D10.5.1 The outer container shall conform to the applicable regulations regarding the mode of transportation or shipping.
- D10.5.2 The outer container shall be made of material adequate to withstand leakage of contents, shocks, pressure changes, and other conditions incident to ordinary handling during transport or shipping.
- D10.5.2.1 The temperature of the shipping container shall be continuously monitored during shipment of cellular therapy products.
- D10.5.2.2 The shipping facility shall maintain a record of the temperature over the period of travel.
- D10.5.3 The outer container shall be secured.
- D10.5.4 The outer container shall be labeled as defined in the Cellular Therapy Product Labels for Shipping and Transport on Public Roads table in Appendix III.
- D10.5.5 There shall be a document inside the outer container that includes all the information required on the outer container, in conformity with the Cellular Therapy Product Labels for Shipping and Transport on Public Roads table in Appendix III.
- D10.5.6 The outer container shall be labeled in accordance with applicable laws and regulations regarding the cryogenic material used and the transport or shipment of biological materials.
-
- D10.6 The transit time shall be within time limits determined by the distributing facility in consultation with the receiving facility to maintain cellular therapy product safety.
-
- D10.7 If the intended recipient has received high-dose therapy, the cellular therapy product shall be transported.
-

D10.8 There shall be plans for alternative means of transport or shipping in an emergency.

D10.9 The cellular therapy products should not be passed through X-Ray irradiation devices designed to detect metal objects. If inspection is necessary, the contents of the container should be inspected manually.

D11: DISTRIBUTION AND RECEIPT

D11.1 DISTRIBUTION CRITERIA

D11.1.1 The processing, collection, and transport or shipping records for each cellular therapy product shall be reviewed by the Processing Facility Director or designee for compliance with Standard Operating Procedures and applicable laws and regulations prior to product release or distribution.

D11.1.1.1 Records shall demonstrate traceability from the donor to the recipient and from the recipient to the donor.

D11.1.2 Each cellular therapy product shall meet pre-determined release criteria prior to distribution from the Processing Facility. The release criteria shall include donor eligibility determination for allogeneic products.

D11.1.2.1 The Processing Facility Director or designee shall give specific authorization for release when the cellular therapy product does not meet technical release criteria.

D11.1.2.2 The Processing Facility Medical Director or designee shall give specific authorization for release when the cellular therapy product does not meet clinically relevant release criteria.

D11.1.2.3 Documentation of agreement of the Processing Facility Medical Director or designee and the recipient's physician consent to use any non-conforming product shall be retained in the processing record if such release is allowed by policies, procedures, or package inserts of licensed products.

D11.1.3 Each cellular therapy product issued for administration shall be visually inspected by two (2) trained personnel immediately before release to verify the integrity of the product container and appropriate labeling.

D11.1.3.1 A cellular therapy product shall not be released when the container is compromised and/or recipient or donor information is not verified unless the Processing Facility Director or designee gives specific authorization for the product's release.

D11.1.4 For each type of cellular therapy product, the Processing Facility shall maintain and distribute or make a document available to clinical staff containing the following:

- D11.1.4.1 The use of the cellular therapy product, indications, contraindications, side effects and hazards, dosage, and administration recommendations.
- D11.1.4.2 Instructions for handling the cellular therapy product to minimize the risk of contamination or cross-contamination.
- D11.1.4.3 Appropriate warnings related to the prevention of the transmission or spread of communicable diseases.

D11.2 The cellular therapy product processing records shall contain a written record of product distribution including, at a minimum:

- D11.2.1 The distribution date and time.
- D11.2.2 Unique identifier of the intended recipient.
- D11.2.3 The proper product name and identifier.
- D11.2.4 Documentation of donor eligibility determination.
- D11.2.5 Identification of the facilities that requested and distributed the product.

D11.3 Records shall permit tracing of the cellular therapy product from one facility to another, and shall include:

- D11.3.1 Date and time cellular therapy product was distributed.
- D11.3.2 Date and time cellular therapy product was received.
- D11.3.3 Identity of the transporting or shipping facility.
- D11.3.4 Identity of the receiving facility.
- D11.3.5 Identity of personnel responsible for cellular therapy product transportation or shipping and of personnel responsible for receiving the product.
- D11.3.6 Identity of the courier.
- D11.3.7 Documentation of any delay or problems incurred during transportation or shipping.

D11.4 RECEIPT OF CELLULAR THERAPY PRODUCTS

- D11.4.1 Procedures shall be established and maintained for acceptance, rejection, and quarantine of cellular therapy products.
- D11.4.2 The receipt of each cellular therapy product shall include inspection to verify:

- D11.4.2.1 The integrity of the cellular therapy product container.
- D11.4.2.2 The appearance of the cellular therapy product for evidence of mishandling or microbial contamination.
- D11.4.2.3 Appropriate labeling.
- D11.4.3 If the primary container or temperature of the cellular therapy product has been compromised, the Processing Facility Director or designee shall give specific authorization to return the product to inventory.
- D11.4.4 There shall be procedures to verify that the cellular therapy product was appropriately transported or shipped.
 - D11.4.4.1 The receiving facility shall document the temperature of the outer container upon arrival.
 - D11.4.4.2 For cryopreserved cellular therapy products, receiving facility records shall include documentation of the outer container temperature during shipping.
- D11.4.5 The receiving facility shall review and verify product specifications provided by the manufacturer, if applicable.
- D11.4.6 There shall be procedures to maintain cellular therapy products in quarantine until they have been determined to meet criteria for release from quarantine.
- D11.4.7 The receiving facility shall have readily available access to a summary of documents used to determine allogeneic donor eligibility.
 - D11.4.7.1 For cellular therapy products received from an external facility, there shall be documented evidence of donor eligibility screening and testing in accordance with applicable laws and regulations.
- D11.4.8 When cellular therapy products are returned to the Processing Facility after distribution for administration, there shall be documentation in the Processing Facility records of the events requiring return, the temporary storage temperature when at the clinical facility, the results of inspection upon return, and subsequent action taken to protect product safety and viability.
 - D11.4.8.1 The Processing Facility Director or designee shall consult with the recipient's physician regarding reissue or disposal of the returned product.

D12: DISPOSAL

- D12.1 Disposal of cellular therapy products shall include the following requirements:

- D12.1.1 A pre-collection written agreement between the storage facility and the designated recipient or the donor defining the length of storage and the circumstances for disposal of cellular therapy products.
- D12.1.2 The option to transfer the cellular therapy product to another facility if the designated recipient is still alive after the agreed upon storage interval.
- D12.1.3 Documentation of no further need for the cellular therapy product before any product is discarded.
 - D12.1.3.1 For HPC products, this shall include documentation of the designated recipient's death, if applicable.
- D12.1.4 Approval by the Processing Facility Medical Director or the recipient's physician for cellular therapy product discard or other disposition, and method of disposal.
- D12.1.5 A method of disposal and decontamination that meets applicable laws and regulations for disposal of biohazardous materials and/or medical waste.
- D12.1.6 Processing Facilities, in consultation with the Clinical Program, shall establish policies for the duration and conditions of storage and indications for disposal.
 - D12.1.6.1 Recipients, donors, and associated Clinical Programs should be informed about policies for directed cellular therapy products as part of the informed consent process and before the cellular therapy product collection.
- D12.1.7 If there is no pre-existing agreement describing conditions for cellular therapy product storage and/or discard or if the intended recipient is lost to follow-up, the storage facility shall make a documented effort to notify the donor, cellular therapy product manufacturer, or designated recipient's physician and facility about product disposition, including disposal or transfer.

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- D12.2 The records for discarded or transferred cellular therapy products shall indicate the product was discarded or transferred, date of discard or transfer, disposition, and method of disposal or transfer.
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D13: RECORDS

- D13.1 There shall be a records management system for quality and cellular therapy product record creation, assembly, review, storage, archival, and retrieval.
 - D13.1.1 The records management system shall facilitate the review of records pertaining to a particular cellular therapy product prior to distribution and for follow-up evaluation or investigation.

- D13.1.2 The records management system shall facilitate tracking of the cellular therapy product from the donor to the recipient or final disposition and tracing from the recipient or final disposition to the donor.
- D13.1.3 For cellular therapy products that are to be distributed for use at another institution, the Processing Facility shall inform the receiving institution of the tracking system and requirement for tracking the product in writing or electronic format at or before the time of product distribution.
- D13.1.4 Records shall be maintained in such a way as to secure their integrity, preservation, and retrieval.
- D13.1.5 Records shall be accurate, legible, and indelible.
- D13.1.6 Safeguards to secure the confidentiality of all records and communications between the collection, processing, and clinical facilities and their recipients and donors shall be established and followed in compliance with applicable laws and regulations.

D13.2 ELECTRONIC RECORDS

- D13.2.1 The Processing Facility shall maintain a current listing of all critical electronic record systems. Critical electronic record systems shall include at a minimum systems under the control of the Processing Facility that are used as a substitute for paper, to make decisions, to perform calculations, or to create or store information used in critical procedures.
- D13.2.2 For all critical electronic record systems, there shall be policies, procedures, and system elements to maintain the accuracy, integrity, identity, and confidentiality of all records.
 - D13.2.2.1 There shall be a means by which access to electronic records is limited to authorized individuals.
 - D13.2.2.2 The critical electronic record system shall maintain unique identifiers.
 - D13.2.2.3 There shall be protection of the records to enable their accurate and ready retrieval throughout the period of record retention.
- D13.2.3 For all critical electronic record systems, there shall be an alternative system for all electronic records to allow for continuous operation of the Processing Facility in the event that critical electronic record systems are not available. The alternative system shall be validated and Processing Facility staff shall be trained in its use.
- D13.2.4 For all critical electronic record systems, there shall be written procedures for record entry, verification, and revision.
 - D13.2.4.1 A method shall be established or the system shall provide for review of data before final acceptance.

- D13.2.4.2 A method shall be established or the system shall provide for the unambiguous identification of the individual responsible for each record entry.
- D13.2.5 For all critical electronic record systems, there shall be the ability to generate true copies of the records in both human readable and electronic format suitable for inspection and review.
- D13.2.6 For all critical electronic record systems, there shall be validated procedures for and documentation of:
 - D13.2.6.1 Systems development.
 - D13.2.6.2 Numerical designation of system versions, if applicable.
 - D13.2.6.3 Prospective validation of systems, including hardware, software, and databases.
 - D13.2.6.4 Installation of the system.
 - D13.2.6.5 Training and continued competency of personnel in systems use.
 - D13.2.6.6 Monitoring of data integrity.
 - D13.2.6.7 Back-up of the electronic records system on a regular schedule.
 - D13.2.6.8 System maintenance and operations.
 - D13.2.6.9 System assignment of unique identifiers.
- D13.2.7 All system modifications shall be authorized, documented, and validated prior to implementation.

D13.3 RECORDS TO BE MAINTAINED

- D13.3.1 Processing Facility records related to quality control, personnel training and competency, facility maintenance, facility management, complaints, or other general facility issues shall be retained for a minimum of ten (10) years by the Processing Facility, or longer in accordance with applicable laws or regulations, or with a defined program or institution policy.
 - D13.3.1.1 Facility maintenance records pertaining to facility cleaning and sanitation shall be retained for at least three (3) years or longer in accordance with applicable laws or regulations, or with defined program or institution policy. All other facility maintenance records shall be retained as in D13.3.1.

- D13.3.2 Records to allow tracing of cellular therapy products shall be maintained for a minimum of ten (10) years after final distribution of the product, or as required by applicable laws and regulations. These records shall include collection and processing facility identity, unique numeric or alphanumeric identifier, collection date and time, product identity, and donor and recipient information as found on the original container.
- D13.3.3 All records pertaining to the processing, testing, storage, or distribution of cellular therapy products shall be maintained for a minimum of ten (10) years after the date of administration, or if the date of administration is not known, then a minimum of ten (10) years after the date of the cellular therapy product's distribution, disposition, or expiration, or the creation of the cellular therapy product record, whichever is most recent, or according to applicable laws and regulations or institutional policy, whichever requires the longest maintenance period.

D13.4 RECORDS IN CASE OF DIVIDED RESPONSIBILITY

- D13.4.1 The Processing Facility shall maintain a listing of the names, addresses, and responsibilities of other facilities that perform manufacturing steps on a cellular therapy product.
- D13.4.2 The Processing Facility shall furnish to the facility of final disposition a copy of all records relating to the collection, processing, and storage procedures performed in so far as the records concern the safety, purity, or potency of the cellular therapy product involved.
- D13.4.3 If two (2) or more facilities participate in the collection, processing, or distribution of the cellular therapy product, the records of the Processing Facility shall show plainly the extent of its responsibility.

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APPENDIX I

MINIMUM NUMBER OF NEW PATIENTS FOR ACCREDITATION

Clinical Programs shall transplant at least the following number of new patients¹ before initial accreditation and annually thereafter:

Transplant Population	Clinical Site(s)	Type of Transplant	Twelve (12) Months Prior to Initial Accreditation	Average Per Year Within Accreditation Cycle
Adult OR Pediatric (only one of these two)	Single Clinical Site	Autologous only	5 autologous	5 autologous
		Allogeneic and Autologous	10 allogeneic recipients	10 allogeneic recipients
	Multiple Clinical Sites	Autologous only	5 autologous recipients at each site	5 autologous recipients at each site
		Allogeneic and Autologous	5 allogeneic recipients at each applicable site ² 5 autologous at each applicable site ²	5 allogeneic recipients at each applicable site ² 5 autologous at each applicable site ²
Combined Adult AND Pediatric	Single Clinical Site	Autologous only	5 adult autologous And 5 pediatric autologous recipients	5 adult autologous and 5 pediatric autologous recipients
		Allogeneic and Autologous	5 adult allogeneic recipients 5 pediatric allogeneic recipients	5 adult allogeneic recipients 5 pediatric allogeneic recipients
	Multiple Clinical Sites	Autologous only	5 adult autologous at each applicable site 5 pediatric autologous recipients at each applicable site	5 adult autologous recipients at each applicable site 5 pediatric autologous recipients at each applicable site
		Allogeneic and Autologous	5 adult allogeneic recipients at each applicable site 5 pediatric allogeneic recipients at each applicable site 5 adult autologous at each applicable site ² 5 pediatric autologous at each applicable site ²	5 adult allogeneic recipients at each site 5 pediatric allogeneic recipients at each site 5 adult autologous at each applicable site ² 5 pediatric autologous at each applicable site ²

¹The term “new allogeneic patient” or “new autologous patient” includes only a patient who received his/her first transplant of that type during the period of time in question.

²Programs performing allogeneic and autologous transplantation that have more than one clinical site may or may not perform both types of transplant at each site. The requirement for five autologous transplant recipients per site only applies to those sites that do not perform allogeneic transplant.

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APPENDIX II

CELLULAR THERAPY PRODUCT LABELING

Each label shall include at least the elements detailed in the following table¹:

Element ²	Partial label	Label at completion of collection	Label at completion of processing	Label at distribution for administration ⁴
Unique numeric or alphanumeric identifier ³	AF	AF	AF	AF
Proper name of product ⁵	AF	AF	AF	AF
Product attributes ⁵			AC	AC
Recipient name and/or identifier		AT	AT	AT
Identity and address of collection facility or donor registry		AT	AC	AC
Date, time collection ends, and (if applicable) time zone		AT	AC	AC
Approximate volume		AT	AT	AT
Name and quantity of anticoagulant and other additives		AC	AC	AC
Donor identifier and (if applicable) name		AT	AT	AT
Recommended storage temperature range		AT	AT	AT
Biohazard and/or Warning Labels (as applicable, see CM7.4, C7.4, D7.4).		AT	AT	AT
As applicable: - Statement "NOT EVALUATED FOR INFECTIOUS SUBSTANCES" - Statement "WARNING: Advise Patient of Communicable Disease Risks" - Statement "WARNING: Reactive Test Results for [name of disease agent or disease]"		AT AT AT	AT AT AT	AT AT AT
Identity and address of processing and distribution facility(ies)			AC	AC
Statement "Do Not Irradiate"			AT	AT
Expiration Date (if applicable)			AC	AC
Expiration Time (if applicable)			AC	AC
ABO and Rh of donor (if applicable)			AC	AC
RBC compatibility determination (if applicable)				AC
Statement indicating that leukoreduction filters shall not be used.				AT
Statement "FOR AUTOLOGOUS USE ONLY" (if applicable)		AT	AT	AT
Date of distribution				AC

AF=Affix, AT=Attach or Affix, AC=Accompany, Attach, or Affix

¹ Container and full package labeling requirements for licensed products or products under Investigational New Drug (IND) application shall follow applicable laws and regulations. In the U.S., see 21 CFR 312.6(a).

² Facilities registered with ICCBBA who have fully implemented ISBT 128 labeling shall follow the ISBT 128 Standard for the location of information on the label and/or the accompanying documentation.

³ Overlay labels for supplementary identifiers shall not obscure the original identifier.

⁴ Products thawed at the bedside do not require a new label unless repackaged into a new container.

⁵ Product proper names and attributes are listed in Chapter Three of the ISBT 128 Standard Terminology for Blood, Cellular Therapy, and Tissue Product Descriptions. Available at: www.iccbba.org > Subject Area > Cellular Therapy > Standard Terminology.

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APPENDIX III**CELLULAR THERAPY PRODUCT LABELS FOR SHIPPING AND TRANSPORT ON PUBLIC ROADS**

Each container for shipping and transport on public roads shall include a document on the inside of the container and a label on the exterior of the container with at least the elements detailed in the following table:

Element	Inner container document	Outer container label
Date of distribution	AC	AC
Time ¹ of distribution, if appropriate	AC	AC
Statement "Do Not X-Ray" and /or "Do Not Irradiate", if applicable	AC	AF
Statements "Human Cells for Administration" or equivalent and "Handle with Care"	AC	AF
Shipper handling instructions	AC	AF
Shipping facility name, street address, contact person, and phone number	AC	AF
Receiving facility name, street address, contact person, and phone number	AC	AF
Biohazard and/or Warning Labels (as applicable, see CM7.4.2, C7.4.2, D7.4.2).	AC	
If applicable: Statement "NOT EVALUATED FOR INFECTIOUS SUBSTANCES"	AC	
Statement "WARNING: Advise Patient of Communicable Disease Risks"	AC	
Statement "WARNING: Reactive Test Results for [name of disease agent or disease]"	AC	

AC= Accompany, AF=Affix

¹Time shall include the time zone when shipping or transport of the cellular therapy product involves crossing time zones.

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APPENDIX IV

ACCOMPANYING DOCUMENTS AT DISTRIBUTION

Products collected in or designated for use in the U.S. shall be accompanied upon leaving the Collection or Processing Facility with at least the elements detailed in the following table¹:

Documentation	Allogeneic Donors-Eligible	Allogeneic Donor-Ineligible ²	Allogeneic Donor-Incomplete ²
Statement that the donor has been determined to be either eligible or ineligible, based upon results of donor screening and testing	X	X	
Summary of records used to make the donor-eligibility determination ³	X	X	
Name and address of the establishment that made the donor-eligibility determination	X	X	
Listing and interpretation of the results of all communicable disease testing performed	X	X	X
Statement that the communicable disease testing was performed by a laboratory meeting regulatory requirements ⁴	X	If applicable	If applicable
Statement noting the reason(s) for the determination of ineligibility		X	
Statement that the donor-eligibility determination has not been completed			X
Statement that the product must not be transplanted or infused until completion of the donor-eligibility determination, except under condition of urgent medical need			X
Listing of any required screening or testing that has not yet been completed			X
Results of donor screening and testing that has been performed			X
Documentation that the physician using the cellular therapy product was notified of incomplete testing or screening			X
Instructions for product use to prevent the introduction, transmission, or spread of communicable diseases ¹	X	X	X
Instructions for reporting serious adverse reactions or events to the distributing facility ^{1,5}	X	X	X

¹For autologous cellular therapy products, instructions for product use to prevent the introduction, transmission, or spread of communicable diseases and for reporting serious adverse reactions or events to the distributing facility are always required for autologous products. Furthermore, a donor eligibility determination is not required by FDA. However, if any donor screening or testing is performed and risk factors or reactive test results are identified, accompanying documentation shall be provided.

²May only be distributed after release by the Processing Facility Medical Director due to urgent medical need. For ineligible cellular therapy products or incomplete donor eligibility determination, the product shall be shipped in quarantine. For products distributed prior to completion of donor eligibility, determination shall be completed and the physician shall be informed of the results.

³ Access (electronic or otherwise) to the source documents by the distributing facility and/or receiving facility is sufficient.

⁴This includes laboratories certified to perform such testing on human specimens under the Clinical Laboratory Improvement Amendments of 1988 or those laboratories that have met equivalent requirements as determined by the Centers for Medicare and Medicaid Services, or those that have met equivalent non-U.S. requirements.

⁵ Access to the Clinical Program SOPs and forms could suffice when the distributing and clinical facilities are within the same facility.

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APPENDIX V

CHANGES TO SIXTH EDITION STANDARDS

The table below outlines the changes made to the *FACT-JACIE International Standards for Cellular Therapy Product Collection, Processing, and Administration* with each version of the sixth edition of these Standards.¹

Version Number ²	Standard	Change
6.1	A3	<u>CAR (Chimeric antigen receptor)</u>
6.1	A3	<u>CNS (Central nervous system)</u>
6.1	A3	<u>CRS (Cytokine release syndrome)</u>
6.1	A3	<u>MSC (Mesenchymal stromal cell or mesenchymal stem cell)</u>
6.1	A3	<u>NC (Nucleated cell)</u>
6.1	A4	Cellular therapy product: Somatic cell-based product (e.g., mobilized HPC, mononuclear cells, cord blood cells, mesenchymal stromal cells, <u>T cells, natural killer cells</u>) that is procured from a donor and intended for processing and administration.
6.1	A4	<u>Chimeric antigen receptor: Artificial receptor that combines an antigen specificity domain coupled with an intracellular signaling domain typically expressed by an immune effector cell (e.g., T cell or natural killer cell).</u>
6.1	A4	Corrective action: Action taken to eliminate the <u>root</u> causes of an existing discrepancy or other undesirable situation to prevent recurrence.
6.1	A4	<u>Cytokine release syndrome: A non-antigen-specific toxicity that occurs as a result of high-level immune activation. For example, a reaction from the release of cytokines from cells targeted by an antibody or immune effector cells.</u>
6.1	A4	<u>Immune effector cell: A cell that has differentiated into a form capable of modulating or effecting a specific immune response.</u>
6.1	A4	Preventive action: Action taken to eliminate the <u>root</u> cause and prevent occurrence of a potential discrepancy or other undesirable situation.
6.1	A4	<u>Product identity: Unique title that identifies the cellular composition of the product in a way that can be directly tied back to a manufacturing entity or process (e.g., a protocol number, a commercial product title, or a site-defined unique identifier).</u>

Version Number ²	Standard	Change
6.1	A4	Quality assurance: The actions, planned and performed, to provide confidence that all systems and elements that influence the quality of the product or service are working as expected <u>or exceed expectations</u> individually and collectively.
6.1	B1.2.1	<u>If cellular therapy products are received directly by the Clinical Program from a third-party provider, the following responsibilities at a minimum shall be defined in a written agreement:</u>
6.1	B1.2.1.1	<u>Traceability and chain of custody of cellular therapy products.</u>
6.1	B1.2.1.2	<u>Cellular therapy product storage and distribution.</u>
6.1	B1.2.1.3	<u>Verification of cellular therapy product identity.</u>
6.1	B2.6	There shall be written guidelines for communication, patient monitoring, and prompt transfer of patients to an intensive care unit, <u>emergency department</u> , or equivalent when appropriate.
6.1	B2.8.1	<u>Pharmacies shall have access to medications adequate to treat expected complications of immune effector cell administration, including cytokine release syndrome.</u>
6.1	B3.3.3	Clinical Program Directors and attending physicians shall have received specific training and maintain competency in each of the following areas <u>as applicable to the Clinical Program's services:</u>
6.1	B3.3.3.12	Diagnosis and management of veno-occlusive disease of the liver <u>and other causes of hepatic dysfunction.</u>
6.1	B3.3.3.13	Management of thrombocytopenia and bleeding, <u>including recognition of disseminated intravascular coagulation.</u>
6.1	B3.3.3.17	<u>Graft versus host disease.</u>
6.1	B3.3.3.18	<u>Cytokine release syndrome.</u>
6.1	B3.3.3.19	<u>Tumor lysis syndrome.</u>
6.1	B3.3.3.20	<u>Macrophage activation syndrome.</u>
6.1	B3.3.3.21	<u>Cardiac dysfunction.</u>
6.1	B3.3.3.22	<u>Renal dysfunction.</u>
6.1	B3.3.3.23	<u>Respiratory distress.</u>
6.1	B3.3.3.24	<u>Neurologic toxicity.</u>
6.1	B3.3.3.25	<u>Anaphylaxis.</u>
6.1	B3.3.3.26	<u>Infectious and noninfectious processes.</u>
6.1	B3.3.5.7	<u>Cellular therapy product administration.</u>

Version Number ²	Standard	Change
6.1	B3.7.3.4	Care interventions to manage transplant <u>cellular therapy</u> complications, including, but not limited to, <u>cytokine release syndrome, tumor lysis syndrome, cardiac dysfunction, respiratory distress, neurologic toxicity, renal and hepatic failure, disseminated intravascular coagulation, anaphylaxis, neutropenic fever, infectious and noninfectious processes, mucositis, nausea and vomiting, and pain management.</u>
6.1	B3.7.4.6	<u>Detection and management of immune effector cellular therapy complications including, but not limited to, those listed in B3.7.3.4.</u>
6.1	B3.8.2.1	An overview of hematology/oncology patient care, including the cellular therapy process, <u>cytokine release syndrome, and neurological toxicities.</u>
6.1	B3.8.3	Pharmacists should <u>shall</u> be involved in the development and implementation of guidelines or SOPs related to the pharmaceutical management of transplant-cellular therapy recipients.
6.1	B3.8.4.1	Continuing education shall include, but is not limited to, activities related to the field of HPC transplantation <u>and cytokine release syndrome and neurological toxicities resulting from cellular therapies.</u>
6.1	B3.10.2	<u>The Clinical Program Quality Manager should have a reporting structure independent of cellular therapy product manufacturing.</u>
6.1	B4.7.3.2	<u>For immune effector cells, an endpoint of clinical function as approved by the Clinical Program Director.</u>
6.1	B4.7.3.3	Overall and treatment-related morbidity and mortality at <u>thirty (30) days, one hundred (100) days, and one (1) year after transplantation cellular therapy product administration.</u>
6.1	B4.8.3.1	<u>Periodic audit of the accuracy of clinical data.</u>
6.1	B4.8.3.2	<u>Annual audit of safety endpoints and immune effector cellular therapy toxicity management.</u>
6.1	B4.10.2.1	A thorough investigation shall be conducted by the Clinical Program in collaboration with the Collection Facility, and Processing Facility, and other entities involved in the manufacture of the cellular therapy product, as appropriate.
6.1	B5.1.10	<u>Management of toxicities of immune effector cellular therapies, including cytokine release syndrome and central nervous system complications.</u>

Version Number ²	Standard	Change
6.1	B6.3.9	Collection from a donor who does not meet Clinical Program collection safety criteria shall require documentation of the rationale for his/her selection by the transplant <u>recipient's</u> physician.
6.1	B7.10	<u>There shall be policies and procedures addressing the administration of immune effector cells and management of complications.</u>
6.1	B7.10.1	<u>There shall be a consultation with the referring physician prior to initiation of immune effector cellular therapy to review the goal and plan of the treatment.</u>
6.1	B7.10.2	<u>There shall be regular assessment of the recipient to detect complications, including cytokine release syndrome and neurologic dysfunction.</u>
6.1	B7.10.3	<u>There shall be a written plan for rapid escalation of care, increased intensity of monitoring, and relevant workup to address complications.</u>
6.1	B7.10.4	<u>Communication to the clinical staff, intensive care unit, emergency department, and pharmacy shall be timely.</u>
6.1	B7.10.5	<u>The Clinical Program shall have written guidelines for management of complications, including the use of cytokine-blocking agents and corticosteroid administration.</u>
6.1	B8.1.2	<u>There shall be a process to manage investigational cellular therapy products.</u>
6.1	B9.2	<u>The Clinical Program should collect all the data elements included in the applicable CIBMTR Cellular Therapy forms or EBMT forms.</u>
6.1	B9.3	<u>The Clinical Program shall define staff responsible for collecting data and, as appropriate, reporting data to institutional repositories and CIBMTR or EBMT.</u>
6.1	C3.3.2	<u>The Quality Manager should have a reporting structure independent of cellular therapy product manufacturing.</u>
6.1	D3.3.2	<u>The Processing Facility Quality Manager should have a reporting structure independent of cellular therapy product manufacturing.</u>

¹ This appendix does not include minor numbering or reorganization changes that were a result of the substantive changes listed above.

² The effective date of version 6.1 is March 1, 2017.

ACKNOWLEDGEMENTS

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NHS Greater Glasgow & Clyde

Finance & Planning Committee

4 April 2017



Gary Jenkins
Director, Regional Services

Paper No: 17/??

BONE MARROW TRANSPLANTATION: OPTIONS APPRAISAL

Recommendation

The Acute Services Committee is asked to agree the temporary relocation of BMT Services to 4B QEUH.

At the same time, BMT services should be considered as part of the acute services review of cancer services to deliver a longer term sustainable option that meets both service and environmental considerations.

This recommendation is made on the basis that service delivery considerations require prioritisation over the Infection Control and Prevention Teams concerns on meeting national standards and HPS recommendations.

Purpose of Paper

This paper details the option appraisal of potential locations for the Adult BMT service within NHS Greater Glasgow and Clyde.

It describes the options considered against agreed benefit criteria with clear recommendations on the preferred option to deliver this service both in the short and longer term.

Key Issues to be considered

Key issues that need to be considered are:

- Impact on Staffing arrangements including out of hours cover
- Delivery of environmental standards
- Delivery of service standards
- Strategic fit with longer term direction of cancer services
- Timescale to deliver; and
- Long term sustainability.

Any Patient Safety /Patient Experience Issues

There are patient safety/experience issues with the current arrangements.

Any Financial Implications from this Paper

There are capital works required to implement Option Two.

Any Staffing Implications from this Paper

Yes

Any Equality Implications from this Paper

No

Any Health Inequalities Implications from this Paper

No

Has a Risk Assessment been carried out for this issue? If yes, please detail the outcome.

A service risk assessment of the current arrangement was carried out in 2016. A risk assessment of each option is detailed in section six of this paper.

Highlight the Corporate Plan priorities to which your paper relates

BMT Services are specifically highlighted in the corporate plan.

Author Gary Jenkins

Contact

Date

1st March, 2017

1. Introduction

This paper details the option appraisal of potential locations for the Adult BMT service within NHS Greater Glasgow and Clyde.

It describes the options considered against agreed benefit criteria as well as a risk assessment of each option with clear recommendations on the preferred option to deliver this service both in the short and longer term.

2. Background

The BMT service moved to the QEUH in May 2015 due to concerns that the planned level of support for acutely unwell patients on the Gartnavel General Hospital (GGH) site would be insufficient for such a high intensity speciality and would not meet the JACIE accreditation standards. The move also allowed for an increase of beds from 19 to 24 to support the agreed increase in the national transplant programme. Capital funding of £1million was invested to support enabling works to 4B such as the upgrade air filtration plant.

Unfortunately, the unit had to return to the Beatson West of Scotland Cancer Centre in July 2015 following the identification of air quality issues in the new transplant unit. This return was predicated on it being short-term with further remedial works to be undertaken to improve the air quality in ward 4B, QEUH to acceptable levels. Remedial works were completed by October 2015 and at this time the service began to make plans to move back to QEUH.

The Infection Control Team raised concerns regarding the specification of works that had been completed and requested input from Health Protection Scotland (HPS) at this time. Following the receipt of recommendations from HPS with regard to the required specification (Appendix One), the Infection Control Team advised that the specification did not meet the required environmental standards for a BMT Unit and therefore, they were unable to support return to the QEUH.

A further schedule of works was agreed and scoped in early 2016 requiring additional costs of c. £1m which would deliver further improvements but would still fail to meet the full specification outlined by HPS in the following areas:

- HEPA Filtered Corridors;
- Room Air Changes of 10/hour;
- Room Positive Pressure of 10pa.

It was therefore concluded that whilst further improvements could be made to facilities within 4B, due to limitations of the current plant and lack of space to expand, the fourth floor QEUH could not be configured to meet the full specification of requirements as detailed by HPS/Infection Control.

In the autumn of 2016, a further feasibility study commenced into potential options utilising retained estate on the QEUH site as well as the Laboratory Building and GRI, the study was supported by Currie and Brown. A report was produced in January 2017 detailing a technical and financial analysis of 6 options to be considered as part of the optional appraisal exercise.

A group representing the Clinical Team, Infection Control, Capital Planning, Estates and Regional Service Management met twice in February, 2017 to consider the report, review the options within the

feasibility study and make recommendations on the options to the Board. The membership of this group is detailed in Appendix Two.

3. Current Service

NHS Greater Glasgow and Clyde is commissioned by National Services Division to provide all adult donor stem cell transplantation for the population of Scotland. The national service covers both stem cell donation from family members and unrelated donors. The SLA value in 2016/17 was £7,904,092 for 70 transplants. This is proposed to increase to £8,114,359 for 73 in 2017/18.

The West of Scotland Haemopoietic Stem Cell Transplant Service was established in 1980, when the first sibling donor transplant was performed. Autologous stem cell transplantation was introduced in 1982 and the use of unrelated donors for allogeneic transplant from 1988. From 2006, the Service was designated to provide a National Service for alternative donor transplantation, which includes volunteer unrelated, cord blood and haplo-identical donors.

In 2012, NSD performed a review of adult allogeneic transplant provision in Scotland. This concluded that there should only be a single centre providing allogeneic haemopoietic stem cell transplantation in Scotland and that Centre should be in Glasgow. The Service started taking all the sibling donor transplants from Edinburgh and Aberdeen in 2015.

The review had suggested that the number of patients being transplanted in Scotland was less than elsewhere in the UK and predicted 75 patients a year should be receiving allogeneic transplants, increasing to 85 p.a. It is expected that transplant activity will increase to this level and possibly beyond short to medium term. It was anticipated that the Service would move to the new QEUH in summer 2015 and would have more beds to accommodate the predicted increase in activity.

Transplant numbers are predicted to continue rising. This is because the incidence of haematological malignancy is rising in the population and also increases with age. Transplant outcomes have improved significantly in the past few years for older patients and so, the median age of patients at the time of transplant has also risen. In addition, the improvement in outcome for transplants using haplo-identical donors broadens, meaning these are being utilised in patients who otherwise would not previously have had a donor option.

Currently the unit is performing around 70 allografts per year, the agreed level of activity with NSD is 70 allografts for 2016-17, and 73 for 2017-2018. In addition, the unit performs almost all the autologous transplants for the West of Scotland, currently around 90 transplants per annum, which is also increasing (~60 in 2015, 80 in 2016). This activity is also likely to continue to rise.

4. Option Appraisal

The option appraisal was conducted over two meetings in February 2017. The first meeting was to agree the options to be considered as well as benefits criteria and weighting. The second meeting then proceeded to scoring of the agreed options to provide a ranking of the available options.

4.1 Options Considered

A long list of 8 options was included in the feasibility study, and these were discussed in depth at the Group's first meeting. The capital cost of the options range from £0 to approx. £20m, however, the group's appraisal did not take cost into account, using the preferred Capital Investment Manual methodology of Weighted Benefits Scoring.

At the initial meeting, the Group agreed that four of the options were not feasible at all, based on the findings of Currie and Brown.

This left four options to take forward to scoring:

- remain at BWOSCC;
- return to Level 4 QEUH;
- relocate to the roof of the existing QEUH maternity building;
- relocate to the Institute of Neurological Sciences' Neurology Building at QEUH.

No	Description	Comments
1.	Remain at BWOSCC	Would require significant changes to level of clinical support on site
2.	Return to QEUH Level 4	Unlikely to be a long term option Quality of build environment is main issue
3.	QEUH Maternity roof	Difficult to sustain services during construction, but technically feasible
4.	Neurology Levels 1 and 2	Only technically feasible on paper
5.	Neurology Ground and 1st Floor	Only technically feasible on paper Significant concerns that building could never be fit for purpose
6.	Neurology Ground Floor with external extension	Only realistic Neurology option Difficult, but feasible
7.	QEUH Laboratory roof	Feasibility report indicates that building cannot support extension
8.	St Mungo Building, GRI	Only technically feasible on paper Not feasible from service delivery point of view

4.2 Benefits Criteria and Weighting

At the initial meeting, the group also agreed the benefits Criteria, against which the proposals would be ranked.

No	Description	Definition
A.	Improves the patient journey	Services should be delivered on as few sites as possible to minimise the need for patient and carer travel. The site(s) should be easily accessible with good patient/carers facilities.

No	Description	Definition
B.	Staffing	The extent to which there is adequate safe staffing, both within the unit's staff complement and within other services, e.g. Hospital at Night/resident on-call support.
C.	Meets published/recognised environmental standards	The extent to which the option satisfies both SGHD guidelines on Infection Control and other technical standards (SHTM, HSE, etc). This will take into account the ability to manage the risk associated with not meeting the standards, and any need for derogations.
D.	Meets published/recognised service standards	The service will meet standards set by JACIE and within the NSD service level agreement, and meets BSH Level 3. This includes immediate 24/7 access to the full range of acute services required to support patients who undergo stem cell transplant, including ITU-level critical care services and specialist support and review by other clinical teams.
E.	Minimises service disruption	The extent to which clinical services can be maintained during any required construction and/or implementation phase.
F.	Strategic fit	Links to national, regional and local clinical strategies for delivering cancer services, but with specific reference to wider GGC discussions on future location of BWOSCC and the configuration of haematology services.
G.	Timescale to deliver	There is a clinical urgency to make a decision on the location of the service.
H.	Long-term sustainability	The extent to which the facility improves the current and future capacity to deliver appropriate services to the population of Scotland, in line with ongoing planned expansion.

Prior to completing the benefits matrix, there had been two separate criteria identified for *Clinical Adjacencies* and *Meets Service Standards*:

Description	Definition
Delivers clinical co-dependencies and adjacencies	Having immediate 24/7 access to the full range of acute services required to support patients who undergo stem cell transplant, including ITU-level critical care services and specialist review.
Meets published/recognised service standards	The service will meet standards set by JACIE and within the NSD service level agreement, and meets BSH Level 3.

Whilst completing the Benefits Matrix to agree the weighting to be given to each criteria, the group agreed that the content of point A was encompassed within the service standards, particularly JACIE, referenced in point E, and that these two criteria should be amalgamated under *Meets Service Standards*.

Following identification of Benefit Criteria, the Benefits Matrix was completed, in which individual criteria are compared against each other.

The results were:

		A	B	C	D	E	F	G	H
Improves Patient Journey	A		B	C	D	A	F	G	H
Staffing	B			B	B	B	B	B	B
Environmental standards	C				D	C	C	C	H
Service standards	D					D	D	D	D
Minimises disruption	E						F	G	H
Strategic fit	F							F	H
Timescale to deliver	G								H
Sustainability	H								
		Improves Patient Journey	Staffing	Environmental standards	Service standards	Minimises disruption	Strategic fit	Timescale to deliver	Sustainability

This represented the majority decision of those in the room at the time of the exercise.

The identified benefit criteria were therefore ranked as follows:

Criteria	Score	Rank
B Staffing	7	1
D Service standards	6	2
H Sustainability	5	3
C Environmental standards	4	4
F Strategic fit	3	5
G Timescale to deliver	2	6

A	Improves patient journey	1	7
E	Minimises disruption	0	8

Following the scoring of the Benefits Matrix, *Minimises Service Disruption* scored 0. It was agreed at the Options Scoring meeting on Monday 20 February 2017 that this would be dropped from the scoring process.

Converting this to weighted scoring, this left the options with the following weights:

No	Description	Score
A.	Improves the patient journey	4
B.	Staffing	25
C.	Meets published/recognised environmental standards	14
D.	Meets published/recognised service standards	21
E.	Minimises service disruption	0
F.	Strategic fit	11
G.	Timescale to deliver	7
H.	Long-term sustainability	18

4.3 Option Scoring

The second meeting held was to agree the scoring of each option against the weighted benefits criteria with the membership of the scoring team detailed in Appendix Two.

Each member of the scoring team agreed to provide an individual score from 1-10 which would then be collated to provide an average.

OPTION 1: REMAIN AT BWOSCC

Option one scored low against ability to meet service standards. There are internationally agreed Standards for the staffing, facilities and management for transplant provision, inspected in Europe by JACIE. The Glasgow service was accredited in 2011, but this has now lapsed as the Beatson-based unit cannot meet the necessary Standards for the provision of critical care. Likewise, as option one would involve the continued split of outpatient services on QEUH and inpatients on BWoSCC, it scored low against improvements to the patient journey.

Benefit criteria		Weight	Score	Weighted score
1	Improves Patient Journey	4	4	14
2	Staffing	25	6	150
3	Environmental standards	14	8	109
4	Service standards	21	1	21
5	Minimises disruption			
6	Strategic fit	11	5	54
7	Timescale to deliver	7	9	64
8	Sustainability	18	2	36
Total		100		448

Individual scores given were:

				Service Clinicians			Infection Control		
Benefit criteria		IP	MM	DI	MC	GM	TW	SM	TI
1	Improves Patient Journey	4	4	3	3	3	4	5	5
2	Staffing	6	6	6	6	6	6	6	6
3	Environmental standards	8	8	7	7	7	8	8	8
4	Service standards	1	1	1	1	1	1	1	1
5	Minimises disruption								
6	Strategic fit	5	5	5	5	5	5	5	5
7	Timescale to deliver	9	9	9	9	9	9	9	9
8	Sustainability	2	2	2	2	2	2	2	2

The two clinical groups, the service team and the Infection Control team, evaluated this option only slightly differently, with service clinicians feeling that split-site working deserved a lower rating due to sub-optimal patient care caused by the requirement to transfer patients off site as well as having inpatient and outpatient services split over two sites.

OPTION 2: QEUH, LEVEL 4B

Option two was felt to deliver both an improved patient journey with the consolidation of services onto one site and the most likely to enable the service to meet their specific standards. However, option

two did not score well against criteria to meet environmental standards for the reasons identified above, nor was it felt to be a sustainable option for the longer term.

Benefit criteria		Weight	Score	Weighted score
1	Improves Patient Journey	4	7	25
2	Staffing	25	9	225
3	Environmental standards	14	2	29
4	Service standards	21	8	171
5	Minimises disruption			
6	Strategic fit	11	5	54
7	Timescale to deliver	7	6	43
8	Sustainability	18	3	54
Total		100		600

Individual scores given were:

				Service Clinicians			Infection Control		
Benefit criteria		IP	MM	DI	MC	GM	TW	SM	TI
1	Improves Patient Journey	7	7	7	7	7	7	7	7
2	Staffing	9	9	9	9	9	9	9	9
3	Environmental standards	1	3	3	3	3	1	1	1
4	Service standards	8	8	8	8	8	8	8	8
5	Minimises disruption								
6	Strategic fit	5	5	5	5	5	5	5	5
7	Timescale to deliver	6	6	6	6	6	6	6	6
8	Sustainability	3	3	3	3	3	3	3	3

OPTION 3: MATERNITY BUILDING, QEUH

Benefit criteria		Weight	Score	Weighted score
1	Improves Patient Journey	4	5	18
2	Staffing	25	7	175
3	Environmental standards	14	9	129
4	Service standards	21	6	129
5	Minimises disruption			
6	Strategic fit	11	3	32
7	Timescale to deliver	7	1	7
8	Sustainability	18	7	125
Total		100		614

Option three scored well against criteria to meet environmental standards given it would be purpose built to the required specification. However, there were concerns regarding strategic fit in terms of the longer term strategy for cancer services as well as the ability to adequately staff the unit e.g. Hospital at Night given the relative distance to the main Hospital.

The group agreed a consensus score against each of the criteria.

OPTION 4: GROUND FLOOR + EXTENSION, INSTITUTE OF NEUROLOGICAL SCIENCES

Benefit criteria		Weight	Score	Weighted score
1	Improves Patient Journey	4	5	18
2	Staffing	25	7	175
3	Environmental standards	14	9	129
4	Service standards	21	6	129
5	Minimises disruption			
6	Strategic fit	11	3	32
7	Timescale to deliver	7	1	7
8	Sustainability	18	7	125
Total		100		614

The group again agreed a consensus score against each of the criteria and option four therefore, scored identical to option three for the same reasons.

5. Ranking of Options

The scoring of options resulted in both options three and four ranking first with a score of 614 with option two scoring 600 and therefore, a very close second in terms of non financial benefits criteria. Option one scored 448 and was therefore, the ranked last by a clear margin.

6. Risk Assessment

There are a number of potential and actual risks associated with each of the four options in the following areas:

- Clinical;
- Infrastructure;
- Infection Control/Environmental;
- Patient Experience;
- Service Capacity;
- Accreditation Process;
- Strategic Direction.

Each option presents different risks as identified below. There are additional measures that could be taken to mitigate the risk.

OPTION 1: REMAIN AT BWOSCC

Clinical

The service completed a risk assessment which was submitted to the Strategic Management Group in 2016.

The service is admitting patients for an elective procedure in the knowledge that around 10% of them will require critical care levels that are not available on the Gartnavel site. This is contrary to current quality standards required for HSCTS in NHS England and for JACIE Accreditation and was the major drive for the service to move to the QEUH in 2015. This has also been highlighted by the BWOSCC Future Steering Group.

Whilst of huge value overall, the provision of a High Acuity Unit/Critical Care Outreach service on the Beatson site is of limited benefit to the BMT transplant population. The majority of these patients are being treated with curative intent and therefore will be for full supportive care, including ventilation and inotropes if needed. HAU can deliver level 1 care but if a patient is deteriorating and predicted to require level 2 care or beyond, they need to be transferred early to the critical care service at QEUH before that requirement is reached. This means that some patients are transferred, who do not ultimately deteriorate to level 2. It is also important to ensure that patients have recovered sufficiently and that their condition is stable before transferring them back to the BWOSCC when they could have been sent back to a QEUH ward at an earlier date. If the BMT unit was on the same site as critical care services, patients would not require pre-emptive transfer and delayed returns with reduced requirement for critical care beds. The BMT service is the highest user of the HAU/CCO service, with 46 transfers since returning to the BWOSCC 18 months ago. Of particular concern is that 10 patients required more than one transfer, one patient being moved four times during their inpatient stay. Patients also have to be transferred to QEUH if they require specialist opinion and or interventions such as endoscopy, cystoscopy, ureteric stent placement.

BMT in patients on the QEUH site are placed in wards whose staff are unaware of the requirements and complexities of BMT patients. They struggle to manage the demands of unfamiliar problems even in the critical care setting, due to high numbers of unfamiliar drugs, frequently given as multiple IV infusions. There have been several instances of patients not getting prescribed drugs in this

situation. BMT patients require frequent infection and drug level monitoring which can at times be missed either due to failure to request or incorrect samples being sent when they are the QEUH.

There is no dedicated transplant nursing, pharmacy or AHP staff on site at QEUH and it is extremely challenging to ensure optimal management for these complex patients. If the BMTU was on the same site there would be far greater input from the multidisciplinary BMT team to patients admitted to critical care.

Some medical and surgical wards are not capable of managing patients with central access so that peripheral venepuncture and cannulas are used unnecessarily if nursing staff are untrained in the use of these lines.

Certain types of transplant bring a high risk of cytokine storm with requirement for intensive support for both circulatory and respiratory systems and it is not safe to have these patients on the BWOSCC at certain times during their inpatient stay. Patients have been electively transferred to the QEUH critical care facility for observation and, if required critical care support, at the time of highest risk. BMT nursing staff have been seconded as chemotherapy needs to be given as part of the management, impacting on nursing numbers available for the BWOSCC ward.

Mitigation

In an effort to mitigate against the risks identified above, patients who are transferred to the QEUH site are reviewed daily by a member of the BMT consultant team. They direct the care of the patient and try to ensure that all appropriate tests, drugs etc. are arranged and available. They can be contacted via switchboard or mobile phone at any time.

Nursing staff who attend the BMT clinics at the QEUH on Monday, Tuesday and Thursday visit patients admitted to the QEUH to provide a familiar face and help the nursing staff with any problems they have. One of the consultant clinical psychologists visits any patients who have been transferred to the QEUH.

There are information sheets for the different drugs detailing how they should be administered and contact details for the BWOSCC ward for advice. A supply of any unusual drugs are transferred with the patient.

BMT outpatients from GGC, who present with symptoms that might indicate they are having GI blood loss, respiratory distress or cardiac symptoms although BMT complications can also cause similar symptoms, have to be told to go to their local ED for assessment as it is not safe to see them at the BWOSCC due to lack of critical care support.

Infrastructure

The BWOSCC Unit is now 10 years old and it is becoming more common for rooms to be closed for repair for water leaks, flood damage etc. The HEPA filtration plant has no back up and cannot be switched off for maintenance. With increasing age comes concern about risk of catastrophic failure with loss of a safe environment.

Patient Experience

NHS GGC provides the national service for patients which by definition have a life-threatening disease and are receiving treatment which could also be life-threatening. Patients and their families are coming from all over Scotland. Many will have formed strong attachments to their referring unit following prolonged stays and find it hard to make the transition to a new team. This formation of a relationship with the BMT team can be disrupted by the transfer. Psycho-social care and support for patients and their families is critical, during what is likely to be the most stressful experience of their lives, potentially a long way from home and their own support network. This is an integral part of the service provided, but cannot be delivered effectively when patients are transferred off-site.

A number of patients and their families have felt very isolated at QEUH, during a very traumatic and critical part of their treatment, being moved to an unfamiliar environment, to be managed by unfamiliar staff, who have limited or no experience in transplant.

The following comment is from correspondence from the wife of a patient who recently passed away:

"In total xxx spent 59 nights at the Beatson and 47 nights at QEUH!!!! For 47 nights xxx was nursed by people with no post transplant experience despite the Leaflet 'A patient's guide to Allogenic Bone Marrow Stem Cell Transplant' stating "the nursing staff involved in your care have specialist experience in transplantation"

Several patients have vowed they will not return, even if this is deemed medically necessary. Patients who do not recover sufficiently to transfer back to the BWOSCC have to remain at the QEUH for palliative care.

Service Capacity

It had been planned to increase bed capacity from 19 to 24 beds to accommodate anticipated growth in activity as the designated single centre for NHS Scotland. As the service remains in BWOSCC, this has not been possible and capacity is limited to 20 beds.

Every effort is made to admit a patient once they are fit for transplant and a donor has been identified. However, some patients do have to receive additional therapy or are not admitted as promptly as they might be, particularly those who have a relatively indolent disease eg. MDS, myelofibrosis. It is very difficult to quantify this number, but probably 5-6 patients per year are admitted 2-3 months later than they needed to be, because of lack of bed space. So far no patient has developed accelerated disease during the delay, however, it could occur with any of these individuals.

It is often not possible to admit patients to a BMT bed, who have been transplanted and developed complications requiring specialist care. All patients are managed in their local hospitals whenever possible, but some should be transferred and are not due to lack of beds.

Accreditation

There is an expectation from commissioners that the nationally commissioned service will be JACIE accredited. Whilst the service will meet environmental requirements as outlined in appendix five, it is unlikely to be accredited due the lack of support services including critical care on site.

OPTION 2: QEUH, LEVEL 4B***Infection Control/Environmental***

As noted, the facility in 4B QEUH does not meet the standards set out by SHTM 03-01 (Appendix six) for neutropenic rooms or HPS guidance and therefore, the main concern is that of airborne infection particularly invasive fungal infection (IFI) due to organisms such as aspergillus and zygomycosis due to air quality. Based on published literature, mortality rates in outbreaks related to construction or demolition in patients with Haematological malignancies are quoted at 57.6%. Concentrations of aspergillus species below 1 colony forming unit/m³ are sufficient to cause infection in high risk patients.

Currently, the BMT Unit in NHS GGC's Royal Hospital for Children does not meet the standard either however, the rooms do have a positive pressure of 10 PA hepafiltration and have anterooms. It has been agreed to upgrade four of these rooms to meet the full standards.

Mitigation

Appendix three provides benchmarking of BMT units across the UK. NHS GGC's Lead Infection Control Doctor has contacted two of the centres – Nottingham and Devon (two adult units with a specification that does not meet HPS guidance) to ascertain their infection rates and what if any mitigating actions they have in place.

Improvements to the environment in ward 4B are achievable with additional capital expenditure including the sealing of the bathroom ceilings and creation of a double door entry system. Further measures would include introduction of twice daily cleaning of the ward as well as the use of portable HEPA filtration units in the corridors.

There is now very effective anti-fungal prophylaxis and sensitive screening tests, which can be used to manage risk in this patient population. A strategy of effective prophylaxis and confining patients to their rooms with the ward closed to all through traffic will minimise the risk of acquiring fungal infection whilst an inpatient.

A robust monitoring regime as detailed in Appendix Four and which is currently in place in the current BMT unit in B8/9 at BWoSCC.

Infrastructure

In addition to the fact that ward 4B does not provide the required specification for BMT services, it is also served by only one air handling plant. As a consequence, there is no way to carry out maintenance\service PPM\annual verification without shutting down the ventilation plant, which would affect all isolation rooms served by the single air handling unit. This would require the ward to be vacated during each period of planned preventative maintenance.

Mitigation

The recently proposed upgrade works to ward 4B includes the addition of a standby air handling unit, albeit of reduced capacity which would mitigate against the concerns identified above. This would require significant capital investment as previously identified.

Accreditation

There remain a risk to JACIE accreditation given the infrastructure/environmental risks highlighted above. That said, JACIE does not specify environmental requirements to the standard previously provided by HPS as outlined in Appendix five. Therefore, it is anticipated that provided the monitoring regime does not identify any issues, that this should provide sufficient evidence that this requirement is being met.

OPTION 3: MATERNITY BUILDING, QEUH

Clinical

There are concerns that the risk of this option is around the ability to safely staff the unit 24/7. The BMT service does not have their own junior medical team and is instead supported by the BWoSCC. Should services relocate, they will require to be covered by the Hospital at Night team as is currently the case. Whilst this is likely to be deliverable within the main ward block of QEUH, there is concern that the service will not be safely covered in an option that would see them relocate outwith the main QEUH ward block.

Further, any option that requires a significant build is unlikely to be delivered within a timeframe of less than two – three years. The clinical risk associated with remaining on the BWoSCC site for this period of time has already been highlighted above.

Strategic Direction

There is concern with the strategic fit of this option with the long term direction of cancer services. Work is ongoing regarding the long term direction of cancer services. The preference would be to remain co-located with cancer services in the future but capital investment in this option may preclude this in the future.

OPTION 4: GROUND FLOOR + EXTENSION, INSTITUTE OF NEUROLOGICAL SCIENCES

The risks identified with this option are identical to those with option 3.

7. Conclusions

Whilst Options three and four clearly scored the highest with regard to delivery of environmental standards, there are concerns regarding the staffing, strategic fit and timescale for delivery.

Given the close scoring between options two, three and four against non financial benefits criteria the group discussed option two as an interim solution for a time limited period.

Whilst option two would not provide the required environmental standards, benchmarking across the Centres in the UK has demonstrated that only those services that have moved into purpose built facilities are currently delivering this standard as outlined in Appendix Three.

8. Recommendations

The Acute Services Committee is therefore, asked to consider option two as an interim solution and support the relocation of BMT Services to 4B QEUH. To support the move, it is proposed that further refurbishment works be commissioned as detailed in the risk assessment. Thereafter, a period of air

quality monitoring should be undertaken as outlined in Appendix Four. To enable this, the ward will need to be vacated and positive pressure switched on which will preclude the use of the ward for medical surge capacity.

At the same time, BMT services should be considered as part of the acute services review of cancer services to deliver a longer term sustainable option that meets both service and environmental considerations as detailed in Appendix one.

This recommendation is made on the basis that service delivery considerations require prioritisation over the Infection Control and Prevention Teams concerns on meeting national standards and HPS recommendations.

Appendix One

Recommendation	To allow the provision of a protective environment for patients within the bone marrow transplant unit (Ward 4B) • The rooms must be positively pressured at 10 pa • ALL air entering the room must be via the HEPA filter • The HEPA filter should as a minimum be E12 (H13) and located within the supply air diffuser • The rooms must be sealed and no air which has not passed via the HEPA filter should access the room • A strict protocol which minimises the length of time the door is opened and reduces air entry via an open door is required. • There must be a continuous pressure monitoring system for each room which alarms and gives an early indication of a pressure drop within the room • Bedroom Air changes of 10 ACH must be achieved • The walls and ceilings within the rooms and ensuite must be sealed. • All room services must be sealed • All service access hatches within the bedrooms/ensuite must be sealed • The pentamidine room must be negatively pressured and comply with health and safety legislation • There must be at least one room available in the critical care unit capable of providing the same level of protection as those proposed in ward 4B • HPS will continue to co-ordinate and provide support with this issue and subsequently the Children's unit and additional areas of ventilation concern (Critical care, ID Unit, theatres) • HPS will co-ordinate and provide support a required relating to water control and testing in this unit
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Appendix Two

Option Appraisal: National Adult Stem Cell Transplant Programme – Agreement of Options/Benefits Criteria and Weighting.

Meeting 8th February 2017

Dr Anne Parker
Dr Grant McQuaker
Ms Myra Campbell
Mr David Loudon
Dr Teresa Inkster
Ms Melanie McColgan
Ms Marjorie Johns (Facilitator - did not score or rate options)

Option Appraisal: Adult BMT Service - Scoring of Options

Meeting 20th February 2017

Dr Grant McQuaker
Dr Dave Irvine
Ms Myra Campbell
Mr Ian Powrie
Dr Teresa Inkster
Mrs Sandra McNamee
Mr Tom Walsh
Ms Melanie McColgan
Ms Marjorie Johns (Facilitator - did not score or rate options)

Appendix Three**UK Benchmarking**

Of the 9 centres who responded to a local survey (across the UK), all are operating within varying environments as follows:

Hospital	HEPA filtered Rooms Y / N	HEPA filtered Corridors Y / N	Room Air Changes 10/hour Y / N (if different, please specify)	Room Pressure Positive 10Pa Y / N (if different please specify)	Sealed Rooms (fixed ceilings etc) Y / N	Air Lock Entrance to Ward Y / N	Is Air Pressure Monitoring System Alarmed Y / N	Is there a "Back-up" air handling plant for Wards Or Separate plant for each room	Rooms with anteroom at negative pressure for infectious BMT patients Y / N (Please state approx. Pa)	Do you operate a programme of Environmental Monitoring (Particle Counting / Microbial air sampling etc – please state acceptable limits)	HDU / ICU on-site	Comment
QEUH Proposal	Y	N	N Approx. 6 AC/hr	N 6-8 Pa running pressure	Y	Y	Y Audible alarm outside each room	N Independent (back-up) AHU unit available if primary unit fails	Y (Available via adjacent Renal Ward)	Y Monthly programme of Microbial Air Sampling and Particle Monitoring	Y	
Beatson WoSCC (current position)	Y	Y	Y	Y Rooms vary between 6-15Pa	N	Y	No, pressure gauge on wall	Y Each Ward has dedicated AHU – each Ward is back-up for each other	Y Approx -5Pa	Y Monthly programme of Microbial Air Sampling and Particle Monitoring	N	
UCLH	Y	N	Y	Y	Y	N	No, pressure gauge on wall	No	-10KPa on separate floor	Micro sampling of all wards (contact plates etc) led by infection control. HEPA qualified annually by external company.	ITU + HDU	
St Bartholomews (Barts Health)	Y	Y	Y	Y	Y	Y	Y	Back up	Y	Done by infection control. No SOP that I'm aware of.	ICU on-site for BMT patients. Other ICU'/HDU' for cardiac patients	Whole floor is HEPA filtered (Brand new facility – last year)
Nottingham University Hospital	Y	N	Y	Y Runs at <10	N Suspended ceilings	N	N But is checked every morning by	Y Back up generators Monitored by estates dept	N/Y Negative pressure can be achieved by leaving the	Y NUH Infection control dept coordinates this – air particle sampling and micro sampling	Critical Care Unit on-site	

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							ward staff and then alarm raised if out of range.		bathroom door open. ?Pa	done. Also water sampling showers and sinks. Throughout ward. Results go through to ward Manager.		
KCH	Y	Y	Y	Y	Y	Some	Y	N	Y	No. Rooms verified on opening. Regular HEPA filter replacement.	HDU + ICU	
ANON	Y	No. Each room positive to corridor	Y	Y	Y	Y	Yes, local and central	Separate AHU for each patient room. Main Ward on separate system.	Yes, 15Pa in anteroom and 10Pa in patient room.	No. Rooms verified on opening. Regular HEPA filter replacement.	ICU (ITU)	
Royal Devon & Exeter	Y	N	Y	Y	Y	N	N	N	Y	Y	ITU (+HDU)	
Leeds Adult	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	ICU + HDU	
Sheffield Children's Hospital	Y	N	N	N	N	N	N	N	N	Y	ICU + HDU	
Manchester Children's Hospital	Y	Y	N	N	N	Y	No air pressure monitoring of any rooms just a general alarm should the AHU or booster fan fail. This is displayed at the nurses' station via a red LED showing airflow fail.	N	TOILET ONLY	Particle counts to ISO 14644 Class 5 and 6	ICU + HDU	

Appendix Four**SBAR – Air sampling , BMT units**
Dr T Inkster 09/03/17

Situation	Air sampling has been performed on a monthly basis in B8/9 as a quality assurance check. There is no requirement as such to air sample and no agreed standards or guidance for interpretation of air sampling for UK BMT units. Practice is variable across the UK and three units which meet a high ventilation specification do not routinely air sample. The ventilation spec in 4B, QEUH is less than that of B8/9 therefore it is unclear what interpretative criteria to apply and what actions to take when results are elevated. Currently medical patients are housed in 4B with positive pressure ventilation turned off
Background	Particle counts and air sampling are undertaken in B8/9 unit on a monthly basis. Particle counts < 1000 are deemed acceptable limits (ISO standard for clean rooms) and fungal air sampling results <0.1 CFU/m³. Particle count results are available in real time however it is important to note the environmental conditions while sampling. Particles are not just fungus or bacteria but can be skin, dust, hair, cosmetics etc The commonest explanation for high particle counts are people in the vicinity of sampling or failure of the sampling to be carried out remotely. Particle counts can be higher when rooms have just been cleaned . If the aforementioned factors have been excluded high particle counts can alert infection control teams early to possible air quality issues and fungal contamination. They cannot be used in isolation as an accurate indicator of air quality. Air sampling results and fungal culture take 7 days to initial identification and a further 7 days for species identification .
Assessment	Literature review; <u>Indications for air sampling</u> Indications for air sampling are listed in the table below from Morris <i>et al.</i>¹ Note that regular maintenance is considered more important than air sampling. Air sampling is only one parameter of many with regards to assessment of the efficacy of a ventilation system.

Table I Objectives of air sampling

To correlate outbreaks of invasive aspergillosis with hospital construction/demolition

To identify potential sources of nosocomial aspergillosis, eg. potting soil, damp ceiling voids, damp fire proofing material, carpeting, etc.

To predict environmental spore contamination from outside sources

To identify defects/breakdown in hospital ventilation/filtration systems*

To monitor cleaning procedures that may release bursts of airborne *Aspergillus conidia*

To determine the efficacy of HEPA filters in laminar flow facilities

To monitor efficacy of procedures to contain hospital building work from hospital wards and other areas where high-risk patients are managed

To determine level of contamination prior to initial occupancy of special controlled environments

*regular engineering maintenance of the air supply system (whether HEPA-filtered or not) is more important than regular air sampling

Result interpretation

Interpretation of results can be difficult. The table below gives some recommendations.¹ For BMT rooms the HEPA filtered air value would apply i.e. <0.1 CFU/m³

Table III Interpretation of air sampling data and recommendations

Levels of fungal spores vary by several orders of magnitude during the course of a day due to:

- Activity levels in any one particular area
- Fluctuations in temperature
- Fluctuations in humidity
- Fluctuations in air flow
- Changes in light level

A single air sample will often underestimate the fungal contamination in the air: multiple air sampling has to be performed

No strict numerical guidelines are available which are appropriate for assessing whether the contamination in a particular location is acceptable or not but the following threshold levels have been recorded:

Outdoor air: total fungal count: 10³ to 10⁵ CFU/m³

Aspergillus: 0.2–3.5 conidia/m³

Note: seasonal variation recognised

HEPA filtered air (> 95% efficiency and > 10 air changes per hour): < 0.1 CFU/m³

No air filtration: 5.0 conidia/m³

Construction/defective ventilation: 2.3–5.9 conidia/m³

If total fungal count exceeds 1.0 CFU/m³ on several occasions the air systems or procedural practice in patient areas requires intensive evaluation.

There is no agreed level at which the risk can be numerically defined for Invasive Aspergillosis. Vonberg et al state that concentrations below 1 cfu/m³ were sufficient in high risk patients.² It is best to conduct a series of samples over time to detect trends.³

Burst phenomenon

Understanding the burst phenomenon of fungi particularly *Aspergillus* is important. Spores can be released in bursts and the difficulty is capturing these bursts. No amount of air sampling will yield a preventative response to this phenomenon.⁴ Negative air sampling may provide false reassurance. Striefel et al suggest that the emphasis should

	be on maintaining environmental controls and minimising the in house release of spores ⁴
Recommendations/ Conclusions	1. In the absence of any definitive guidance the BOC parameters could be applied to level 4B, QEUH i.e. particle counts <1000/m³, fungal counts <0.1/m³ 2. Air sampling has been performed on a monthly basis in BOC as a quality assurance check, however, this would not be an accurate indicator of air quality in an area where we know that the ventilation is of a lesser specification. The specified parameters are less reliable in an area where we expect to encounter higher counts. 3. Difficulties are likely to arise in the management of sustained elevated particle counts and repeated fungal growth with no obvious source should they occur – this is a possible scenario given the ventilation specification in 4B and the inability to HEPA filter all air entering the unit 4. Negative air sampling may provide false reassurance due to the burst phenomenon 5. To enable a period of monitoring prior to BMT patients moving in to 4B medical patients would have to be vacated and the positive pressure reinstated. 6. Ideally a minimum period of 4-6 weeks monitoring prior to BMT patients occupying the ward should be undertaken

References

1. Morris G et al Sampling of Aspergillus spores in air. Journal of Hospital infection 2000;44:81-92
2. Vonberg RP, Gastmeier P. Nosocomial aspergillosis in outbreak settings. Journal of Hospital Infection 2006;63:246-254
3. Humphreys H. Positive pressure isolation and the prevention of invasive aspergillosis. What is the evidence? Journal of Hospital Infection 2004;56:93-100
4. Falvey DG, Striefel A. Ten year air sample analysis of Aspergillus prevalence in a University hospital. Journal of Hospital Infection 2007; 67: 35-41

Appendix Five

The sixth edition of the *FACT-JACIE International Standards for Hematopoietic Cellular Therapy Product Collection, Processing, and Administration* have been published and became effective from June 2015.

The standards are available at: <http://www.jacie.org/standards/6th-edition-2015>

The applicable standard for air quality is B2.1. **Both QEUH and BWOSCC meet this standard.**

B2.1 There shall be a designated inpatient unit of appropriate location and adequate space and design that minimizes airborne microbial contamination.

Explanation:

Clinical unit facilities may vary among centers. Variability may reasonably be based on a number of factors, including the number and/or type (autologous or allogeneic) of transplants performed, the patient case mix, the graft source, epidemiological factors influencing the prevalence of opportunistic infections, potential economic factors, and an increasing use of ambulatory facilities for transplantation.

This standard is not meant to imply that every clinical unit must have laminar airflow available, but HEPA filtration with positive pressure is recommended for high risk patients. If non-HEPA filtered rooms are used for lower risk patients or if there is a shortage of HEPA filtered rooms, the SOP(s) on infection control, biosafety, and chemical and radiological safety should indicate how allocation of rooms is prioritized. Further, auditing of airborne microbial infections in non-HEPA rooms should be performed as part of the QM Program.

Evidence:

The inspector will tour the inpatient unit during the on-site inspection. Because different patients have different infection control needs, the Clinical Program must have policies and procedures that define infection control requirements based upon differing patient conditions and room configurations. The type of air handling should be documentable from a facilities management office. An SOP detailing alternatives in case there is a shortage of isolation rooms; steps for preventing and controlling specific healthcare-associated infections, such as MRSA, C. Difficile and community respiratory virus infections; and procedures for monitoring airborne infections will provide evidence of compliance.

Signs posted around the clinical unit and the behavior of the staff consistent with expectations for the type of infection control described in the policies and procedures demonstrate compliance with this Standard. If there are renovation or construction projects underway, the appropriate environmental controls must be present. The risk of spread of communicable disease agents must be minimized in any setting where patients could reasonably be expected (including dialysis or intensive care units). Care should be taken that the ventilation from other isolation rooms (where

infected patients may reside) does not pass through the rooms used for HPC patients. Evidence of compliance with this Standard will require preinspection documentation of infection control policies, specifications of air handling, and floor plans.

When an accredited Clinical Program is to be relocated, qualification and validation must be performed to confirm the new space meets the Standards. The requirements for maintaining FACT accreditation in the event of relocation are outlined in the FACT accreditation policies, available on the FACT website.

The Clinical Program is expected to submit a description and floor plans of the new facility, QM documents, and an expected relocation date. If a JACIE-accredited facility intends to relocate, the program should submit plans and descriptions of the relocation to the JACIE office. Most relocations will be assessed during regularly scheduled inspections or interim audits; however, if there are any concerns with the information submitted by the facility, a relocation inspection may be necessary.

Example(s):

HEPA filtration with positive pressure is recommended for high-risk patients, but is not required for every unit. Single patient rooms should be located on a patient care unit where infection control policies can be implemented. Portable, industrial-grade HEPA filters may be available to accommodate vulnerable patients in case of a shortage of rooms.

Visitors should receive information concerning communicable infections. Signs posted to inform the public about visitation restrictions could also include information about incubation periods and risks of live vaccines.

In ambulatory settings, patients may be accommodated in a hostel, hotel, or home-based setting for periods of the transplant with frequent day case review and potential rapid inpatient admission. Clinical Programs should share criteria with these facilities regarding practices to prevent the spread of communicable infections.

The following standard can be **met at QEUH but not at BWOSCC**:

B2.5 There shall be provisions for prompt evaluation and treatment by a transplant attending physician available on a 24-hour basis.

Explanation:

A transplant attending physician must be available at all times to manage transplant recipients. The transplant attending physician does not necessarily need to be the only health care provider on call nor be the first to see any patient requiring attention.

Evidence:

An on-call schedule should be available for inspector review. Inspectors may choose to test attending physician availability by activating the on-call schedule during the period of the on-site inspection.

Example(s):

Numerous post-transplant complications may require prompt attention, such as central venous line-associated bacterial sepsis. If needed because of distance to the in-patient facility or for other reasons, a protocol should exist for outpatient facilities to contact emergency medical services if needed for prompt care (for example, 911 in the U.S. or 112 in the EU).

Notes on GGC performance:

While a transplant physician is on-call 24/7 for attending the BWOSCC, it is not possible for the team to cover two sites and, as described above, transplant support for patients in critical care is delivered predominantly by phone, and not in person. While in ITU, patients do not have direct access to transplant physicians, nurses or specialist pharmacists. This standard would be met if the Transplant Unit and critical care facilities were co-located.

The following standard can be **met at QEUH but not at BWOSCC**:

B2.13 There shall be an intensive care unit or equivalent coverage available.

Explanation:

The Clinical Program must have documentation that there is ready access to an ICU or equivalent coverage in an immediate fashion for its patients when appropriate. This requires the ability to provide multisystem support including assisted respiration. Ordinarily, this would be within the institution but contractual arrangements with another institution may be considered if transfer procedures are in place to ensure prompt service and patient safety.

Outpatient facilities must document a plan for immediate transfer to an ICU, emergency department (ED), or inpatient unit if clinically warranted. The outpatient plan for providing inpatient care if needed should be discussed with the patient regardless of the type of outpatient setting (e.g., home, day unit, hotel, etc.). The outpatient plan should address specific needs of transplant recipients, such as the need for isolation protocols for immunocompromised patients, transfer to transplant-designated units related to clinical indications, and transplant-specific discharge plans.

Notes on GGC performance:

The key phrase within the standard is 'ready access [...] in an immediate fashion.' While there are currently transfer arrangements in place, the standard envisions that patients will still be managed by appropriately trained transplant physicians, as per B2.5 above. This level of care cannot be provided while the service is provided by two non-adjacent sites.

The following standard can be **better met at QEUH than at BWOSCC**

B3.9.1 The Clinical Program shall have access to certified or trained consulting specialists and/or specialist groups from key disciplines who are capable of assisting in the management of patients requiring medical care, including, but not limited to:

B3.9.1.1	Surgery
B3.9.1.2	Pulmonary medicine
B3.9.1.3	Intensive care
B3.9.1.4	Gastroenterology
B3.9.1.5	Nephrology
B3.9.1.6	Infectious disease
B3.9.1.7	Cardiology
B3.9.1.8	Pathology
B3.9.1.9	Psychiatry
B3.9.1.10	Radiology.
B3.9.1.11	Radiation oncology with experience in large-field (e.g., total body or total lymphoid) irradiation treatment protocols, if radiation therapy is administered.
B3.9.1.12	Transfusion medicine
B3.9.1.13	Neurology
B3.9.1.14	Ophthalmology
B3.9.1.15	Obstetrics/Gynecology
B3.9.1.16	Dermatology
B3.9.1.17	Palliative and end of life care

Explanation:

In addition to the specialties specifically listed in these standards, Clinical Programs should also have access to other specialists directly related to the diseases being treated, such as metabolic diseases or immunodeficiencies.

Notes on GGC performance:

While telephone advice is available from all of these specialties within BWOSCC, and Ophthalmology is available on-site at Gartnavel campus, part of the rationale of designating NHSGGC as the single national centre for allograft transplantation in Scotland was to achieve co-location with these specialties on the QEUH campus.

Further guidance which applies to the BMTU

Haematological cancers: improving outcomes

NICE guideline [NG47]

Published date: May 2016

Available at: <https://www.nice.org.uk/Guidance/NG47>

	BWOSCC	QEUH
Centre size		
Haematology units that care for adults and young people who are receiving high-intensity chemotherapy should provide high-intensity (non-transplant) chemotherapy for induction or re-induction of remission to a minimum of 10 patients per year who have new or relapsed haematological malignancies and who are at risk of more than 7 days of neutropenia of 0.5×10^9 /litre or lower.	Y	Y
Isolation facilities		
Inpatient isolation facilities for adults and young people who have haematological malignancies and are at risk of more than 7 days of neutropenia of 0.5×10^9 /litre or lower should consist of a single-occupancy room with its own bathroom.	Y	Y
Consider installing clean-air systems into isolation facilities for adults and young people who have haematological malignancies and are at risk of more than 7 days of neutropenia of 0.5×10^9 /litre or lower.	Y	Y
Ensure that there is provision for direct admission to the haematology ward or other facilities equipped to rapidly assess and manage potentially life-threatening complications of chemotherapy (such as neutropenic sepsis or bleeding) in adults and young people, according to agreed local protocols.	Y	Y
Ensure that there are specific beds available in a single dedicated ward within the hospital with the capacity to treat the planned volumes of patients.	N	Y
Other facilities		
Ensure that there is a designated area for outpatient care that reasonably protects the patient from transmission of infectious agents, and provides, as necessary, for patient isolation, long duration intravenous infusions, multiple medications, and/or blood component transfusions.	Y	Y
Ensure that there is rapid availability of blood counts and blood components for transfusion.	Y	Y
Ensure that there are on-site facilities for emergency cross-sectional imaging.	Y	Y
Ensure that cytotoxic drug reconstitution is centralised or organised at the pharmacy.	Y	Y
Ensure that there is on-site access to bronchoscopy, intensive care and support for adults and young people with renal failure.	N	Y

Notes

- The recommendations apply to young people (16–24 years) and adults (over 24 years) with haematological malignancies who are receiving high-intensity (non-transplant) chemotherapy for induction or re-induction of remission or consolidation
 - They apply to all patients treated within the transplant unit, as patients receive both pre-transplant conditioning regimes and, where clinically required, post-transplant treatment within the unit
- The increasing transplant activity requires additional beds which are not available at BWoSCC (max 19 beds, as opposed to 24 beds within QEUH)
- Patients have to be transferred off-site for ITU care and acute renal failure for dialysis. It is possible to dialyse patients at the BWoSCC, but this would realistically only be for patients with chronic renal failure, already established on dialysis. Bronchoscopy can be performed on site, but most patients requiring this would be too unwell for it to be performed at BWoSCC. In addition, anyone with an acute bleed requiring endoscopy needs to be transferred.

Appendix Six**Recommended air-change rates**

Application	Ventilation	Ac/Hour	Pressure (Pascals)	Supply Filter	Noise (NR)	Temp (°C)	Comments For further information see Section 6
General ward	S / N	6	-	G4	30	18-28	
Communal ward toilet	E	10	-ve	-	40	-	
Single room	S / E / N	6	0 or -ve	G4	30	18-28	
Single room WC	E	3	-ve	-	40	-	
Clean utility	S	6	+ve	G4	40	18-28	
Dirty utility	E	6	-ve	-	40	-	
Ward isolation room	-	-	-	-	-	-	See SHPN 4; Supplement 1
Infectious disease Iso room	E	10	-5	G4	30	18-28	Extract filtration may be required
Neutropenic patient ward	S	10	+10	H12	30	18-28	
Critical Care Areas	S	10	+10	F7	30	18-25	Isolation room may be -ve press
Birthing Rooms	S & E	15	-ve	G4	40	18-25	Provide clean air-flow path
SCBU	S	6	+ve	F7	30	18-25	Isolation room may be -ve press
Preparation room (Lay-up)	S	>25	35	F7*	40	18-25	*H12 if a lay-up for a UVC Theatre
Preparation room/ bay sterile pack store	S	10	25	F7	40	18-25	*50NR if a bay in a UCV Theatre
Operating theatre	S	25	25	F7	40	18-25	
UCV Operating theatre	S	25*	25	H12	40	18-25	Fresh air rate; excludes re-circulation

Anaesthetic room	S & E	15	>10	F7	40	18-25	Provide clean air-flow path
Theatre Sluice/ dirty utility	E	>20	-5	-	40	-	
Recovery room	S & E	15	0	F7	35	18-25	Provide clean air-flow path



**Situational Assessment
Wards 2A/B
Royal Hospital for Children
NHS Greater Glasgow and Clyde**

Status: Confidential Draft

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Background

NHS Greater Glasgow and Clyde (NHSGGC) are currently investigating and managing a contaminated water system across the Queen Elizabeth University Hospital (QEUP) and Royal Hospital for Children (RHC) with probable linked cases of bloodstream infections associated with wards 2A/2B RHC. During this investigation it was identified that there was a higher than expected level of Healthcare Associated Incidents (HCAI) linked to wards 2A/2B. The National Support Framework (<http://www.nipcm.scot.nhs.uk/documents/the-national-support-framework-2017/>) was invoked by the Scottish Government HAI/AMR Policy Unit to request Health Protection Scotland (HPS) undertake a review of Ward 2A/2B.

Due to the ongoing water contamination investigation and resultant summary report being prepared by HPS for Scottish Government it was agreed that whilst the review of wards 2A/2B was ongoing the report would not be undertaken until final submission of the water investigation report was completed. The final submission of this report was on 21st December 2018.

Wards 2A/2B RHC is a paediatric haemato-oncology unit, also known as Schiehallion, and houses the National Bone Marrow Transplant (BMT) Unit. The RHC is a 256 bedded childrens hospital which was handed over to the Board on 26th January 2015 with migration of patients occurring between 10th and 14th June 2015 from the previous Yorkhill site. The RHC was fully occupied from 15th June 2015.

All water related issues linked to wards 2A/B are discussed in the water incident report submitted to Scottish Government 21st December 2018 and not within this report. In addition a ventilation review of wards 2A/2B is currently being undertaken and will be covered within a separate NHSGGC report.

Wards 2A/2B closed on 26th September 2018 to allow for a works relating to water contamination to be completed. At this time the opportunity was taken to review the ventilation. Patients were transferred to wards 6A/4B at the Queen Elizabeth University Hospital.

Introduction

Since January 2016 NHSGGC have reported 15 Healthcare Infection Incident Assessment Tool (HIIAT) incidents/outbreaks within wards 2A/2B RHC. Comparative data for this setting (all paediatric hospitals) within NHSScotland identified no reported incidents or outbreaks outwith NHSGGC. The HIIAT allows NHS boards to assess the impact of a healthcare infection incident/outbreak on patients, services and public health and should be used by the Infection Prevention and Control Team (IPCT) or Health Protection Team (HPT) in their assessment of any incident/outbreak within a healthcare setting. In addition it supports a single communication channel for infection incident/outbreak assessment and reporting both internally within an NHS board area and externally to Health Protection Scotland (HPS) and Scottish Government Health and Social Care Department (SGHSCD).

Mandatory HIIAT Green (non-norovirus) reporting for NHS boards was introduced in April 2016; providing a more robust epidemiological picture of incidents and outbreaks across acute healthcare in NHSScotland. A HIIAT assessment is scored Red, Amber or Green according to a four part criteria:

- Severity of illness
- Impact on services

- Risk of transmission
- Public anxiety

Of the 15 HIIATs reported from 2A/2B since 2016 there have been 5 reds, 2 ambers and 8 greens reported to Health Protection Scotland (HPS). Details of the incidents reported are contained in [appendix 1](#). Four of these HIIATs (2 red and 2 green) are attributed to the ongoing water incident. It could be hypothesised that ventilation may have been a contributory factor in several incidents however this cannot be confirmed until a full ventilation review has been completed.

Wards 2A/2B Assessment

Observational assessment walk rounds of wards 2A/2B was undertaken by a Senior Nurse Infection Control from HPS on 18th to 22nd June, 2nd July and 8th August 2018.. During these walk rounds practice and environmental hygiene were observed.

A meeting was held between the Chief Nurse Hospital Paediatrics and Neonatology, Consultant Surgeon and two Nurse Consultants Infection Control (HPS) to discuss ongoing work into central line-associated blood stream infections (CLABSI). This meeting took place on 17th July 2018.

It is noted that overall practice was described as good with no major issues observed or reported. Compliance with standard infection control precautions (SICPS), particularly hand hygiene, use of personal protective equipment and environmental cleanliness was observed to be good. Awareness of infection control practices were high with notable visibility of the local infection prevention and control team (IPCT).

Ward 2A Overview (Floor plan [appendix 2](#))

- Ward 2A consists of 25 ensuite single rooms.
- There are three distinct areas to the ward; the BMT bedrooms, standard rooms and the remaining Teenage Cancer Trust (TCT) and haemato-oncology rooms.
- The main entrance to the ward is through the entrance at the BMT section of the ward .
- Children with haemato-oncology and haematology disorders are the main patient population within this ward.

Ward 2B Overview (Floor plan [appendix 3](#))

- Ward 2B consists of five consultation rooms and two 4-bed-bay areas.
- Ward 2B has a main waiting area at the reception of the ward with a TCT waiting area beside the TCT bay area.
- Ward 2B cares for children with haemato-oncology and haematology disorders on a Monday to Friday day care basis.

Water

A detailed summary report was prepared and submitted to HAI/AMR Policy Unit on 21st December 2018. This summary report documents all the findings from water-related investigations carried out until the decant of patients from Ward 2A/2B.

Ventilation

Work has been undertaken to convert the positive pressure ventilated lobbied rooms (PPVL) used predominantly for bone marrow transplant recipients into specification compliant positively pressured isolation rooms.

Ventilation within these wards is subject to a review by NHSGGC and will be covered in the resultant report. An SBAR covering initial findings has been prepared at the request of Scottish Government (SG) and submitted to SG by NHSGGC (November 2018).

Chilled beams

Chilled beams were noted to have significant level of dust present in two separate rooms (Ward 2A) there was also discolouration to the edges of the ceiling around the supply. This is potentially due to water contamination and was under review by estates department.

Dripping from the chilled beams had been observed by staff on a number of occasions. This was reported to estates and it has been identified that there were no dew point controls on the chilled beams. A dew point control has been fitted to the central system to alleviate the issue.

Temperature

Ward 2A was observed to be very warm and humid on the day of the visit and staff reported this was common for the ward.

HEPA filtration

The corridors within these wards are not HEPA filtered. The previous facility within Yorkhill hospital was reported to have 8 HEPA filtered rooms with all other rooms being conventionally ventilated.

Pressure stabilisers

Pressure stabilisers were noted in the rooms and also to the corridor of all the BMT rooms. There was no noted issue with overall pressures during this time however some of the stabilisers were noted to have no oscillation when the doors were opened.

Air Changes

It is noted from an SBAR prepared by NHSGGC on 12th November 2018 that the single room accommodation has a nominal air change rate of 2.5 air-changes per hour (ACH).

Air flow/pressure

The single rooms are negative to neutral pressure relative to the ward corridor. There is a further potential risk whereby extract air via the ensuite toilets may combine with the air supply passing through the thermal wheel which may result in an increased chance of cross contamination between single rooms.

All aspects of ventilation including the mixing of extract air with air supply and the potential resultant cross contamination risk will be explored as part of the ventilation review by NHSGGC.

Standard Infection control precautions (SICPs)

Compliance with SICPs was noted to be good, including hand hygiene and the use of personal protective equipment. A programme of monthly SICPs monitoring is in place. All SICPs audits reviewed at the time of the visit were of an optimal score. The IPCT undertake environmental audits in line with the agreed NHSGGC IPCT monitoring programme. At the time of the walkround it was reported that both wards had been given a GREEN audit score at the last IPCT audit. Follow up audit results from August 2018 have been reported as 96% (GOLD) for ward 2A and 98% (GOLD) for ward 2B.

Central Venous Line Management

Significant work has been undertaken across RHC relating to line management. A central venous line quality improvement project steering group was formed in May 2017 following a noted increase in line infections. The group collected data on central line-associated blood stream infections (CLABSI) on a week-by-week basis on lines inserted on the RHC site and includes all patients within the haemato-oncology cohort (including those cared for at home, shared with other hospital sites and inpatients). It was reported that the figures for CLABSI (outwith the BSIs identified as part of the water related incident) are reducing. The group is led by the Chief Nurse (RHC) and a consultant paediatric surgeon.

HPS undertook an epidemiological review of all positive blood samples from patients recorded as being admitted to wards 2A/2B and compared these to samples obtained prior to the move from Yorkhill and those obtained from patients in other areas of the hospital. A detailed report on the findings is included in [appendix 4](#).

Summary

Any issues identified during the walkround visits were reported to staff at the time to ensure they were addressed. Overall there were no significant practice related concerns identified and awareness of infection prevention and control by all staff was high. There was a good presence of the infection prevention and control team on both wards with daily visits (Monday to Friday) being undertaken. A joint weekly walkround with infection control staff, nursing staff, facilities and estates staff is undertaken in an attempt for early identification of any issues which require to be addressed.

Based on the ward reviews and the epidemiological data presented in this report it is hypothesised that the increased number of HIIAT reports could all be linked to environmental factors and are not considered to be indicative of poor or compromised practice.

Recommendations

Consideration should be given to:

- The ventilation review underway within wards 2A/2B is completed with the involvement of the IPCT.
- A ventilation review is undertaken in other areas across RHC/QEUIH in particular areas where high risk patients are to ensure compliance with national guidance.
- Issues identified within the ventilation review which are considered by the IPCT to pose an increased risk of cross infection should be addressed and signed off by the IPCT prior to repatriation of the patients.
- High visibility of IPCT within the wards should continue.

- CLABSI work continues.
- IPCT continue to observe infection rates and trigger breaches and report as per HIIAT where required.

Appendix 1: HIIAT Assessments

NHSScotland Incident and Outbreak Summary Ward 2A RHC (January 2016- Dec 2018).

NHS Greater Glasgow and Clyde have reported a total of 10 outbreaks and incidents for the clinical setting paediatric haemato-oncology. Of the 15 incidents and outbreaks HIIAT assessed; 5 were Red, 2 were Amber and 8 were Green. The data is displayed in the tables below providing a breakdown of the outbreaks reported by annual period with exception of the current period to date for 2018 and HIIAT Green in 2016 following introduction of mandatory report (non-Norovirus) from April 2016. Comparative data for this setting within NHSScotland identified no reported incidents or outbreaks outwith NHS Greater Glasgow and Clyde.

2018:

Table 1 NHS Greater Glasgow & Clyde, RHC haemato-oncology (ward 2A), HIIAT RED 2018 – Total (2)		
Date reported	Organism	Infection Category
01/03/2018	<i>Pseudomonas aeruginosa</i> or <i>Cupriavidus pauculus</i>	BSI
18/05/2018	<i>Stenotrophomonas maltophilia</i>	BSI

Table 2 NHS Greater Glasgow & Clyde, RHC haemato-oncology (ward 2A), HIIAT AMBER 2018 – Total (1)		
Date reported	Organism	Infection Category
10/04/2018	Astrovirus	Respiratory

Table 3 NHS Greater Glasgow & Clyde, RHC haemato-oncology (ward 2A), HIIAT GREEN 2018- Total (4)		
Date reported	Organism	Infection Category
03/05/2018	Vancomycin- Resistant <i>Enterococci</i>	GI
18/05/2018	<i>Enterobacter cloacae</i>	BSI
20/07/2018	<i>Aspergillus fumigatus</i>	Respiratory
05/09/2018	Various	BSI

2017:

Table 4 NHS Greater Glasgow & Clyde, RHC haemato-oncology (ward 2A), HIIAT RED 2017 – Total (3)		
Date reported	Organism	Infection Category
07/03/2017	<i>Aspergillus fumigatus</i>	Airborne
13/04/2017	Rotavirus	GI
26/07/2017	<i>Stenotrophomonas</i>	BSI

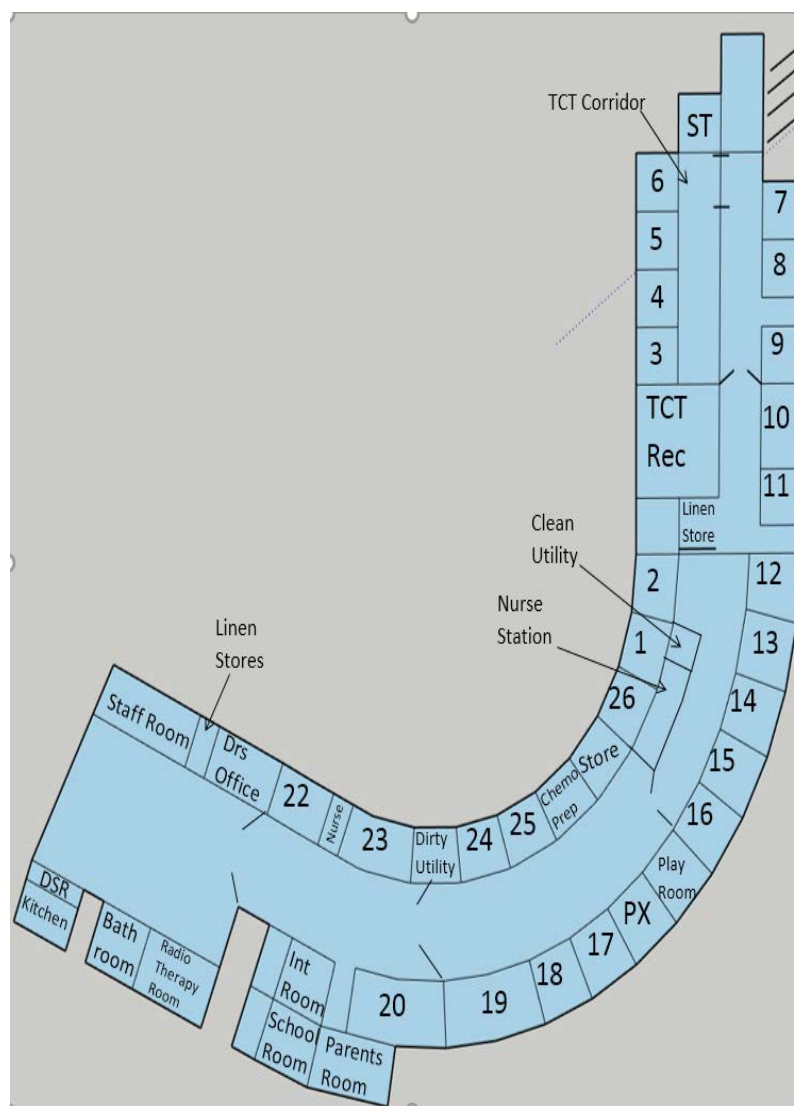
Table 5 NHS Greater Glasgow & Clyde, RHC haemato-oncology (ward 2A), HIIAT GREEN 2017 – Total (3)		
Date reported	Organism	Infection Category
03/03/2017	<i>Elizabethkingia miricola</i>	BSI
03/03/2017	Mixed	BSI
31/05/2017	Norovirus	GI

2016:

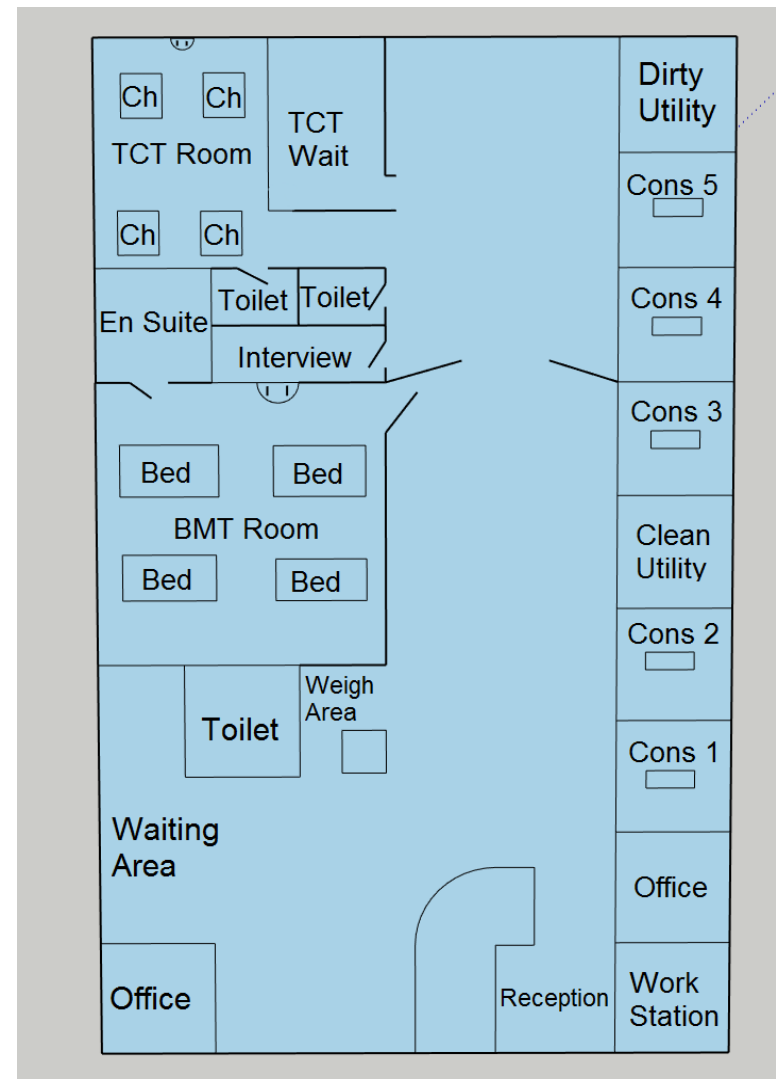
Table 6 NHS Greater Glasgow & Clyde, RHC haemato-oncology (ward 2A), HIIAT AMBER 2016- Total (1)		
Date reported	Organism	Infection Category
05/08/2016	<i>Aspergillus</i>	Respiratory

Table 7 NHS Greater Glasgow & Clyde, RHC haemato-oncology (ward 2A), HIIAT GREEN 2016- Total (1)		
Date reported	Organism	Infection Category
04/08/2016	Vancomycin- Resistant <i>Enterococci</i>	GI

Appendix 2: Ward Floor Plan 2A



Appendix 3: Ward Floor Plan 2B



Appendix 4: Health Protection Scotland - Epidemiology Report, December 2018

Royal Hospital for Children, NHS Greater Glasgow & Clyde

Background

Health Protection Scotland (HPS) were asked to support NHS Greater Glasgow and Clyde (NHSGGC) with the ongoing investigation of the potentially contaminated water system at the Royal Hospital for Children (RHC). The RHC opened in June 2015 replacing Yorkhill Hospital (YH). The patient population that was cared for in Schiehallion ward and Ward 7A of Yorkhill Hospital are now cared for in Wards 2A and 2B of RHC. The purpose of this report is to describe the incidence of positive blood cultures in the patient population cared for in these wards and more widely across RHC/YH hospitals, before and after the move to the RHC.

Methods

For the purposes of this report, the patient population was categorised into two groups:

- 2A/2B Group
 - Patients cared for in Yorkhill Hospital (YH) Schiehallion or Ward 7a; Royal Hospital for Children (RHC) Wards 2A and 2B; patients cared for in haematology/oncology specialties including A&E admissions with previous admission to RHC haematology/oncology specialties.
- RHC Other Group:
 - Patients cared for in other specialties in RHC/YC

Case and episode definitions

Data were extracted from the Electronic Communication of Surveillance in Scotland (ECOSS) system. An extract of all positive blood cultures for any patient under 16 years of age in NHSGGC was taken from ECOSS on the 13th June 2018 with an update taken on 20th August 2018. The case definition was a positive blood culture reported in patients aged less than 16 years in RHC/YC between July 2013 and June 2018. An episode was defined as one positive sample per species in a rolling 14-day period.

Microbiology

Positive blood cultures of the following micro-organisms were included:

- Gram-negative bacteria
- Gram-positive bacteria
- *Staphylococcus* species
- Environmental bacteria (all species of the following: *Achromobacter*; *Acinetobacter*; *Aeromonas*; *Brevundimonas*; *Brevibacillus* species; *Brevundimonas*; *Burkholderia*; *Chryseobacterium*; *Citrobacter*; *Cupriavidus*; *Delftia acidovorans*; *Elizabethkingia*; *Enterobacter*; *Klebsiella*; *Pantoea*; *Pseudomonas*; *Rhizobium*; *Rhodococcus*; *Serratia*; *Sphingomonas*; *Stenotrophomonas*).

- Non environmental bacteria (all species of the following: *Abiotrophia*; *Actinomyces*; *Aerococcus*; *Bacillus*; *Bacteroides*; *Bifidobacterium*; *Brevibacterium*; *Capnocytophaga*; *Clavibacter*; *Clostridium*; *Corynebacterium*; *Dermacoccus*; *Dietzia*; *Enhydrobacter*; *Enterococcus*; *Escherichia*; *Fusobacterium*; *Gemella*; *Granulicatella*; *Haemophilus*; *Kingella*; *Kocuria*; *Lactobacillus*; *Lactococcus*; *Leclercia*; *Leuconostoc*; *Microbacterium*; *Micrococcus*; *Moraxella*; *Mycobacterium*; *Neisseria*; *Paenibacillus*; *Propionibacterium*; *Proteus*; *Raoultella*; *Roseomonas*; *Rothia*; *Salmonella*; *Staphylococcus*; *Streptococcus*; *Veillonella*).
- Fungi (all species of the following: *Candida*; *Rhodotorula*).

The following species were previously isolated in water samples from 2A/2B:

Achromobacter; *Acinetobacter*; *Brevundimonas*; *Burkholderia*; *Chryseobacterium*; *Comamonas*; *Cupriavidus*; *Delftia acidovorans*; *Elizabethkingia*; *Pantoea*; *Pseudomonas*; *Rhizobium*; *Sphingomonas*; *Stenotrophomonas*.

The following species were previously isolated in drain samples from 2A/2B: *Citrobacter*; *Cupriavidus*; *Delftia acidovorans*; *Enterobacter*; *Klebsiella*; *Pantoea*; *Pseudomonas*; *Serratia*; *Stenotrophomonas*.

Analytical methods

The total numbers of episodes of positive blood cultures in the included micro-organisms were described and polymicrobial episodes, where more than one species was identified in the blood sample, were compared in the 2A/2B Group with the RHC Other Group. Monthly incidence rates were calculated using bed-days at specialty level as the denominator. These data were obtained from the Information Services Division ISD(S)1 data source. The denominators for the 2A/2B Group were the monthly number of bed-days for haematology/oncology specialties in RHC/YH. The monthly bed-days for all other specialties in RHC/YH were used as the denominators for the RHC Other Group.

The incidence rates between July 2013 and June 2018 were analysed using statistical process control (SPC) U charts.¹ The SPC charts describe the incidence of positive blood cultures over time with the opening of the RHC represented in the charts with a vertical black line. In addition, the following control measures have been added to the 2A/2B chart – filters added to taps marked as an orange vertical line and cleaning of drains marked as purple vertical line.

The incidence rates for Gram-negative bacteria, Gram-positive bacteria, environmental bacteria and fungal blood cultures before and after the move to RHC were calculated and compared using rate ratios. In addition, two SPC charts were created each for Gram-negative, Gram-positive and environmental bacteria positive blood cultures; one for 2A/2B Group and one for the RHC Other Group. The centreline of the SPC was calculated as the median of the monthly rates between July 2013 and June 2018. The following SPC rules were applied:

TABLE 1: Statistical Process Control (SPC) rules

Rule	Description	Marker
Outlier	Data point(s) exceeding the upper or lower control limit (as 3 standard deviations)	Red diamond
Trigger point	Data point(s) exceeding the upper or lower warning limit (as 2 standard deviations)	Yellow triangle
Shift	A run of 8 or more consecutive data points above or below the centreline	Circle drawn round points
Trend	A run of 6 or more consecutive data points either increasing or decreasing.	N/A

The incidence rate of positive blood cultures over the 5-year period and the latest two-year period were compared with the combined incidence rate of the other two Scottish children's hospitals (Royal Aberdeen Children's Hospital (NHS Grampian) and Royal Hospital for Sick Children (NHS Lothian)). These were compared by calculation of rate ratios and accompanying p-values.

Results

Episodes

A total of 1,786 episodes were identified in 1,149 patients in RHC/YH over the five-year period from July 2013 to June 2018. In the 2A/2B Group, there were 542 episodes in 234 patients (range 1 - 23 episodes per patient) with a median age of 4 years. In the RHC Other Group there were 1,244 episodes in 927 patients (range 1 – 17 episodes per patient) with a median age < 1 years. The number of episodes in each patient group is described in TABLE 2. As the episode definition is by species, a patient could have more than one episode at any one time. TABLE 2 also describes the number of polymicrobial episodes when more than one species was identified in blood sample(s). Patients in the 2A/2B group were more likely to have a polymicrobial episode of positive blood culture ($p < 0.001$).

TABLE 2: Total number of episodes (n=1,786) broken into each subgroup of 2A/2B Group and RHC Other Group over 5 years

	2A/2B Group			RHC Other Group		
	Monomicrobial (n = 413) ¹	Polymicrobial (n = 129) ²	Total (n= 542)	Monomicrobial (n = 1,101) ¹	Polymicrobial (n = 143) ²	Total (n=1,244)
Gram-negative bacteria	110 (65%)	59 (35%)	169	193 (85%)	35 (15%)	228
Gram-positive bacteria	291 (82%)	66 (18%)	357	884 (89%)	105 (11%)	989
Staphylococcus species	208 (87%)	30 (13%)	238	643 (94%)	41 (6%)	684
Environmental	77 (61%)	50 (39%)	127	101 (81%)	23 (19%)	124
Non-Environmental	324 (81%)	75 (19%)	399	976 (89%)	117 (11%)	1,093
Fungi	12 (75%)	4 (25%)	16	24 (89%)	3 (11%)	27

¹ Monomicrobial was only one species isolated on the episode reporting date.

² Polymicrobial if more than one species was isolated from cultures of blood samples on the same day as the episode reporting date.

Incidence rates

Figures 1 to 3 describe the incidence rates using SPC charts showing the incidence of positive blood cultures before and after the move to the RHC (23 months of data from YH and 37 months from RHC).

Figure 1 describes the incidence of Gram-negative blood cultures in both patient groups. The incidence of Gram-negative blood cultures in the 2A/2B Group prior to the move and in the months following were below the centreline of the SPC.

From March 2017, there was a run of 10 months/data points above the centreline identifying an upward shift in the rate with one point above the upper warning limit (UWL).

In March and May 2018, the 2A/2B Group had a rate above the upper control limit (UCL) highlighting a higher than expected incidence of positive blood cultures.

No shift in rates was observed in the RHC Other Group however the rate was above the UWL in April 2014, February 2016 and April 2017. In addition, comparison of the overall incidence of Gram-negative blood cultures before and after the move to RHC indicated the rate was higher after the move in the 2A/2B Group (RR = 1.47, CI: 1.05 to 2.04, $p = 0.023$) and did not change in the RHC Other Group (RR = 1.15, CI: 0.87 to 1.52, $p = 0.34$).

FIGURE 1: SPC charts of Gram-negative blood culture incidence rates per 1,000 total occupied days for 2A/2B Group and RHC Other Group.

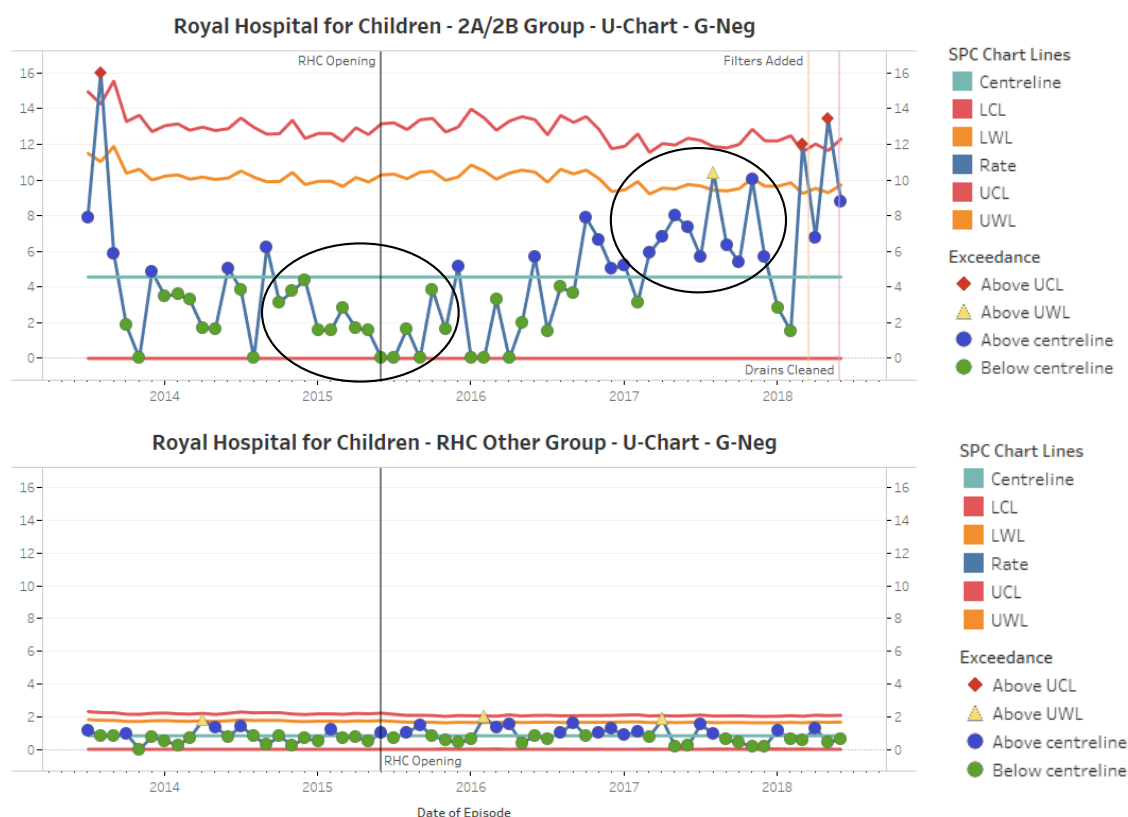
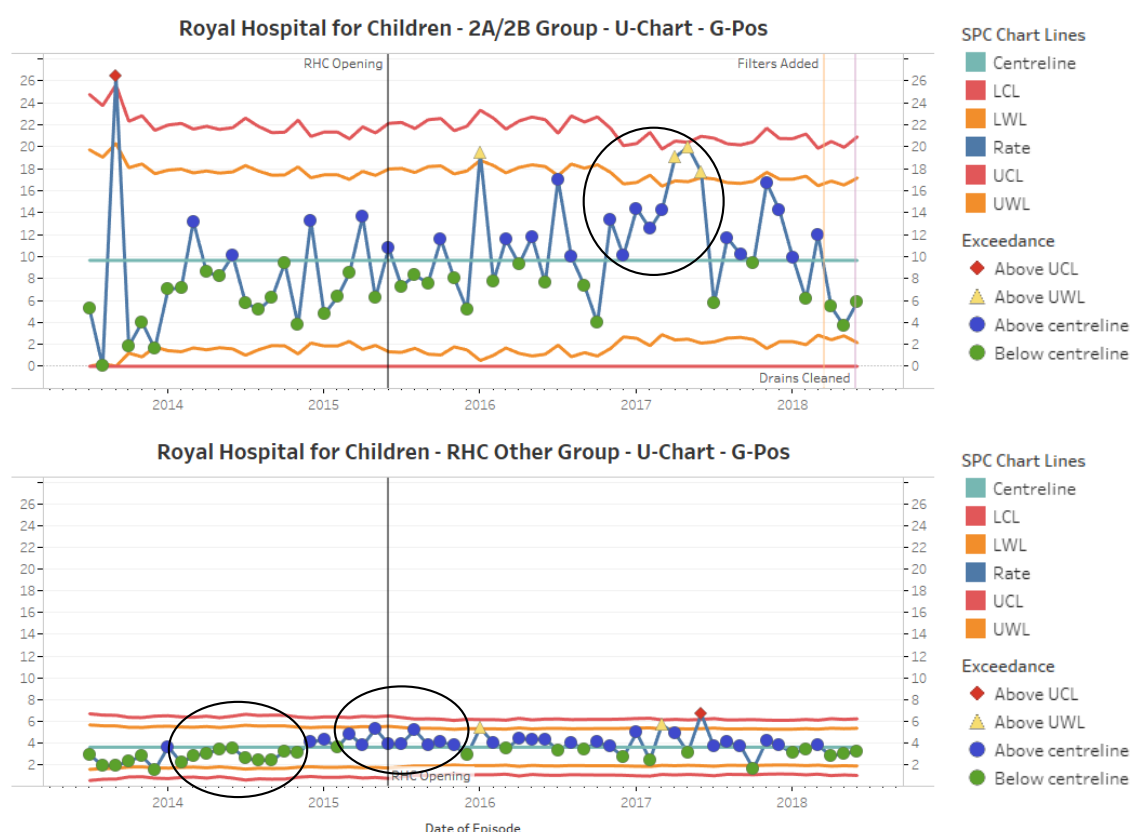


Figure 2 describes the incidence of Gram-positive blood cultures in both patient groups.

There was an upward shift in incidence of Gram-positive blood cultures in the RHC Other Group prior to the move with rates above the UWL in January 2016 and March 2017 and an outlier (above the UCL) in June 2017.

In 2A/2B Group, there was an upward shift after the move and the rate was above UWL in January 2016, and in April, May and June 2017. *Staphylococcus* species accounted for 52% of the Gram-positive blood culture episodes with 45% of those being *Staphylococcus epidermidis*. In addition, comparison of the overall incidence of Gram-positive blood cultures before and after the move to RHC indicated the rate was higher after in both the 2A/2B Group (RR = 1.43, CI: 1.14 to 1.81, $p = 0.002$) and the RHC Other Group (RR = 1.23, CI: 1.07 to 1.41, $p = 0.003$).

FIGURE 2 SPC charts of Gram-positive blood culture incidence rates per 1,000 total occupied days for 2A/2B Group and RHC Other Group.



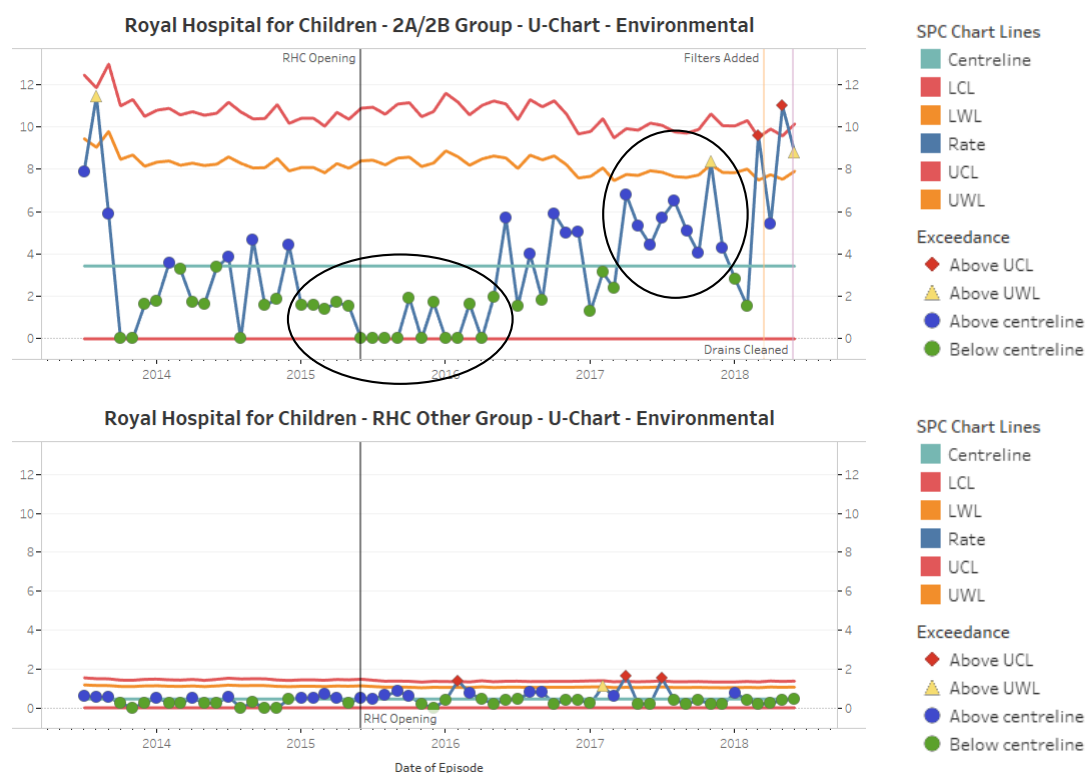
The incidence of positive blood culture caused by species of environmental bacteria (described in the methods section) which included all species isolated in water or drain samples taken from 2A/2B are shown in Figure 3.

In the 2A/2B Group, the SPC chart shows a shift below the centreline for 17 months from January 2015 to May 2016, then a shift above the centreline from April 2017 to December 2017. The rate was also above the UCL, and therefore higher than expected, in March and May 2018 and was above the UWL in November 2017 and June 2018.

There were no shifts in the incidence rates in the RHC Other Group, though the incidence was above the UCL in February 2016, April 2017 and July 2017 and above the UWL in February 2017.

In addition, comparison of the overall incidence of environmental bacteria positive blood cultures before and after the move to RHC indicated the rate was marginally higher in both the 2A/2B Group (RR=1.45, CI 0.98 to 2.13, $p=0.06$) and RHC Other Group (RR = 1.52, CI: 1.02 to 2.29, $p=0.04$) however the 2A/2B group the increase was not significant ($p > 0.05$) which may be due to the small sample size.

FIGURE 3: SPC charts of environmental bacteria blood culture incidence rates per 1,000 total occupied days for 2A/2B Group and RHC Other Group.



A comparison of the overall incidence of fungal positive blood cultures before and after the move to RHC indicated the rate did not change after the move in either group (2a2b group RR = 1.65, CI: 0.53 to 5.12, $p = 0.40$; RHC Other group RR = 0.86, CI: 0.40 to 1.89; $p = 0.71$).

Figure 4 describes the environmental bacteria blood culture isolates in both groups. The episodes with dots represent the first and recurrent episodes of the same species in the same patient. There were 20 patients with two episodes, one patient with three episodes and one patient with five episodes.

FIGURE 4: Quarterly episodes of environmental organism blood cultures in 2A/2B group and RCH other group. Dots represent the first and recurrent episodes of the same species from the same patient.



Comparison with other health boards

When comparing the overall rate over 5 years at RCH/YH to the combined rate of the other two Scottish children's hospitals (Royal Aberdeen Children's Hospital (NHS Grampian) and Royal Hospital for Sick Children (NHS Lothian)), the incidence of positive blood cultures in RCH/YH was higher compared with the other hospitals for environmental bacteria (RR = 1.70, CI: 1.34 to 2.16, $p < 0.001$) and fungi (RR = 5.36, CI: 2.12 to 13.53, $p < 0.001$), but lower for Gram-positive bacteria (RR = 0.71, CI: 0.66 to 0.77, $p < 0.001$) and non-environmental bacteria (RR = 0.79, CI: 0.73 to 0.85, $p = 0.001$). There was no difference in the rates of Gram-negative blood cultures (RR = 1.12, CI: 0.95 to 1.33, $p = 0.16$).

When compared over 2 years (July 2016 to June 2018), the rate of positive blood cultures was higher in RCH/YH for environmental bacteria (RR = 2.74, CI: 1.47 to 5.10, $p < 0.001$), Gram-negative bacteria (RR = 1.29, CI: 1.01 to 1.66, $p = 0.038$) and fungi (RR = 12.26, CI: 1.65 to 90.97, $p < 0.001$) and lower for Gram-positive bacteria (RR = 0.81, CI: 0.72 to 0.92, $p = 0.001$), and non-environmental bacteria (RR = 0.79, CI: 0.70 to 0.89, ($p < 0.001$)).

Summary and Recommendations

In summary, the overall incidence of Gram-negative, Gram-positive and environmental bacteria blood cultures increased in the 2A/2B Group after the move to the RHC. The RHC Other Group, the incidence of Gram-negative bacteria and fungal blood culture did not change and the incidence of Gram-positive and environmental bacteria blood cultures increased. SPC charts provide an alternative method of analysis that identifies variation at a level of detail not provided by comparison of incidence rates before and after the move to RHC. The SPC charts indicated that the Gram-negative, Gram-positive and environmental bacteria blood culture incidence rates in the 2A/2B Group were higher than expected following the move to RHC. The same changes in the incidence of blood cultures were not observed in the RHC Other Group. Whilst this conclusion must be interpreted with some degree of caution, as changes in the patient population have not been accounted for in this analysis, the shift in the incidence identified by the SPC charts indicates that the trends in blood culture incidence changed after this time.

Patients in the 2A/2B Group were more likely to have a polymicrobial episode than patients in the RHC other group. This was highest in the patients with a positive blood culture of environmental bacteria where nearly 40% had a polymicrobial blood culture. This is similar to figures reported in the literature with higher risk of polymicrobial bloodstream infection being associated with younger age groups and presence of central venous catheter.³⁶ The rate of environmental bacteria and fungal blood cultures were higher at RHC/YH than the other Scottish paediatric hospitals over 5 years and over the latest 2-year period. In contrast, the incidence of Gram-positive blood cultures, often considered to be associated with devices and device care, was lower in RHC/YH compared with the other Scottish paediatric hospitals.

Ward 2A and 2B have been closed since the 26th September 2018. It is recommended that when the wards re-open that all positive blood cultures are monitored in particular those related to an environmental organism.

Limitations

There are a number of limitations associated with the use of ECOSS blood culture data. All positive blood samples apart from those reported through mandatory surveillance programmes are non-validated records. The cases may include contaminants, and may include non-blood cases which are incorrectly mapped to a blood sample within either the laboratory system or within ECOSS. From the data collected through the enhanced *Staphylococcus aureus* bacteraemia (SAB) surveillance programme, 10% of episodes in under 16s were classed as contaminants² whereas the enhanced *Escherichia coli* bacteraemia (ECB) surveillance the figure was less than 1% (unpublished data).

The cases were identified using only laboratory data without any clinical review of patients. It is not possible to determine whether changes in incidence are confounded by changes in the patient population and their underlying medical conditions. Duplication per species in ECOSS may mean that a patient is recorded as having more than one episode of positive blood culture in a 14-day period leading to an overestimate of the number of episodes. The breakdown of polymicrobial samples only included isolates recorded on the same day as the episode reporting date which may underestimate the numbers of polymicrobial episodes.

In addition, the comparison between RCH/YC and paediatric hospitals in other health boards should also be interpreted with caution. Differences in the patient population between the RHC/YC and the other children's hospitals may introduce bias to the comparison.

References

1. Information Services Division of National Services Scotland, 2018. Statistical Process Control Monitoring Quality in Healthcare. Available at: https://www.isdscotland.org/Health-Topics/Quality-Indicators/Statistical-Process-Control/_docs/Statistical-Process-Control-Tutorial-Guide-180713.pdf
2. Murdoch F, Danial J, Morris AK, *et al*. The Scottish enhanced Staphylococcus aureus bacteraemia surveillance programme: the first 18 months of data in children. *Journal of Hospital Infection* 2017;**97**:127-132.
3. Downes KJ, Metlay JP, Bell LM, McGowan KL, Elliott MR, Shah SS. Polymicrobial bloodstream infections among children and adolescents with central venous catheters evaluated in ambulatory care. *Clin Infect Dis* 2008;**46**:387-394.
4. Onder AM, Chandar J, Coakley S, Abitbol C, Montane B, Zilleruelo G. Predictors and outcome of catheter-related bacteremia in children on chronic hemodialysis. *Pediatr Nephrol* 2006;**21**:1452-1458.
5. Onland W, Pajkrt D, Shin C, Fustar S, Rushing T, Wong WY. Pediatric patients with intravascular devices: polymicrobial bloodstream infections and risk factors. *J Pathog* 2011;**2011**:826169.
6. Zakhour R, Hachem R, Alawami HM, *et al*. Comparing catheter-related bloodstream infections in pediatric and adult cancer patients. *Pediatr Blood Cancer* 2017;**64**.

MECHANICAL SERVICES SPECIFICATION and SCOPE of WORKS

FOR

WARD 2A VENTILATION UPGRADE

AT

QUEEN ELIZABETH UNIVERSITY HOSPITAL

ROYAL HOSPITAL for CHILDREN

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WGM\1215\Specification\Aug2019\QEUH, RHC, Ward 2A Upgrade - Electrical Services Specification

Revision 1

STATUS: Tender Issue

Revision Notes

Revision 0: September 2019: Preliminary Tender Issue

Revision 1: September 2019: Tender Issue

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A Preliminaries / General Conditions

A1 THE PROJECT GENERALLY

A10 PROJECT PARTICULARS

110.000 THE PROJECT AND BIM REQUIREMENTS:

- Particulars of the project as a whole are
 - Provided within the Main Contract Preliminaries.
 - Building Information Modelling (BIM) requirements
 - Contractor to demonstrate collaborative 3D Level 2 BIM maturity through defined and compliant information and data on the project.
- BIM Execution Plan and Master Information Delivery Plan
 - Provide pre-contract BIM Execution Plan in response to the EIR.
 - Contribute to the pre-contract BIM Execution Plan in response to the EIR.
 - After contract award provide further BIM Execution Plan confirming the supply chain's capabilities and providing a Master Information Delivery Plan (MIDP).
 - After contract award contribute to a further BIM Execution Plan confirming the supply chain's capabilities and providing a Master Information Delivery Plan (MIDP).
- Comply as appropriate with the following codes and standards
 - BS EN ISO 19650-1
 - BS EN ISO 19650-2
 - PD 19650-0 (transition guidance)
 - PAS 1192-3
 - BS 1192-4
 - PAS 1192-5

120.000 THE EMPLOYER:

- NHS Greater Glasgow & Clyde Health Board

130.000 CONTRACT ADMINISTRATOR:

- The term Contract Administrator (CA) is used throughout this specification and their duties will be carried out by
- the Project Manager WGM Consulting Engineers

140.000 DESIGN AND PROJECT TEAM:

- Client Representative - Steve Russell: NHS GGC Capital Planning
- Principal Designer - Stephen Kerr: Wylie Shanks Architects
- M&E Designers – Chris O'Reilly: WGM Consulting Engineers
- Architects – Stephen Kerr: Wylie Shanks Architects
- Quantity Surveyors - Danny McKinney: Storrier & Donaldson
- Structural Engineers - Scott Morrison: David Narro Associates

BS APPENDIX

BS 1192-4:2014

Collaborative production of information. Fulfilling employer's information exchange requirements using COBie. Code of practice

BS EN ISO 19650-1:2018

Organization and digitization of information about buildings and civil engineering works, including building information modelling (BIM). Information management using building information modelling. Concepts and principles

BS EN ISO 19650-2:2018

Organization and digitization of information about buildings and civil engineering works, including building information modelling (BIM). Information management using building information modelling. Delivery phase of the assets

PAS 1192-3:2014

Specification for information management for the operational phase of assets using building information modelling

PAS 1192-5:2015

Specification for security-minded building information modelling, digital built environments and smart asset management

A11 TENDER AND CONTRACT DOCUMENTS/PRELIMINARIES

110.000 THE TENDER DRAWINGS:

- The tender drawings are as per the drawing registers/document issue sheets, issued as part of the contract information

140.000 PRE-CONSTRUCTION INFORMATION:

- Comply with The Construction (Design and Management) Regulations 2015. Preliminaries Section

The Contractor and associated Sub-Contractor for this package of works, will be bound by the Preliminaries, Contract Conditions, Form of Tender etc. pertaining to the Building Services.

No claim will be entertained which may arise from the Contractor's and associated Sub-Contractor's failure to have examined the Conditions of Contract fully, and it will be assumed that any costs arising from same are included within their tender submission.

The Contractor is recommended to visit the site prior to submitting his tender to ascertain all local conditions and restrictions likely to affect the execution of his works. No claims arising from failure to do so will be considered.

Standard Specification

The design and installation will comply with this Performance Specification for the M&E Services, as detailed below and as further detailed within sections A, B, R, S & T and within the associated appendices and tender drawings where relevant.

Design Responsibilities

Reference to the QS's detailed contractor design items, including those noted below, however the list is not exhaustive:

BMS and Automatic Control Systems

KNX Control System(s) for Radiant Panel and ancillary miscellaneous systems

Fire Smoke Damper Systems including controls and interface to existing fire smoke damper systems

Primary/Secondary support and fixing and bracketing systems.

Secondary steelwork supports for main plant items

Builderswork Drawings

Equipment base details.

All holing and general builderswork requirements.

Access requirements.

Installation and Co-Ordinated Drawings

Allow for all necessary contractor designs/design elements, design development and working drawings, including Level 2 BIM co-ordination for all services/service elements and building/structural elements for areas that are heavily serviced including for the following areas:

- Plant Rooms
- Service Risers
- Ductwork and Pipework systems

Allow for the preparation of record information

Allow for the preparation of Operating and Maintenance Manuals and record drawings/information.

General

Dimensioned layout and fabrication drawings.

Fully detailed arrangements of Plant Rooms/Areas, Control Panels, Ductwork and duct mounted ancillaries, dampers, smoke dampers etc.

Detail drawings of power/control systems, primary and secondary co-ordinated support and bracket systems and connections to plant and equipment.

Power, control and miscellaneous systems wiring diagrams.

Drawings showing the work of Specialist Sub-Contractors and Manufacturers.

Manufacturers drawings generally.

The Sub-Contractor will submit drawings as required to suit the construction programme. The drawings will be progressed to a level sufficient to allow full co-ordination with other services and to permit proper installation of the works. The main Contractor will be responsible for making sure the Mechanical, Electrical and Plumbing drawings are fully co-ordinated.

Drawings prepared for each area will be produced to allow a minimum period of 20 working days (4 weeks) for appraisal by the Employer/Contract Administrator, who may wish designs to be amended or require the addition of further detail or clarification of matters. A further 10 working days (two weeks) will be allowed for formal issue of the drawings. Work associated with the corresponding area on site will not commence until each drawing has been submitted for comment and formal acceptance has been given, in accordance with this specification.

The appraisal procedure is considered to be vital to the successful incorporation of the Sub-Contractor's designs, and it is essential that the programme for preparation, appraisal and formal issue of drawings is maintained to allow full consideration prior to the formal issue of construction drawings, by the contractor.

Suitability of M&E/Subcontractors

The selection of the correct M&E contractor will be an integral part of the project and will clearly need to be of a suitable standard and have the necessary skills, credential and track record for carrying out large complex Design and Build projects, with suitable and readily available resources. The M&E Contractor must be acceptable to all of the design team in its entirety, and where any selected M&E Contractor is not found to be acceptable to any one of the design team members, this contractor will be discounted from the project selection process and deemed not suitable for this project.

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A2 THE CONTRACT

Refer to the details/information issued by Storrier & Donaldson along with any supporting supplementary information that may be issued by the employer.

B0 Project Particular Specification

B01 GENERAL REQUIREMENTS

- 1.1 This specification provides the outline project details and scope of works along with the necessary detailed requirements for the alterations to provide fully upgraded Ward 2A Project for the Ventilations and associated services installations to be carried out within the Royal Hospital for Children, Queen Elizabeth University Hospital Campus, Glasgow.
- 1.2 Throughout the project works the existing electrical services shall be altered, extended and renewed in line with Current Codes of Practice (COP), British and European Standards (BS's and BSEN's) along with the Local Authority (LA) requirements. The contractor shall also be and make themselves familiar with all relevant Health Technical Memorandum (HTM), Scottish Health Technical Memorandum (SHTM) and Scottish Health Technical Notes (SHTN), SCART Compliance and HAI Scribe requirements and compliance that are fully applicable to the elements of the project works that are to be carried out, in particular for installation and for commissioning of systems associated with this project.
- 1.3 All sections of the mechanical services installations and works shall be co-ordinated before and during installation with all other trades, for example Mechanical Services Contractors, Plumbing and Public Health Contractors and Building Works Contractors etc. The Contractor shall be held liable for any abortive work carried out due to this procedure not being followed.
- 1.4 All project works and alterations / installations covered under this project shall be programmed and carried out in accordance with the client and principle contractors agreed contract programme, and make all necessary allowances including extended working hours and weekends as required to achieve this.
- 1.5 Our Client expect only the highest possible quality of installation for the entire project and the electrical services, and will not accept anything short of the highest possible standards, any part of the installation that is deemed to be not up to the Clients or engineers expectations and the highest possible standard will have to be rectified and brought up to in line with the highest standard for a quality installation at the contractors own expense.
- 1.6 All project works and installations or alterations covered under this project shall be programmed and carried out in accordance with the Clients agreed contract programme, as the project is within a live hospital environment the contractor must make all necessary allowances for the following:
 - a) Out of hours and weekend working
 - b) Programming shutdown in advance and giving at least 10 days' notice in writing (to NHS Estates Pro-Forma) to the local estates department.
 The contractor must recognise that the works include for areas of works that lie out with the contract works areas, where working access and access times will require to be out with the normal working contract period, and the programming and interface of works to these areas is crucial to the project running smoothly, and being complete on programme.
- 1.7 Our Client GGC NHS expects the highest possible quality of installation for the entire project and the electrical services, and will not accept anything short of the highest possible standards, any part of the installation that is deemed to be not up to the Clients or engineers standard will have to be rectified and brought up to in line with the highest standard for a quality installation at the contractors own expense.
- 1.8 The existing fire alarm systems serving the areas associated with the works shall be altered as required, to allow the new systems components and devices to be incorporated, this shall include for all necessary isolations, taking down and reinstatement as detailed and required and as part of these works, the contractor shall allow for a fully working temporary fire alarm system interfaced to the main Fire alarm system panels, to cover the main corridors and areas of works, along with all

areas that require to be isolated to allow the works to proceed – This particular item is for reference only and will be carried out under the electrical works package.

- 1.9 Contractor liaison and co-ordination of the works with the QEUH Estates team and the occupants of the live building where the works are being carried out shall be the responsibility of the contractor, this needs very careful thought and full co-ordination by the contractor so that all systems can be installed as required and completed, along with commissioned and the necessary QEUH Estates personnel being given sufficient notice and having the opportunity to witness the testing, commissioning of all systems for the project works, as detailed within this specification and detailed on the project layout drawings.

Programming and co-ordination needs to be thought out, prepared and implemented well in advance for all aspects of the project. The principle contractor must appoint a designated project manager to run, programme be responsible for and to co-ordinate and carry these duties out, including services installation co-ordination.

The contractor must provide full site services co-ordination, in terms of installation and programme, either by means of an in house dedicated project engineering manager or by sub-contracting these services out to a specialist co-ordination company, these duties shall include but not be restricted to the following:

- As the principle contractor for the project provide all necessary H&S Information and a suitably prepared Construction Phase Health and Safety Plan, as detailed by the CDMD/Principle Designer
- Full Co-ordination of all Builderswork, Mechanical and Electrical installations, as required for the project, including existing services and systems.
- Provide M&E Co-ordinated services drawings as required, including all builderswork requirements.
- Ensure services are installed in accordance with the specification and drawings, and that all relevant regulations, SHTM's, SCART requirements etc. and are fully adhered to, provide working and installation drawings as required to demonstrate compliance with these items where necessary or where requested by the client and CA.
- Co-ordination with other trades, by way of installation and programme.
- Provide in advance weekly detailed programmes of planned works, so that technical issues can be properly co-ordinated.
- Co-ordination of commissioning of all M&E systems/services as detailed and to ensure programmes are met, witness testing takes place and all systems are properly commissioned and certified prior to the Client taking possession or assuming beneficial use of the systems.

B02 MECHANICAL SERVICES PROJECT PARTICULAR

300.000 GENERAL

300.010 SITE LOCATION:

- Queen Elizabeth University Hospital, 1345 Govan Road, Govan, Glasgow G51 4TF

300.020 DESCRIPTION OF THE SITE:

- Acute Hospital Campus, incorporating adult and children's hospitals and facilities

310.000 DESCRIPTION OF THE WORKS

310.010 GENERAL

The following Mechanical Services Particular Specification details the Project Works in connection with the Upgrade of the existing Hematoma Oncology Teenage Cancer Trust Ward 2A together with other associated works, all within The Royal Hospital for Children, Queen Elizabeth University Hospital, Glasgow.

Ward 2A HOTCT requires to be substantially upgraded to fully meet the client's present requirements, hence the associated works proposed for this area include the significant replacement and modification of the existing M&E Services and the Building Fabric, such that the main Bedroom Suites and associated main accommodation areas can be effectively positively pressurised with Central Station HEPA filtered air and an appropriate Pressure Cascade system adopted, which includes a Ward Isolation Facility (Transfer Lobby located at the end of Ward 2A, where the HOTCT Corridor connects to the general Hospital Street). Air infiltration to the positively pressurised accommodation areas will be significantly reduced resulting in a reduction in both the infection and cross contamination risks, to the extent where they can be managed more effectively. The Ward 2A Hematoma Oncology/Teenage Cancer Trust area will be served by a new duplicate Supply and Extract Air Handling Unit Facility with duplicate En-suite/Toilet Extract Ventilation Plant, providing a N+1 facility for the Ward.

Works in connection with Ward 2A Bone Marrow Transplant will be far less extensive as it has relatively recently undergone some partial refurbishment in connection with its existing facilities to generally improve infection control issues, however whilst a substantial upgrade of this ward is not being considered at present, other measures relating to the improvement in the general quality of the air supplied to the area will be implemented to reduce general infection risks and risks associated with cross contamination between the Exhaust and Supply air streams within the existing associated Air Handling Unit. A Ward Isolation Facility will also be provided (Transfer Lobby located at the end of Ward 2A), where the BMT Corridor connects to the general Hospital Street. Other works proposed within the Ward 2A BMT area comprise of less extensive general refurbishment works in connection with the MIBG Suite together with more significant new works in connection with the NPVL SCH 010 Suite which involves amending the existing ventilation strategy, although as this work is yet to be fully determined it is covered by a provisional sum allowance at this stage. The NPVL facility will be designed to cater for Immuno-compromised patients that have also contracted diseases such as Measles or Chicken pox.

Works in association with Ward 2B Day Ward are less significant as these works are generally only limited to works in connection with improving the quality of air supplied to the area, to reduce infection risks and risks associated with cross contamination between the Exhaust and the Supply Air Streams within the Air Handling Unit.

This contract also includes for the strip out and safe removal of existing identified redundant plant and equipment. Some equipment will be identified as equipment to be carefully dismantled and laid aside for future use (which may be on this Contract or on some other Contract determined by the Client, in the future), or otherwise require to be removed from the site and safely disposed of. The Tender Drawings indicate what Plant and Equipment is to be stripped out and safely and responsibly removed from site,

and which Plant and Equipment is to be retained for use on this project, or laid aside, for the client's future use. Should there be any ambiguity regarding this matter, as to what is to be removed from site and what is to be retained on site, clarification should be sought from the Contract Administrator, at an early date.

It should be noted that the Existing Hematoma Oncology/TCT & BMT Ward 2A will be shut down entirely for the duration of the Construction Works, to carry out all major works and more minor works (Remedial Works in Connection with Ward 2A BMT Existing AHU) in this area, although it should be noted that it is expected that the Remedial Construction Works in connection with Ward 2B Day Ward will be carried out within a time period of no more than two weeks, meaning that the associated Ward 2B Day Ward will only be shut down for approximately 4 weeks (allowing for decanting and Validation processes), or as short a period of time as is feasibly possible to limit the down time for Ward 2B Day Ward. These Remedial Works briefly comprise of the removal of the existing Thermal Wheel and the Installation of new F9 and HEPA terminal AHU filters and the upgrading of the corresponding Fan/Motor/Inverter Units, together with other associated works (Controls, C&P Wiring, etc), and general making good.

Prior to the progress of the Remedial Works in connection with the existing Ward 2A BMT and Ward 2B Day Ward AHUs Commissioning Works will be carried on the associated main ventilation systems to verify the existing Air Flow rates on all the main branch ducts serving the corresponding AHUs, together with a check on the main AHU system air flow rates and corresponding duct static pressures. The Contractor will be responsible for liaising with the local NHS Estates Department and the CA regarding the timing of these works to ensure they are carried out strictly in accordance with formal pre-arranged agreements. Prior to the progress of the Remedial Works all necessary temporary system isolations will be arranged and otherwise agreed with the Local NHS Estates Department in conjunction with the CA, well in advance of the required implementation of these Works. Should any additional problem issues be discovered with the existing equipment or systems during the course of the works, or prior to the Works, these issues must be reported immediately to the Contract Administrator and the Local NHS Estates Department, for further consideration and instruction on any appropriate remedial action, where this may be required.

In addition to the installation of new Supply and Extract AHUs and corresponding Ventilation Ductwork distribution systems, the Works will also include for the installation of new LTHW Heating and Chilled Water Pipework distribution systems which generally extends from new flow and return branch connections made into the corresponding existing mains pipework at 4th floor level. New Run-Around-Coil type Heat Recovery systems will be provided for each of the new Ward 2A HOTCT AHUs. The existing Domestic Water Services pipework systems will be modified and re-routed as required to accommodate the new Ventilation ductwork running down the main Ward Corridor areas. New Domestic Cold Water supplies will be provided for the Heat Recovery systems located within the new 4th Floor Ventilation Plant Room. The Existing Sprinkler Services system will be extended to cover the new 4th floor Plant Room area and otherwise modified on the 2nd and 3rd floor areas (Bed Store) to cater for all aspects of the Refurbishment Works. Further modifications will be made to the existing Drainage, Rainwater, Medical Gas and Pneumatic Tube Systems as required to cater for the Refurbishment Works, all as generally detailed on the Tender drawings. Thermal Insulation must be applied to all new and modified Ductwork and Pipework distribution systems where particularly required to meet the general requirements of the specification.

A new autonomous BMS will be provided to fully meet the requirements of the Hematoma Oncology Teenage Cancer Trust area powered from a separate Essential Services Power Supply. The new Ward 2A BMS will however be interfaced with the existing Building Wide WAN Controls system such that remote alarm, monitoring and other services can be utilised from other remote Head End facilities within the building. All new Mechanical services Plant and equipment installed to serve Ward 2A HOTCT area that requires either Power or Controls facilities will be wired from the new Ward 2A Mechanical Services Control Panel(s). All power supplies to the new Mechanical Service Control Panels will be provided from an Essential Services Power Supply by the main Electrical Services Contractor.

Modification and general upgrading works will also require to be carried out to the existing Power and BMS Controls serving the Existing Ward 2A BMT and Ward 2B Day Ward AHUs in that uprated Power Supplies and Inverter Drive units will be required for each of the corresponding AHUs (where the

Fans/Motors will be updated). The existing Power and Controls provision associated with the existing Thermal Wheel Units will be removed, new Power and Controls facilities associated with the new terminal AHU F9 and HEPA Filters will be installed, fed from the existing Mechanical Services Control Panels where practicable.

The Contract works will also include for the balancing of the entire new and affected existing elements of the various Supply and Extract Mechanical Ventilation Systems serving Ward 2A HOTCT, Ward 2A BMT and Ward 2B Day Ward including all necessary adjustments to the branch and main duct system Air Flow Volumes, to achieve the necessary Pressure Cascade regime and otherwise to meet the target Ventilation figures agreed following the previous Ventilation Commissioning checks.

Further reference should be made to the Design Logic Tender Drawing (DL)01 for details of the relevant target room pressures. As part of the Commissioning philosophy it is the intention for the ventilation rates to be reduced to approximately that of the minimum level required to meet the basic operating parameters of the associated systems, such that it can be increased slightly at a later date, to possibly cater for conditions including increased pressure drops across the HEPA filters, etc. The minimum ventilation rates should not drop to a level where the basic Heating and Cooling Loads of the various internal spaces cannot be met.

Allowances should also be made for sterile cleaning of the new Supply and Extract/Exhaust Ventilation Ductwork distribution systems that serve the GMP Suite.

All new and existing modified Mechanical Services and associated systems will be fully tested, commissioned and set to work, ready for client inspection and Validation as appropriate, at practical completion stage of the Construction Works.

All appropriate issues in connection with HAI SCRIBE are expected to be fully addressed by the Contractor as part of these works, and appropriate procedures will be agreed prior to the commencement of any works on site, to ensure that infection risks to adjacent hospital areas are controlled, such that they do not present any associated problem issues for the client, during the course of the Construction Works.

The Project will be progressed and otherwise phased in such a manner that will minimise disruption for the client and meet the specific Programme requirements of the Project. It is envisaged that some noisy and/or disruptive work in connection with the Construction Works will have to be carried out either outwith normal working hours, or at specific times, to suit client operations.

During the course of the main element of the Contract Works, when Ward 2A will effectively be closed and made non-operational, normal hours working should be assumed, although it should be noted that where there are specific client concerns with the nature of the works affecting normal operations in other parts of the building, this may be altered to suit their specific requirements. It should be assumed that all main M&E Services isolations and connections to existing M&E services will be progressed outwith normal working hours and in a manner that will limit the disruption to any other services and operations within the building. The Contractor will fully agree the timings of all M&E Services Isolations in writing, in advance of the work being carried out, with the local NHS Estates Department in conjunction with the Client appointed Contract Administrator.

Reference should be made to the Tender drawings and other sections of the Specification for further details of all Mechanical Services systems.

Contract Works Support Documentation

The complete installation covered by this Contract will conform to the requirements of:

- Good Engineering Standards in accordance with the CIBSE Guides and Codes of Practice.
- The Regulations of the Gas, Electricity, Water and Fire Authorities
- The Building Standards (Scotland) Regulations 2014, with latest amendments.
- Home Office Regulations for Public Buildings
- Latest relevant British Standard Specifications and Codes of Practice
- Health & Safety at Work Act 1974
- The Factories Act
- The rules of the FOC for firefighting provision
- Statutory obligations and regulations of all Local Authority, Public Service or Statutory undertaking relating to the execution of the works
- CDM Regulations
- Health Technical Memorandums (HTMs)
- Scottish Health Technical Memorandums (SHTMs)
- Scottish Health Technical Notes (SHTNs)

310.020 SCOPE OF WORKS

The works described within this specification include the following Mechanical Services Installations and Associated Works for the Contract:

- Isolation, disconnection and removal of existing M&E Services plant and equipment, where indicated on Tender drawings.
- Installation of new Supply and Extract Ventilation Plant and Equipment, including AHUs, Terminal Heater Batteries, Grilles, VC Dampers, Shut-off Dampers, Attenuators, External Louvres, Pressure Stabilisers, Smoke/Fire Dampers, etc.
- Mechanical Ventilation Ductwork (including connections to existing).
- LTHW Heating Pipework (including connections to existing and new Heat Recovery Pipework Systems) serving new Air Handling Units (including modifications and temporary isolations to existing LTHW Heating systems).
- Chilled Water Pipework Systems (including connection to existing) serving new AHU (including modifications and temporary isolations to existing Chilled Water system).
- Above Ground Soil Waste Drainage Systems (minor works as detailed on Tender Drawings).

- Domestic Water Services Systems (minor works as detailed on Tender Drawings).
- Specialist Medical Gas Services (minor works as detailed on Tender Drawings).
- Rainwater Services Systems (minor works as detailed on Tender Drawings)
- Pneumatic Tube System (minor works as detailed on the Tender Drawings)
- Sprinkler Services (new works and modifications to Existing Installation).
- Pressure Monitoring System (including provision of new Data Logger Unit for Temp, Pressure, Humidity, Press Difference, etc)
- Electrical Power Supplies to Mechanical Services Plant and Equipment (from Mechanical Services Control Panels). Power supplies to C/Ps by Electrical Contractor/
- Thermal Insulation
- BMS/Controls Systems (including modifications to existing)
- Comprehensive Testing and Commissioning of all M&E Services Systems and associated Equipment, to include pre-testing/commissioning of Existing Ventilation, LTHW Heating and Chilled Water systems
- Setting various Mechanical Services Systems to Work, in full preparation for Client's Validation Process.
- The supply of staged technical information to assist with DQ/IQ and OQ submissions by the Specialist Clean Room Contractor.
- The supply of comprehensive Operating & Maintenance Manuals and Record Drawings.

310.030 DESIGN CRITERIA

The environmental design parameters selected for the building interior should meet the general requirements of the following undernoted NHS Specifications to help ensure good comfortable conditions are provided for the building occupants:

- SHTM 03-01 Part A
- SHPN 04 Supplement 1
- SHPN04-01

a) Thermal

Reference has been made to the definition of thermal comfort as mentioned within ISO 7730 1984 and the CIBSE Guide however the following design parameters have been selected as meeting the Client's User Requirement Specifications:

EXTERNAL

Winter	-10°C dry bulb, saturated
Summer	28°C dry bulb; 19°C wet bulb

INTERNAL

<u>Area</u>	<u>Resultant Temperatures</u>
Bedroom	23°C +/- 2°C
Bedroom (TCT)	23°C +/- 2°C
Contingency Area	23°C +/- 2°C
Play/Dining	23°C +/- 2°C
Bedroom En-Suite	24°C +/- 2°C
Bedroom En-Suite (TCT)	24°C +/- 2°C
Staff/Disabled WC	23°C +/- 3°C
Clean Utility/Corridor Drug Bay	23°C +/- 3°C
Ward Corridor	23°C +/- 3°C
TCT Corridor	23°C +/- 3°C
Staff Base	23°C +/- 2°C

Note:

It should be noted that the above room temperatures are essentially normal target values however the room temperatures will be allowed to float closer to the extremes of the range of 18°C to 28°C in exceptional circumstances, when the external winter and summer temperatures are close to the minimum and maximum design values as advised within above. Temperatures within the Corridor areas may also be subject to some variance when there is a requirement for setting various Bedroom temperatures at temperatures well adrift of the normal average room set point temperature value, however it is not expected that the temperatures within the Corridor will fall outwith the allowable range of the float temperatures as mention above and as otherwise defined within SHTM 03-01.

b) Air Quality

Air re-circulation is not an option with this particular Ventilation System due to H&S Issues and client concerns regarding cross infection within the various spaces concerned, therefore it will be avoided, however appropriate heat recovery devices will be incorporated into the design (Run-around-Coils). Due regard will be given to the quality of the air and the amount of CO₂ and microscopic dust in the air, which is supplied to the various rooms. Three stage filtration will be provided including M5, F9 and H12/H13 HEPA filtration, which will be incorporated within the Duty and Standby Central Station Air Handling Units serving the various designated areas as specifically identified elsewhere within the Particular Specification.

Fresh air will be provided at a rate of significantly more than the normal minimum level of 10 litres per second per person to comply with the client's specific requirements for the Ward and meet the corresponding Heating and Cooling loads, however Fresh Air ventilation rates will also be sufficient to ensure the undernoted room pressures are maintained to comply with the User's Requirements and SHTM 03-01 Specifications:

Area	Air Change Rate	Room Pressure
Bedroom	> 10 A/C per hour	10 Pa
Bedroom (TCT)	> 10 A/C per hour	20 Pa
Contingency Area	> 10 A/C per hour	10 Pa
Play/Dining	> 10 A/C per hour	10 Pa
Bedroom En-Suite	> 5 A/C per hour	5 Pa
Bedroom En-suite (TCT)	> 5 A/C per hour	15 Pa
Staff/Disabled WC	> 5 A/C per hour	5 Pa
Clean Utility/Drug Bay	> 10 A/C per hour	5 Pa
Ward Corridor	> 10 A/C per hour	0 Pa
TCT Corridor	> 10 A/C per hour	10 Pa

Due regard will be provided to minimise the possibility of draft discomfort.

c) Noise Levels

Consideration has been given in the design to control the following:-

- Noise from mechanical services plant items into the Building
- Egress of noise from plant items within the building to external sources
- Ingress of noise from external sources
- Other general M&E noise sources

The following criteria are listed as meeting the client's requirements:-

Area	Room Noise Rating
Bedroom	NR 30
Bedroom (TCT)	NR 30
Contingency Area	NR 35
Play/Dining	NR 35
Bedroom En-Suite	NR 30
Bedroom En-Suite (TCT)	NR 30
Staff Disabled WC	NR 35
Clean Utility/Drug Bay	NR 35
Ward Corridor	NR 35
TCT Corridor	NR 35
Plan Room	NR 50

These criteria will be measured at 1.5m above finished floor level.

Noise breakout from the building will not exceed a level which would cause annoyance to prevent quiet enjoyment within neighbouring premises.

d) Vibration

All plant and services will be fitted with effective vibration insulation measures, including anti-vibration mounts, pipework insulation, resilient penetrations, and flexible connections, all as necessary to ensure that services equipment does not cause perceptible levels of vibration in the building structure.

320.000 HEATING AND COOLING

320.010 GENERAL

Works in connection with the LTHW Heating and Chilled Water Systems are all as generally detailed on the relevant Tender drawings and otherwise as described within the specification and other documentation forming part of the Tender package.

320.020 SCOPE OF WORKS

The scope of Works in connection with the LTHW Heating and Chilled Water Systems includes the following:

1. Inspection of all associated existing LTHW Heating and Chilled Water systems that are considered to form part of the Works.
2. The verification of all existing Heating and Chilled Water system equipment and associated services that must be removed or temporarily laid aside for future use, as part of these works, or for the client to use on some other project.
3. The verification and recording of the various present LTHW Heating and Chilled Water Circuit water flow rates for all main existing associated LTHW Heating and Chilled Water systems that are to be removed (main branches only) and those where it is envisaged that the branch connections to the mains are to be made (main branches and associated main Pumped line circuit), prior to the commencement of any disruptive works in connection with the existing LTHW Heating and Chilled Water systems.
4. The strip out and removal of all existing redundant LTHW Heating and Chilled Water systems and equipment as generally detailed on the Tender drawings together with identified Active Chilled Beams, Radiant Panels and associated supports, etc.
5. The temporary or permanent isolations of all associated existing LTHW Heating and Chilled Water systems to ensure they can be set back to work promptly to meet the client's operational requirements for other areas that are served from common. The branch connections into the corresponding LTHW Heating and Chilled Water mains will necessitate the requirement for pre-fabricated pipework assemblies to ensure the associated LTHW and Chilled Water mains down time is reduced to an absolute minimum, and in the order of 8 hours.
6. The installation of new LTHW Heating, Chilled Water and Run-Around Coil Heat Recovery circuits as generally detailed on the Tender drawings and as required to meet the specification, including LTHW Heating and Chilled Water Services Pipework distribution systems, Commissioning Valves, Isolating Valves, Strainers, Venting/Draining devices, Expansion Bellows, Pressure Gauges, Temperature Gauges, Pumps (Heat Recovery System only), Pressurisation Units & Expansion Vessels (Heat Recovery System only), Check Valves, etc, together with all necessary supports. It is not envisaged at this stage that any work will be required to the existing main LTHW Heating Pumps and the main Chilled Water Pumps located within the 4th Floor Plant Room, however a Provisional Sum allowance will be made for this eventuality, should the commissioning results highlight any significant issues. It should be noted that the existing main LTHW Heating and Chilled Water Pump sets are arranged as Duty and Standby, meaning that potential work such as the upsizing of impellers and/or motors is less likely to be problematic from a system shut-down perspective.
7. The Flushing and Chemical Treatment of all LTHW Heating, Chilled Water and Heat Recovery Systems forming part of the Works, including the provision of all necessary additives including Glycol (where specifically specified) to match the existing systems. All external surfaces of LTHW Heating Pipework systems and associated equipment must also be appropriately painted and kept visibly clean and free from dust and general debris throughout the course of the works.
8. The Testing, Balancing and Setting to Work of all new and existing LTHW Heating and Chilled Water Services systems forming part of the Works.

320.030 SYSTEM DESCRIPTION

Within the Ward 2A Hematoma Oncology Teenage Cancer Trust area, it is proposed to remove all redundant existing LTHW Heating and Chilled Water Services pipework distribution systems together with all associated Radiant Heating Panels and Ceiling Mounted Active Chilled Beams, valves, etc., and blank-off these circuits accordingly at their corresponding risers. The existing Radiant Heating Panels located within the En-Suite and Toilet areas, will however be stripped out and laid aside for refitting at a later stage in the Construction Works when the existing ceiling is replaced by a plasterboard ceiling (using new ceiling trims). The removal of the existing services includes all Chilled Water distribution pipework within the Ward 2A HOTCT area together with the Constant and Variable Temperature LTHW Heating circuits. The existing Constant Temperature LTHW Heating circuit presently serves a few Air Heater Batteries and the Existing Variable Temperature LTHW Heating circuit appears to serve both the existing Active Chilled Beams and the Radiant Heating Panels (all mounted on the ceilings). The Chilled Water circuit only appears to serve the Active Chilled Beams.

As part of the present works, it is proposed to run a new Chilled Water F&R circuit from the main existing 4th Floor Plantroom to the new proposed 4th Floor Plantroom with flow and return branches cut into an appropriate section of the existing Primary Chilled Water Circuit, in a way that any associated down time is reduced to an absolute minimum. This will require the off-site fabrication of suitable valved branch connection pieces, which may be readily connected to say an existing flanged connection piece, all designed to effectively minimise the down time of the main Chilled Water Circuit to a maximum of 8 hours. Similarly, it is proposed to cut in new flow and return branches into the existing Constant Temperature LTHW Heating circuit to serve the new proposed Ward 2A HOTCT Air Handling Units together with the various proposed new Re-heater Batteries mounted within the Ward 2A HOTCT Corridor ceiling void, that serve the associated Bedroom Suites and the other main accommodation areas within Ward 2A Hematoma Oncology Teenage Cancer Trust area. As part of the new Ward 2A HOTCT Duty/Standby Air Handling Unit installation, separate Run-Around-Coil Heat Recovery systems will be provided which will be designed to recover a significant amount of heat or coolth from the corresponding Exhaust Air Streams.

Prior to the commencement of any disruptive works in connection with the LTHW Heating and Chilled Water Systems, Commissioning verification works will be carried out to confirm the existing water flow rates of the corresponding Systems. This work should generally be restricted to work in connection with the main flow circuits and main branch circuits, such that the main existing LTHW Heating and Chilled Water Circuits can be re-commissioned to provide the required flow rate for the new circuits whilst still maintaining the existing flow rates to all the various associated main branch circuits, which would be carried out as a second phase of the Commissioning Works. It is envisaged that there will be sufficient flow capability on the existing main LTHW Heating and Chilled Water Services Pumps to cater for the slightly increased loads, however should this not prove to be the case, then the corresponding Pumps will be upgraded to suit including possibly an Impellor and/or Motor upgrade. It should be noted that both the main LTHW Heating Pump set and the main Chilled Water Pump set serving the side of the Building we are concerned with are Duplicate Pump sets, therefore it should not prove to be hugely problematic to upgrade each pump together with associated Inverter Units and Power Supply only if it proves to be absolutely necessary. Following all appropriate Testing, Flushing and Commissioning works including the addition of all necessary system corrosion inhibitors and additives, the LTHW Heating and Chilled Water Systems will be set to work, ready for final validation.

Work in connection with the local pipework system isolations will be carried out outwith normal working hours, and in a way that any associated down time is kept to an absolute minimum (no more than 8 hours on any one Heating/Chilled Water pipework system, and 2 hours on an electrical board that may serve other areas) and will be otherwise arranged to ensure the LTHW Heating and Chilled Water supplies to other areas not forming part of the Refurbishment Works are thereafter maintained to allow proper operation of their associated Heating and Cooling equipment. Additional Isolating and Commissioning Valves will be installed where necessary on the LTHW Heating and Chilled Water branch pipework to ensure this condition can be met. Where new pipework systems are installed as generally indicated on

the Tender drawings, it should be noted that new Isolating, Commissioning, Control, Drain, etc Valves and AAVs will be fitted where indicated. The new LTHW Heating and Chilled Water Services pipework will be of a similar type to the existing and otherwise suitable for the associated operating pressures and temperatures.

Following appropriate pipework pressure testing (to at least 1.5 times the maximum system working pressure) and heat testing, the pipework will be thermally insulated to generally match the existing and otherwise meet the requirements of the Specification. The Thermal Insulation on the Chilled Water Pipework will also be vapour sealed. All LTHW Heating and Chilled Water pipework, Valves, etc will be covered with aluminium cladding within Plant room areas and generally accessible areas, to provide suitable protection. Valves and other line fittings will be covered with appropriate readily accessible insulated valve boxes or proprietary insulated valve bags. All new LTHW Heating and Chilled Water pipework systems and line fittings will be provided with appropriate means of identification and labelling respectively, to generally match the existing.

Supports for Chilled Water pipework systems will not be fixed such that they are in direct contact with the pipework; insulator block will be installed to maintain the efficiency of the corresponding vapour barriers. Drain valves will be fitted at all low points in the LTHW Heating and Chilled Water Systems to ensure the system can be fully drained. Automatic Air vents will be installed at all high points (and at Air Heating/Cooling Coils) in the LTHW Heating and Chilled Water systems to allow appropriate venting.

320.040 VALVES, STRAINERS, TEMPERATURE GAUGES, PRESSURE GAUGES, ETC

Valves, strainers, flexible connections, temperature gauges, pressure gauges etc., will be provided where shown on the Tender Issue Drawings and where otherwise required to meet the requirements of the specification. The types to be used are specified elsewhere within the specification. In addition, drain cocks and air vents will be provided where required at all low points and at all high points in the LTHW Heating and Chilled Water systems, to fully drain and vent the pipework systems respectively.

320.050 PRESSURISATION UNITS (HEAT RECOVERY SYSTEMS)

Two LTHW Fully Packaged Pressurisation Units will be required for the Run-Around-Coil Heat Recovery systems supplied with the new Duty and Standby Air Handling Units serving Ward 2A HOTCT area, which are located within the new 4th Floor Plant Room.

The Heat Recovery system pressurisation units will be suitable for a maximum safe working pressure of up to approximately 3.0 bar(g) with system flow and return temperatures of approximately 15°C and 6°C respectively. The cold fill pressures will set at approximately 1.2 bar(g) and the Heat Recovery System water volumes will each be approximately 200 litres. The pressurisation units will be provided with the following (in addition to other items deemed necessary by the manufacturer): duty/standby pumps, expansion vessel, pressure transducer, high and low system cut outs, mains water break tank, pump run/tripped and hand/off/auto indicators, BMS serial communications part, volt free signal relay (8 No), pump duty sharing and pulsing facilities, compact wall mounted cabinet, high and low water protection devices (within break tank) etc. The pressurisation units will be manufactured by Aquatech, Model 2ET M45-C1-E supplied with a type 30V expansion vessel. The pressurisation units will be suitable for a 230V/1 Phase/50Hz electrical supply. The Contractor will allow for the fitting of appropriate overflow pipes to be taken to the nearest floor gulley or trapped SWP, for safe discharge.

330.000 COLD WATER

330.010 GENERAL

Works in connection with the Domestic Cold Water Systems are all as generally detailed on the relevant Tender drawings and otherwise as described within the specification and other documentation forming part of the Tender package.

330.020 SCOPE OF WORKS

The scope of Works in connection with the Domestic Cold Water Services includes the following items in addition to other general Works specified elsewhere:

- 1 Inspection of all associated existing Domestic Cold Water Services systems that may form part of the Works.
- 2 The verification of all Domestic Cold Water Services pipework distribution systems and associated services that must be removed or temporarily laid aside for future use, as part of these works or for the client to use on some other project.
- 3 The verification and recording of existing water flow rates at any commissioning devices on the existing Domestic Cold Water Services systems, prior to the commencement of any disruptive works in connection with the existing associated Domestic Cold Water Services.
- 4 The strip out and removal of all existing redundant Domestic Cold Water Services systems and equipment as generally detailed on the Tender drawings together with all associated supports, etc.
- 5 The temporary or permanent isolations of all associated existing Domestic Cold Water Services systems to ensure they can be set back to work promptly to meet the client's operational requirements for other areas that are served from common Domestic Cold Water Services systems.
- 6 The installation of new Domestic Cold Water Services systems as generally detailed on the Tender drawings and as required to meet the specification, including Domestic Cold Water Services pipework distribution systems, Isolating Valves, Regulating Valves, Non-return Valves, etc together with all necessary supports.
- 7 The Flushing out, Chemical Treatment and final refilling of the Domestic Cold Waters Services system in accordance with SHTM procedures to fully satisfy the requirements of the local NHS Estates Department.
- 8 The Commissioning/Balancing and setting to Work of the new and adjacent existing Domestic Cold Water Services systems forming part of the Works.

330.030 SYSTEM DESCRIPTION

It is proposed that the main existing Domestic Cold Water Services runs within the Ward 2A Hematoma Oncology Teenage Cancer Trust area will be extensively removed and thereafter replaced with new relocated mains to primarily suit the new Ventilation Ductwork distribution runs proposed for the main Ward Corridor areas. Significant adjoining branch pipework serving the Bedroom and other adjacent areas will also have to be renewed to suit, including the provision of new associated branch isolating/regulating valves. The various new branch connections will thereafter connect to the existing branch connections within the ceiling voids of the Bedroom Suite, etc areas, as generally indicated on the relevant Tender drawings. We do not foresee any significant requirement to alter the existing Domestic Cold Water Services within the Ward 2A Bone Marrow Transplant area, however some relatively minor alterations may be required to the Domestic Cold Water Services systems in connection with the NPVL and MIBG areas, which are covered by Provisional Sums at this stage. It is not anticipated that there will be any requirement to alter the existing Domestic Cold Water Services systems in connection with the Ward 2B Day Ward area.

A new Domestic Cold water Supply will be required to serve the new proposed 4th Floor Plant Room, and in particular the two Run-Around-Coil Heat Recovery systems.

Appropriate allowances will be made for initially isolating and draining down the existing Domestic Cold Water Services system, such that it will not interfere with the general Domestic Cold Water Services provision to other existing adjacent areas, served by the same system. On completion of the present Contract Works the new Domestic Cold Water Services system will be pressure tested, flushed and treated in accordance with the SHTM requirements to meet the requirements of the specification and local NHS Estates Department, and thereafter ultimately 'set to work'.

The existing and new proposed Domestic Cold Water Services systems are both of the Stainless Steel Press fit type as specifically detailed elsewhere within the specification. The various new and modified Domestic Cold Water Services pipework distribution systems will be installed fully in accordance with the requirements of the specification and to otherwise meet the operational requirements of the local NHS Estates Department, although some distribution pipework may require to be re-routed to accommodate the new proposed Ventilation Ductwork runs. A new branch connection will be required from the existing Boosted Domestic Cold Water Supply to serve the new Heat Recovery Systems incorporated within the new proposed Duty/Standby Supply and Extract Air Handling Units located within the new 4th Floor Plant room serving the refurbished Ward 2A HOTCT area, which will connect to the Heat Recovery systems via a common Pressurisation Unit incorporating a Water Board approved break tank.

The existing and new proposed Domestic Cold Water Services systems are both of the Stainless Steel Press fit type as specifically detailed elsewhere within the specification. The various new and modified Domestic Cold Water Services pipework distribution systems will be installed fully in accordance with the requirements of the specification and to otherwise meet the operational requirements of the local NHS Estates Department, although some distribution pipework may require to be re-routed to accommodate the new proposed Ventilation Ductwork runs. A new branch connection will be required from the existing Boosted Domestic Cold Water Supply to serve the new Heat Recovery Systems incorporated within the new proposed Duty/Standby Supply and Extract Air Handling Units located within the new 4th Floor Plant room serving the refurbished Ward 2A HOTCT area, which will connect to the Heat Recovery systems via a common Pressurisation Unit incorporating a Water Board approved break tank.

335.000 HOT WATER

335.010 GENERAL

Works in connection with the Domestic Hot Water Systems are all as generally detailed on the relevant Tender drawings and otherwise as described within the specification and other documentation forming part of the Tender package.

335.020 SCOPE OF WORKS

The scope of Works in connection with the Domestic Hot Water Services includes the following items in addition to other general Works specified elsewhere:

- 1 Inspection of all associated existing Domestic Hot Water Services systems that may form part of the Works.
- 2 The verification of all Domestic Hot Water Services pipework distribution systems and associated services that must be removed or temporarily laid aside for future use, as part of these works or for the client to use on some other project.
- 3 The verification and recording of existing water flow rates at any commissioning devices on the existing Domestic Hot Water Services systems, prior to the commencement of any disruptive works in connection with the existing associated Domestic Cold Water Services.

- 4 The strip out and removal of all existing redundant Domestic Hot Water Services systems and equipment as generally detailed on the Tender drawings together with all associated supports, etc.
- 5 The temporary or permanent isolations of all associated existing Domestic Hot Water Services systems to ensure they can be set back to work promptly to meet the client's operational requirements for other areas that are served from common Domestic Hot Water Services systems.
- 6 The installation of new Domestic Hot Water Services systems as generally detailed on the Tender drawings and as required to meet the specification, including Domestic Hot Water Services pipework distribution systems, Isolating Valves, Regulating Valves, Non-return Valves, etc together with all necessary supports.
- 7 The Flushing out, Chemical Treatment and final refilling of the Domestic Hot Water Services system in accordance with SHTM procedures to fully satisfy the requirements of the local NHS Estates Department.
- 8 The Commissioning/Balancing and setting to Work of the new and adjacent existing Domestic Hot Water Services systems forming part of the Works.

335.030 SYSTEM DESCRIPTION

It is proposed that the main existing Domestic Hot Water Services runs within the Ward 2A Hematoma Oncology Teenage Cancer Trust area will be extensively removed and thereafter replaced with new relocated mains to primarily suit the new Ventilation Ductwork distribution runs proposed for the main Ward Corridor areas. Significant adjoining branch pipework serving the Bedroom and other adjacent areas will also have to be renewed to suit, including the provision of new associated branch isolating/regulating valves. The various new branch connections will thereafter connect to the existing branch connections within the ceiling voids of the Bedroom Suite, etc areas, as generally indicated on the relevant Tender drawings. We do not foresee any significant requirement for altering the existing Domestic Hot Water Services within the Ward 2A Bone Marrow Transplant area, however some relatively minor alterations may be required in connection with works in connection with the NPVL and MIBG areas, which are covered by Provisional Sums at this stage. It is not anticipated that there will be any requirement to alter the existing Domestic Hot Water Services systems in connection with the Ward 2B Day Ward area.

Appropriate allowances will be made for isolating and draining down the existing Domestic Hot Water Services system, such that it will not interfere with the general Domestic Hot Water Services provision to other existing adjacent areas, served by the same system. On completion of the present Contract Works the new Domestic Hot Water Services system will be pressure tested, flushed and treated in accordance with the SHTM requirements to meet the requirements of the specification and local NHS Estates Department, and thereafter ultimately 'set to work'.

340.010 DOMESTIC WATER SERVICES PIPEWORK SPECIFICATION AND STERILISATION PROCEDURES.

Generally all water service pipework shall be carried using Gerberit – Mapress Stainless Steel Pressfitting System in accordance with BSEN-10312 Table 2 and DVGW541 Table 3, DVGW-W270+534, all stainless steel pipework shall be Seamless and shall have a minimum wall thickness of 1.0mm (316 grade).

All pipework systems and components must be stainless steel and WRAS approved, including for the Kemper automatic secondary return/regulating valves – these shall be from their SST range,

The complete water service pipework & associated plant shall be thoroughly and fully sterilised in accordance with BSEN 806-5:2012 & BS8558:2011 and in accordance with the GRI Estates department water sterilisation procedures along with SHTM 04-01 part E, and the entire new system(s) shall be subject to a leachate flushing regime, as detailed within SHTM 04-01 part E section 2 details the sequence for carrying out the procedure (NB – This is a 9 day process). Also as detailed within section 2 of SHTM 04-01 part E is the use of peracetic acid as a suitable disinfectant to be used when stainless steel pipe work has been installed. Prior to hand over, all pipework, valves including TMV's must be free from all Microorganisms, bacteria and viruses, including Pseudomonas, legionella etc. The contractor shall take due note and carryout this regime in accordance with SHTM 04-01 Part E.

Sterilisation and water treatment shall be carried out as part of these works by the client current incumbent contractor:

DMA Canyon Limited
14 Canyon Road
Wishaw
ML2 0EG

T - 01698 536790
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345.000 SOIL WASTE DRAINAGE AND RAINWATER SERVICES

345.010 GENERAL

It is not envisaged that there will be a requirement to modify significant amounts of either Existing Soil Waste Drainage or Rainwater Drainage within the Ward 2A HOTCT, Ward 2A BMT and 2B DW areas, however Drainage facilities will have to be provided for the new Duty/Standby Supply and Extract Air Handling Units located within the new 4th Floor Plant room, to drain away the Condensate from the various Cooling Coils incorporated within the Supply and Exhaust AHUs (2 No Cooling Coils and 2 No Heat Recovery Coils). Details of minor modifications to the Drainage Services on levels 2 (Ward 2A HOTCT & Ward 2A MIBG area) and level 3 (Bed Store) are detailed on the Tender drawings.

350.000 MEDICAL GAS SERVICES

350.010 GENERAL

Works in connection with the Medical Gas Systems are all as generally detailed on the relevant Tender drawings and otherwise as described within the specification and other documentation forming part of the Tender package.

350.020 SCOPE OF WORKS

The scope of Works in connection with the Medical Gas Services include the following items in addition to other general Works specified elsewhere:

- 1 Inspection of all associated existing Medical Gas Services systems that may form part of the Works.
- 2 The verification of all Medical Gas Services pipework distribution systems and associated services that may have to be altered or otherwise modified as part of these works to accommodate the new proposed Ventilation or other Services that have to be installed as part of the Project Works.
- 3 The verification and recording of all appropriate existing certification relating to the Medical Gas Services systems that may be affected by the proposed alterations to the Medical Gas Services Systems, prior to the commencement of any disruptive works in connection with the existing associated Medical Gas Services.
- 4 The strip out and removal of all existing redundant Medical Gas Services systems and equipment as generally detailed on the Tender drawings together with all associated supports, etc.
- 5 The temporary or permanent isolations of all associated existing Medical Gas Services systems to ensure they can be set back to work promptly to meet the client's operational requirements for other areas that are served from common Medical Gas Services systems.
- 6 The installation of new Medical Gas Services systems as generally detailed on the Tender drawings, and as required to meet the specification, including Medical Gas Services pipework distribution systems, Isolating Valves, Pressure Regulating Devices, Pressure Gauges, etc together with all necessary supports.
- 7 The carrying out of all necessary specialist welding and jointing and other general installation work by a Specialist NHS approved Medical Gas Services Company who will be responsible for progressing the works strictly in accordance with the relevant SHTM guidelines for Medical Gas Pipework Installations, to fully comply with the requirements of the local NHS Estates Department.
- 8 The Commissioning/Balancing and general Setting to Work of the new and modified Medical Gas Services system including the provision of all appropriate certification.

350.030 DESCRIPTION

The Medical Gas Services works will be a contractor design element of the works, fully in compliance with SHTM 02-01 Part A. The Medical Gas Services layout shown on the Tender drawings is to indicate general design intent only, and the number and locations of outlets required together with locations for isolating valves, medical gas alarm panels, etc. The specialist design/build subcontractor will provide their own working drawings detailing all items that form part of their works including valves, bacteria filters etc. along with manufacturers technical literature for all system components for the design team's and local NHS Estates/ AE approval, prior to the commencement of any work on site.

The existing medical gas supplies serving Ward 2A as detailed, will be altered as pre required/detailed. The Specialist Medical Gas Contractor will carry out a full site survey of the relevant areas and allow for all appropriate remedial works to be carried out in connection with the Medical Gas Services to allow the necessary refurbishment Works to be progressed. Any penetrations formed through the building fabric as part of the works will be sealed and fire stopped where required and otherwise made good.

All Medical Gas Services works will be carried out in accordance with NHS Specification SHTM 02-01 Part A and QEH Estates Department Engineering Standards. All works to be undertaken by a recognised registered Specialist Medical Gas Services Contractor. Further reference should also be made to notes 1 to 9 on the relevant Tender Medical Gas Services layout drawing. The Specialist Medical Gas Services Contractor must obtain a full compliance verification check and authority to proceed from QEH Estates

and their AE prior to commencing work on site, and the Specialist Medical Gas Services Contractor must seek this within two weeks of main contractor appointment.

The existing Medical Gases installations will be modified as required to facilitate the installation of new M&E Services equipment essentially within the main Ward 2A HOTCT Corridor ceiling void area as generally indicated on the Tender drawings. It is envisaged that these works will be of a relatively minor nature involving modifications to some of the existing pipe runs.

All test certification for Specialist Gas Services Pipework Systems will be issued to the Design Team and the local NHS Estates Department and their AE for approval in a timeous manner to suit the Works Construction Programme.

355.000 SPRINKLERS

355.010 GENERAL

Works in connection with the Sprinkler Services Systems are all as generally detailed on the relevant Tender drawings and otherwise as described elsewhere within the specification and other documentation forming part of the Tender package.

355.030 SYSTEM DESCRIPTION

It is envisaged that the existing Sprinkler System serving Ward 2A Hematoma Oncology Teenage Cancer Trust, will have to be modified to suit the new proposed M&E Services layout proposed for that area. It is likely that alterations to the existing Sprinkler System within the Bedroom Suite and associated areas out with the main Ward Corridor will be of a fairly minimal nature. Every attempt will be made to maintain the existing ceiling level within the main ward corridor, however if as planned it is not reduced in height, this is likely to result in further general pipework modifications to the main pipework services contained therein, including the Sprinkler Pipework Services system, to accommodate the proposed larger Ventilation Ductwork. If the ceiling is however reduced in height the various branch connections to all heads, will have to be extended.

It is unlikely that any alterations will be required to the Sprinkler Services System within the Ward 2A Bone Marrow Transplant area due to the minimal amount of new works proposed for that area, although this may have to be further reviewed if other possible works for that area, that have not yet been fully defined, are developed.

It is also unlikely that any modifications will be required to the Sprinkler Services System within the Ward 2B Day Ward area due to the nature of the new works proposed for that area.

The main associated Sprinkler Zone pipework system serving the above areas will almost certainly have to be drained down, tested and refilled accordingly.

360.000 VENTILATION

360.010 GENERAL

Works in connection with the Ventilation Systems are all as generally detailed on the relevant Tender drawings and otherwise as described within the specification and other documentation forming part of the Tender package.

360.020 SCOPE OF WORKS

The scope of Works in connection with the Ventilation System will include the following items in addition to other general Works specified elsewhere:

- 1 Inspection of all associated existing ventilation systems that may form part of the Works.
- 2 The verification of all ventilation equipment and associated services that must be removed or temporarily laid aside for future use, as part of these works or for the client to use on some other project.
- 3 The verification and recording of present air flow rates on existing Ventilation systems prior to the commencement of any disruptive works in connection with the existing associated Ventilation systems.
- 4 The strip out and removal of all existing redundant Ventilation systems and equipment as generally detailed on the Tender drawings together with all associated supports, etc.
- 5 The temporary or permanent isolations of all associated existing ventilation systems to ensure they can be set back to work promptly to meet the client's operational requirements for other areas that are served from common Ventilation systems.
- 6 The installation of new Ventilation systems as generally detailed on the Tender drawings and as required to meet the specification, including Ventilation Ductwork distribution systems, Grilles/Diffusers, Volume Control Dampers, Fire/Smoke Dampers, Access Panels, Isolation Dampers, Air Heater Batteries, Attenuators, Air Handling Units, Extract Fans, External Louvres, Pressure Stabilisers, etc together with all necessary supports.
- 7 Works in connection with the modification of existing AHUs serving Ward 2A BMT and Ward 2B Day Ward, including removing existing Thermal Wheels, modifying/removing existing filter units, upgrading existing Fans/Motors/Inverter Drive Units and installing new HEPA and high efficiency Bag Filters, including the upgrade of corresponding power supplies where required.
- 8 The Sterile Cleaning of all Ventilation Ductwork internally forming part of the Works, strictly in accordance with the requirements of SHTM 03-01. All other Ventilation Ductwork surfaces should also be kept visibly clean and free from dust and general debris.
- 9 The Testing, Balancing and setting to Work of all new and existing Ventilation systems forming part of the Works.

360.030 SYSTEM DESCRIPTION

Within the Ward 2A Hematoma Oncology/Teenage Cancer Trust area it is proposed to initially remove all redundant Supply and Extract Ventilation ductwork and associated fittings serving the Bedroom Suites and the adjacent Corridor and general Service Areas, which includes most of the Ventilation ductwork within the Ward 2A HO/TCT area, as it is significantly undersized for the new proposed ventilation provision. The present existing common Ventilation ductwork systems will be blanked off close to the where the existing Supply and Extract Ventilation branch ducts serving the Ward 2A HOTCT connect to the common riser ducts. It is proposed that the existing common Supply and Extract system will thereafter be rebalanced such that it only meets the requirements of the remainder of the areas that the common AHU presently serves, being the other general areas on levels excluding level 2, and delivers a similar Ventilation provision to what these other areas are being provided with at present. A pre-commissioning check will be carried out to establish what the existing air flow volumes are prior to any system rebalancing work being carried out. It is expected that the total air flow volume demand for the common system will obviously drop and the air flow duties of the associated AHU Supply and Extract Fans will be

reduced to meet the corresponding fall in demand, by prudent adjustment of the corresponding existing frequency inverter speed control drive units.

It is proposed to provide new separate Duty/Standby Air Handling Units to solely serve Ward 2A Hematoma Oncology Teenage Cancer Trust area. These Air Handling Units will be housed within a new Plantroom located at 4th Floor level. Each AHU will incorporate Supply and Extract Fans (with external motors and Inverter Speed Drive Units), Motorised Isolation Dampers, LTHW Frost Coils, Chilled Water Cooling Coils, Main LTHW Heating Coils, Run-around Heat Recovery Coils, two pre-filters (M5 & F9) and a final HEPA filter (H12/H13). The precise filter types will be selected to meet the local NHS Estate preferences, taking into account all specific operational concerns for the site. It is proposed that the Supply and Extract units will be stacked to make efficient use of the available Plantroom space and mounted on 300mm high runner support beams to assist with spreading the weight of the units over the floor area. The associated Fresh Air will be drawn in via a wall mounted External Louvre and the Extract Air exhausted through the roof above via a low profile Penthouse Louvre. The Supply and Extract ventilation ductwork will be twinned together such that the corresponding Motorised Isolation Dampers will effectively isolate the de-energised Air Handling Unit. It is also proposed that easily cleanable non-shedding Noise Attenuators will be installed on the ventilation ductwork on the room side of the AHU to effectively reduce the in-duct noise levels within the corresponding Supply and Extract ducts. Appropriate attenuation will also be provided on the outdoor side of the AHU where required, should there not be sufficient means of attenuation provided by the component parts of the AHU and the corresponding Fresh Air and Exhaust Air Ventilation ductwork. Special care will be taken on the Fresh Air inlet, as it is recognised that the associated Intake Louvre is located directly above a general roof play area, however steps have been taken to negate any problematic noise issues, by installing appropriate attenuators and reducing the general intake velocity of the corresponding Fresh Air Inlet Louvre.

The new proposed Supply and Extract ductwork will drop down a newly formed riser duct within the 3rd Floor Bed Store to pass down directly into the Ward 2A HOTCT ceiling void. Automatic Fire/Smoke Dampers will be installed at both 3rd and 4th floor levels to maintain the present fire rated compartmentation requirements.

It is envisaged that all new proposed general Supply and Extract ventilation ductwork will then generally run down the central Ward 2A Corridor ceiling void, where individual Supply Air ducts will branch off to serve the Bedroom, etc areas and maintain the Bedrooms and other positively pressurised rooms at a positive pressure of either +10 or +20 Pa with respect to the Main Ward 2A Corridor, depending on the existing provision of any intermediate TCT Lobbies or other rooms, which would be maintained at an intermediate pressure between the Bedroom and the main Ward 2A Corridor. A Pressure Cascade facility will be provided to help minimise the contamination risks from within the Ward and general Hospital areas. The room pressures would be accurately controlled by means of wall mounted Pressure Stabiliser Units which will also effectively close when the corresponding room doors are operated, resulting in an outflow of air from the Bedroom to the Ward 2A Corridor from the Bedroom to a TCT Lobby, then to the main Ward 2A Corridor, where a TCT Lobby is provided. All Bedroom and Special Accommodation Area Supply Air branch ducts will be fitted with a LTHW Re-heater Battery to provide accurate control of air temperature within the corresponding Bedrooms/Special Accommodation Areas. Each Supply Air branch duct will also be provided with a Volume Control Damper for balancing, and a Motorised Gas Tight Control Damper for Room Isolation purposes. Appropriate Swirl type Air Diffusers will be installed at ceiling level within each Bedroom to help provide a good even temperature spread across the room and also help maintain appropriate minimum terminal air velocities. It is also proposed that the Supply Air Diffusers boxes should be capable of incorporating terminal HEPA filters to facilitate their possible easy installation at a future date if it is considered appropriate to do so by the client, either as part of this contract or at some time in the future, which would additionally offer a final stage of HEPA filtration prior to the Supply Air entering the Bedroom, etc areas and provide additional cross contamination infection control within the Ward area. Extract Ventilation for the Bedroom Suites and the general Ward areas will be via Ceiling mounted grilles generally located within the Ward Corridor area (it is not proposed to provide any extract grilles within the Bedrooms) such that the velocities of the outgoing air through either the closed or opened Bedroom door, can be maximised to assist with back contamination issues.

With regards to the Bedroom Suite Toilet Extract Ventilation provision it is proposed to reuse the existing Ventilation Ductwork as much as possible, as generally indicated on the Tender drawings close to where the existing branch duct on the main central station Toilet Extract system will be blanked off, and the relevant associated existing Central Station Toilet Extract Ventilation system recommissioned accordingly maintaining the present air flow volumes to the other areas outwith Ward 2a HOTCT area accordingly, albeit with a reduced total air flow duty. The proposed new Toilet Extract Ventilation System serving Ward 2A HOTCT will incorporate significant sections of the existing system located within Ward 2A HOTCT, however it will ultimately connect to a new separate Toilet Extract Ventilation duct which will thereafter rise up to the new proposed 4th Floor Plant room and connect to a new duplicate Duty/Standby Toilet Extract Fan Units, prior to rising up to discharge through the roof above, by means of a common low profile Penthouse Louvre.

Within the Ward 2A Bone Marrow Transplant area, it is proposed to essentially modify the present Air Handling Unit serving this area such that the existing Thermal Wheel Heat Recovery Device is removed, and the common interconnected opening blanked off, thereby virtually nullifying the risk of cross contamination between the Fresh Air Supply and the Exhaust Air Ventilation air streams. It is anticipated that some of the adjacent electrical lighting modular trunking system will have to be temporarily removed to facilitate the removal of the existing Thermal Wheels, which it is advised by the AHU manufacturer can be removed in part sections. Further proposed works to this AHU include the installation of final HEPA Filters (H12) on the Supply Section with F7 filters immediately upstream, to replace the existing F7/F9 final filters presently installed. In order to maximize the air flow of the existing Supply Ventilation System it is proposed to retain the existing fan unit, however upgrade the corresponding fan motor and inverter unit up to 11 kW, which is likely to result in a potential increase in the Air Supply Flow Volume of approximately 7.9%, or otherwise maintain the set existing air flow at a slightly higher system static pressure, which is likely to be required with an increase in the pressure drop of the new proposed final AHU HEPA filter unit. It should be noted that it is not considered possible by the existing AHU manufacturer, to further effectively increase the performance of the existing AHU in terms of air flow/static pressure beyond these quoted figures, due to space restrictions within the existing AHU.

Within the Ward 2B Day Ward area it is proposed to essentially modify the present Air Handling Unit serving this area such that the existing Thermal Wheel Heat Recovery Device is removed, and the common interconnected opening blanked off, thereby virtually nullifying the risk of cross contamination between the Fresh Air Supply and the Exhaust Air Ventilation air streams. It is anticipated that some of the adjacent electrical lighting modular trunking system will have to be temporarily removed to facilitate the removal of the existing Thermal Wheels, which it is advised by the AHU manufacturer can be removed in part sections. Further works to this AHU include the installation of final HEPA Filters (H12) on the Supply Section with F7 filters immediately upstream, to replace the existing F7/F9 final filters presently installed. In order to maximize the air flow of the existing Supply Ventilation System it is proposed to replace the existing fan unit with a new upgraded Direct Driven Unit with a corresponding 11 kW motor and inverter drive unit, which is likely to result in a potential increase in the Air Supply Flow Volume of approximately 19%, or otherwise maintain the set existing air flow at say a slightly higher system static pressure, which is likely to be required with an increase in the pressure drop of the new proposed final AHU HEPA filter unit. It should be noted that it is not considered possible by the existing AHU manufacturer, to further effectively increase the performance of the existing AHU in terms of air flow/static pressure beyond these quoted figures, due to space restrictions within the existing AHU.

The above modification works in connection with the existing Ward 2A BMT and Ward 2B Day Ward Air Handling Units will be carried out by:

Barkell Ltd.
Unit 22, No 1 Industrial Estate,
Consett, County Durham DH8 6SZ
Contact Tel 01207 590 575
Jamie Donald/P. Fenwick email: ahu@barkell.co.uk

(refer to existing quotation reference Nos AS3822 Rev 00 and AS3698 Rev 2 dated 25th Jan 2019 & 26th Nov 2018 respectively.

Please note that the works in connection with the corresponding Inverter Drive and Power Supply Cable Upgrades will be carried out by the Specialist Controls Contractor as part of these Works.

Part of the Ventilation Works involves a requirement to install additional Smoke Dampers, and interface them with all existing associated Power and Controls systems. All necessary work in connection with extending or otherwise modifying the existing Smoke Damper System (including the installation of new Smoke Dampers and associated Controls and Power and Controls wiring will be carried out by:

Entropic Ltd;

Contact:



365.000 PNEUMATIC TUBE SYSTEMS

365.010 GENERAL

Works in connection with the Pneumatic Tube Systems are all as generally detailed on the relevant Tender drawings and otherwise as described elsewhere within the specification and other documentation forming part of the Tender package.

365.030 SYSTEM DESCRIPTION

It is envisaged that the existing Pneumatic Tube System serving Ward 2A Hematoma Oncology Teenage Cancer Trust area, will have to be modified to suit the new proposed M&E Services layout for that area. It is likely that alterations to the existing Pneumatic Tube System within the Clean Utility/C. Drugs/C.Bay area outwith the main Ward Corridor will be of a relatively minimal nature. Every attempt will be made to maintain the existing ceiling levels within the main ward areas, however this is likely to result in modifications to the Pneumatic Tube System pipework runs as generally detailed on the Tender associated drawings to allow the installation of the proposed larger Ventilation Ductwork.

It is also envisaged that there will be modification works required to the Pneumatic Tube Systems within the ceiling void of the Ward 2A Corridor area adjacent to the Clean Utility/C.Drugs/C.Bay area, to facilitate the installation of new proposed M&E Services therein.

It is however unlikely that any alterations will be required to the Pneumatic Tube System within the Ward 2A Bone Marrow Transplant area due to the minimal amount of new works proposed for that area, although this may have to be further reviewed if other possible works for that area, that have not yet been fully defined, are developed.

It is also unlikely that any modifications will be required to the Pneumatic Tube System within the Ward 2B Day Ward area due to the nature of the new works proposed for that area.

390.000 CONTROLS

390.010 GENERAL

The Works in connection with the Controls element of this project form part of the Mechanical Services Contract Works Package for QEUH Royal Hospital for Children, Glasgow.

Further reference should also be made to the various other relevant sections of the specification for details of all General Preliminaries and Contract Conditions associated with the Works. These other sections also provide details on the general scope of the Complete Works Package, together with information on the general Project Requirements.

It is envisaged that the Mechanical Services Controls element of the works will be split into two main works packages. One essentially relates to the provision of a new autonomous BMS Controls System that serves Ward 2A Hematoma Oncology Teenage Cancer Trust area which is served from four new Mechanical Services Control Panels located within the new 4th Floor Ventilation Plant Room, together with a Nurses Control Panel located at the Nurses' Station within the Ward 2A Corridor. The other Controls Works Package relates to modification work in connection with Existing Controls infrastructure services, which will have to be either altered or partly replaced to meet the specific requirements of the Outline Specification, which includes Power and Controls Work in connection with the modified Existing Air Handling Units serving Ward 2A BMT and Ward 2B Day Ward. Other potential future works that may be incorporated into the Controls package as part of these works include works in connection with the new proposed NPVL SCH010 Room, which have not as yet been fully defined. The Controls and associated Power Works in connection with the proposed NPVL SCH010 Room will be covered by a Provisional Sum, at this stage.

The Control Panels will be located generally where shown on the Tender Issue drawings, however their precise location will be determined following detailed consideration of maintenance and general access requirements to all plant and equipment (and thereafter agreed with the CA in conjunction with the local NHS Estates Department). The Electrical Power supplies to the new Control Panels will be provided by the main Electrical Services Contractor. These will be all be taken from an appropriate Essential Services Power source within the Royal Hospital for Children Building. It should be noted that each Mechanical Services Control Panel will be provided with an integral UPS Unit to help ensure a smooth change over when the Standby Ventilation Plant is energised in a power fail situation (this will allow the initial Duty Unit to shut down and be isolated appropriately). A 15 kVA@ 3 minutes 3 Phase UPS unit will be allowed for each of the two main Ward 2A HOTCT AHU Control Panels, and a 6kVA @ 3 minutes 1 Phase UPS will be allowed for each of the smaller Toilet/Dirty Extract Control Panels. Connections from the RHC Building's Comms Cable (WAN line) to each new Control Panel, will be carried out by others, out with these Contract Works.

In addition to providing appropriate HVCA Controls and Power supplies from the four Ward 2A HOTCT Control Panels to the two new Air Handling Units and the two new Toilet/Dirty Fans and associated equipment housed within the new 4th floor Plant Room, C&P supplies will have to be taken to field mounted equipment located either within or adjacent to the various Bedrooms and other accommodation areas. C&P supplies will also have to be taken to a Nurse's Station Control Panel, located within the Nurse's Station area of Ward 2A Corridor. This new Control Panel will provide Room Pressure monitoring and alarm facilities for the various Bedrooms and other associated accommodation areas within Ward 2A HOTCT area. Due to an increased Power requirement in the power supplies to the existing AHUs serving Ward 2A BMT and the Ward 2B Day Ward AHUs, an allowance will be made for new increased power supplies to the associated Supply Fan Motors, in addition to Controls Supplies to the new Filter facilities. It is likely that other Controls and associated Power works will be required in connection with the new proposed NPVL SCH 010 Room within the Ward 2A BMT area, however as this has not been fully defined as yet, associated costs will be covered by a Provisional Sum Allowance, for the time being.

Reference should be made to other sections of this specification together with associated Tender Drawings for general details of all works that are to be included as part of this Contract (including strip-out/removal works, temporary works, etc).

The Contract also includes for all necessary isolation, down takings and removal works in connection with the existing M & E Services. The Main Contractor will also allow for all necessary down takings and removal works in connection with the Building Fabric, as part of this Project.

All M&E Services systems will be installed, commissioned and set to work in full compliance with the requirements of the specification. All appropriate documentation required as part of these works, must be issued to the Client in advance of the project being officially handed over. All critical (as determined by the CA) snagging or outstanding works that requires to be completed for the operation of the Ward 2A HOTCT, Ward 2A BMT and Ward 2B Day Ward areas covered by this Contract must be carried out satisfactorily prior to project handover, in order that the follow-up Client's Validation Works can be progressed to suit the overall Client's Works Programme.

The Specialist Controls Contractor will fully assist the Mechanical Services Contractor with issues such as temporary shutdowns of existing Plant throughout the progress of the Contract, to meet the client's precise operating requirements.

As part of this Contract it will also be necessary for the Mechanical Services Contractor to liaise with all other specialist contractors and sub-contractors carrying out the works required to complete the Contract, including works not specifically described in detail within this particular specification, however that are otherwise required to complete works in connection with the Contract as a whole. Reference should also be made to other Client's Tender Documentation made available for the pricing of these works, such that due cognisance will be taken of these items in the preparation of the Contract Tender Cost. There will be a significant Builders work element, which will be detailed elsewhere within the Contract Tender Documentation Package. These works will include the forming and making good of various significant holes through the existing structure to facilitate the installation of the M&E Services Installations. Other general builders work including work in connection with the ceilings, walls and general building fabric, including redecoration works, will also be carried out by others outwith the Mechanical Services Works Package and is therefore detailed elsewhere within the Contract Tender Documentation Package. Other Works of a more minor nature in connection with fixings of supports for the Mechanical Services Plant and equipment to the existing structure, will be carried out by the Mechanical Services Contractor.

Following the award of the Contract any existing non-compliant issues, or matters of concern that are uncovered on site, should be highlighted to the Engineer/Contact Administrator at the earliest opportunity to allow due consideration to be made and appropriate remedial action taken.

It is important that operation of the adjacent areas within the hospital are not unduly compromised, and it likely that the Local NHS Estates personnel will strive for only an absolute minimum amount of shutdowns over the shortest permissible periods. These restrictions are further detailed elsewhere within the specification. It should not be expected that other extended shutdown periods will necessarily be either granted or agreed with the NHS Estates Department, therefore every feasible attempt must be made to comply with these parameters. All reasonable means will also be made to minimise the extent of on-site work within the Ward areas to minimise the impact the works may have on the other areas of the hospital, and also to help minimise the length of the Construction Programme period. Adjacent Wards must be able to continue to operate throughout the progress of these contract works, in a fashion that permits the general proper ongoing operation of their duties with minimal impact on the patient's or staff's general comfort.

The Mechanical Services Contractor and Specialist Controls Contractor will take full cognisance of all information contained within the Specification and Tender Documentation package including information included on all relevant Tender drawings and comply fully with all stated requirements, however due allowance should also be made for other equipment not specifically indicated or shown, but that is required for a full and complete system to enable it to perform its design task of operating and monitoring the complete Mechanical Services Systems and other associated equipment.

390.030 DESCRIPTION

The description and operation of the new proposed M&E Services Power and Controls Systems are generally detailed below, to give an overall appreciation of the way the M&E Services installations operate and interrelate with one another. The existing Essential Services Power Systems will serve the new Ward 2A HOTCT Ventilation Plant and associated Controls systems, such that they will continue to operate under general mains Power failure, or additionally if one of the Essential Services Power Cables are compromised in some way. Also, if there is a failure in any component part of the main Ventilation Plant, a standby Ventilation Plant will be installed as part of these works, to provide back-up facilities automatically, within a reasonably short period of time, following Duty Plant failure.

General reference will be made to the Controls Points Schedules and corresponding Controls Equipment Lists for further specific details of the Controls equipment required for each HVAC system. It is expected that all control routines and staged alarm facilities will be programmed, and the necessary software provided to properly operate the M&E Services systems in connection with these works, and that all monitoring and staged alarm functions will be relayed to the existing BMS Front End. It should be noted that extensive use will be made of Virtual Switching/lights facilities, although there are some exceptions as identified within the Controls Points Schedules and the Controls Equipment Lists. The precise location of all control panels will be determined on site with the agreement of the local NHS Estates Department, however general regard will be taken at Tender Stage of the approximate locations of the Control Panels as indicated on the Tender Drawings.

All necessary Containment and Electrical Power and Controls Supplies will be provided for the new and existing upgraded HVAC Controls Systems and associated equipment from the various new and existing Mechanical Services Control (and associated Power) Panels, forming part of the Mechanical Services Contract. The main Electrical Services Contractor will allow for providing new additional separate Electrical Power Supplies to each of the new Control Panels serving the duplicate Supply and Extract Ward 2A AHUs and the associated duplicate Toilet Extract fans. These additional power supplies will be taken to individual isolators mounted on the wall adjacent to the proposed new Mechanical Services Control Panel locations within the new 4th floor Plant room. The Specialist Controls contractor will allow for taking the power from these points up to the various Mechanical Services Control Panels.

The automatic controls system will be of the DDC type comprising of an appropriate number of network controllers and field processing units/outstations which will be capable of stand-alone operation. The FPU's/outstations will also be fully networked such that all units may be interrogated from a portable operator's terminal/keypad connected into any FPU/outstation unit.

The Specialist Controls Contractor will provide a complete Controls and associated Power Installation that is fully and readily compatible with the existing installations on site, including all associated software provision. And be fully responsible for fully setting the systems to work ready for final client Validation.

The Mechanical Services Controls System serving Ward 2A Hematoma Oncology Teenage Cancer Trust area is essentially autonomous in nature, in that it can carry out its duties without any input from the main central Hospital's BMS System, although it must be fully interfaced with the main Hospital's BMS in such a way that all points can be monitored, and the various systems controlled and adjusted remotely from the main BMS. Alarm conditions must also be capable of being picked up by the main central BMS Front End facility. It is understood the Ward 2A Controls System will be connected to a site wide BMS by means of an appropriate Comms Cable infrastructure system, as part of a separate Client's Works Package.

All necessary interlocks will also be provided with the building's fire alarm system to meet the requirements of the local Fire Officer, although the wiring of such will also be carried out as part of the main Electrical Services Works Package.

The new and upgraded existing Supply and Extract Air Handling Units and other associated plant and equipment is designed to meet all basic operational requirements of the new and upgraded facilities, however the precise duty performance of equipment such as Inverter Drive Units will have to be further adjusted as part of the commissioning process to generally meet the precise duty requirements of the

Pressure Cascade Ventilation System forming part of the new HVAC system serving Ward 2A HOTCT, together with the general requirements of the upgraded Ventilation Systems serving Ward 2A BM and Ward 2B. The duplicate Standby Supply and Extract AHUs and will both incorporate single Supply and Extract external motors with individual Inverter Drive Units, to efficiently regulate the speed of the various fans to provide the correct air flow rates and room pressures for the new Ward 2A HOTCT facility. The associated Ward 2A duplicate Toilet Extract Fan Units are similarly designed to meet the duty requirements, however further adjustment will be required to meet the precise Air Flow and room pressure requirements for the new HOTCT facility.

It should be noted that the speed of the new Ward 2A HOTCT AHU Supply Fans will be regulated by means of their associated local individual Inverter Drive Units to maintain specific constant static pressure levels for each supply air system. In the event of a single motor/inverter drive failure or other significant failure in connection with the Duty AHU, the corresponding standby AHU will be arranged to automatically energise, with a fail alarm being generated. All new Frequency Inverter drive Units will be mounted externally to the corresponding Supply and Extract AHU Units, to efficiently regulate the speed of the fan to provide the correct air flow and room pressures for the various Bedroom, etc areas.

This will be regarded as a Critical Alarm condition which will momentarily disengage the general room low pressure alarms until a set time has elapsed whereby the Standby AHU will be expected to be made fully operational (and up to speed). The failure of any significant plant item in connection with the Duty AHU (or its associated Heating/Chilled water Controls), will instigate a shutdown procedure for the associated Duty AHU to effectively isolate it from the general Ventilation system, which will include the closing of associated Ventilation Isolation Dampers, S&E Fans and corresponding Heating, Control Valves, etc., in a controlled and methodical manner that will avoid problematic operating issues. The starting procedure for the Standby AHU will then be progressed in a sequenced manner such that the associated standby Heating and Cooling Valves will energise, and the corresponding Ventilation Isolation Dampers will open and engage the associated end switches, to allow the main Standby Supply Air Fan to ramp up to the appropriate speed and stabilise under control of its corresponding Air Pressure Sensor.

Three stages of air filtration will be provided for the new Ward 2A HOTCT duty and standby Supply AHUs, and Single stage air filtration will be provided for the new Ward 2A HOTCT duty and standby Extract AHUs; Primary Filtration (M5) will be provided within the Supply AHUs prior to the Heat Recovery Coil (M5) and further F9 and HEPA filtration will be provided at the end of the Supply AHUs, and Primary Filtration (M5) will also be provided prior to the Heat Recovery Coil on the Extract AHUs, all as generally indicated on the Tender Drawings. The pressure drops across all filters units will be individually monitored by Differential Pressure Sensors to provide an indication of their individual operating condition and trigger an alarm when the corresponding pressure drops approach their associated desired terminal operating limits.

New Motorised Control Dampers will be provided on the both the intake and discharge side of the various new duty and standby Supply and Extract AHUs and Toilet Extract Fans as generally indicated on the Tender Drawings, to effectively close all appropriate Intake and Discharge Dampers on each corresponding AHU or Extract Fan when they are de-energised. This facility may also be used to help isolate the Ventilation Plant for general maintenance purposes including possible plant cleaning. The use of non-electric backdraught dampers may also be considered in the future to decrease the Changeover Time if deemed acceptable by the client. The corresponding Fan Units will be prevented from operating when their corresponding dampers are not properly opened (and the end switches made).

Frost Control routines will be incorporated where required into the controls software system that provide multi-level protection against Coil/pipework freezing, and other potentially problematic low temperature events. Frost Coils will be provided for each new duplicate Supply AHU, which are designed to provide an off coil condition of 5°C db with an external design temperature of -10°C/sat, although consideration may be given to dropping the off-coil temperature slightly; perhaps around 3°C following general agreement from the local NHS Estates Department, to maximise the heat pick-up from the downstream Heat Recovery Coil. Frost Thermostats will also ensure the Heating Valve opens during Frost Conditions on a proportional basis. A pipeline mounted Police Sensor will ensure hot water is circulated through the

Frost Coils when required at low temperature conditions, prior to allowing the corresponding Supply Fans to operate. The new duplicate Ward 2A HOTCT Supply and Extract AHUs also both incorporate Run around Coil Heat Recovery Systems incorporating a single Circulating Pump and a corresponding 3-port Control Valve, as part of a packaged Run Around Coil Heat Recovery Unit provided by the AHU manufacturer/supplier. The Heat Recovery Coils will be designed to raise the Supply Air temperatures up to a minimum of approximately 13°C at the external Winter design temperatures, or up to approximately 18°C where the external temperatures are higher, however not when Cooling is required. Additional Control and monitoring facilities will be provided for the Ward 2A HOTCT AHU and Toilet Extract Control Systems, as generally indicated on the Tender Drawings. A sequenced Heating facility will be provided to meet the Heat demands of the space as economically as possible, however the Primary Frost Coil must not be prevented from ensuring that the off-coil temperature is no less than a set minimum value (which has notionally been set at 5°C at design stage. It is also important that when there is a cooling demand in the space that the supply air temperature is not unnecessarily raised to a temperature where it has to be thereafter lowered by the Cooling Coil within the Supply AHU. The Heating output of the Heat Recovery Coil may have to be regulated by diverting Heating Water from the H/R Coil. A transitional stage will be incorporated where the Heat Recovery Device is effectively isolated when full use is to be made of free Cooling to meet the Cooling Demand of the space. When the external temperature thereafter rise to an exceptionally high value the Controls system will allow effective and controlled Pre-Cooling to take place at the Heat Recovery Device operating in reverse. When Cooling is otherwise required from the Chilled Water Cooling Coil It will be arranged for it to lower the Supply Air temperature from 28°C db/19.5°C wb to approximately 14.5°C db/13.5°C wb, when it may thereafter pick up approximately 1.5°C in sensible gain thereafter, prior to supplying air to the various accommodation areas.

The Heating and Cooling output of the corresponding Heating, Heat Recovery and Cooling Coils will be regulated by altering the position of a corresponding Control Valves mounted on the associated pipework systems serving the Coils. The various Heating, Heat Recovery and Cooling Coils will operate under the dictates of their corresponding duct mounted temperature sensors mounted downstream of the various Coils with appropriate input from other Room and Duct mounted Temperature Sensors to fully evaluate the Heating and Cooling load requirements.

Appropriate Reheat will also be made possible from the following main Heater Battery where required, if specific dehumidification is required due to high humidity levels detected within the general Return Air Duct from the accommodation areas. The Heating and Cooling Coils will be capable of being controlled to provide a sliding dew point control for limiting the upper humidity levels whilst at the same time providing close db temperature control of the Supply Air. It should be noted that if the Heat Recovery System fails for some reason, the Main Heating Coil is designed such that it will still be able to raise the Supply Air Temperature within the Air Handling Unit to at least 18°C at the external Winter design temperature of -10°C/saturated. When there is a general heating load requirement within the Ward 2A areas the various LTHW Re-Heater Batteries will operate under the dictates of their various local Room Temperature Sensors to meet the heating demands of their respective rooms, by the automatic adjustment of the various corresponding local Heating Control Valves. It will be possible to adjust the Room Temperatures set point value for the various Bedroom, etc areas by means of limited adjustment locally of the local Room temperature controller units (although limits to this will be set by the local BMS System to avoid indiscriminate tampering). Cooling to the various Bedroom, etc areas is provided by Central Cooling with input from the local Room Temperature Sensors. It is however important that the Cooling provision will be carried out as economically as possible, with the air flow volumes having been adjusted slightly to cater for the various different room cooling loads of the various rooms concerned. It is however acknowledged that some re-heating will be required in certain circumstances especially if close temperature control is desired within the various temperature controlled Bedrooms, etc., however the facility of building in some flexibility with the acceptable range of room temperatures will be built into the Controls Software to help minimise wasteful re-heat.

It is assumed that the existing Central Chilled Water Cooling System operates the associated existing Chiller Units in a stepped manner where appropriate, to meet the varying Cooling Load requirements. throughout the year and vary the corresponding Chilled Water flow rates accordingly. It is also

understood that the existing Chilled Water system essentially operates essentially at constant Chilled Water Flow and Return design temperatures of approximately 8°C flow and 14°C return.

The two new main AHUs serving Ward 2A HOTCT area are provided with individual Run-Around-Coil Heat Recovery Systems incorporating a Circulating Pump, 3-Port Control Valve, Temperature Sensors, etc which should be provided in a general kit form on a rig, by the AHU manufacturer. The Heat Recovery Systems will both be provided with automatic water make-up facilities in the form of a Pressurisation Unit, all located within the new 4th Floor Plant Room.

Air Flow Static Pressure sensors will be installed downstream of the various Supply and Extract Fans (final location of the pressure sensors will be determined on site). Additional corresponding differential pressure switches will otherwise prove the general satisfactory operation of the Supply Fan. Any significant issues relating to air flow will initially raise a first stage alarm on the BMS and thereafter be capable of shutting down the associated Ventilation System at a pre-set condition.

A Digital Electronic Differential Pressure Monitoring and display system will be provided to record the differential air pressure across the various Bedroom/Corridor, Play Room/Corridor and Contingency Room/Corridor compartments within the Ward 2A HOTCT areas. The individual room Air Pressure Monitoring Devices will be located within the ceiling voids immediately adjacent to each of the corresponding Pressure Controlled Rooms. Each Air Pressure Monitoring Device will be connected to two ceiling mounted Air Probes (c/w Stainless Steel Facia Plates) by means of appropriately coloured PVC Tubing. A pair of Air Probes will be provided for each Pressure Controlled Room, with one being mounted on the ceiling of the Pressure Controlled Room and the other on the ceiling of the adjacent Corridor. Individual Stainless Steel (recessed facia plate) Digital Pressure Display Units will be provided for each pressure controlled room, to be mounted on the wall of the adjacent Corridor to the Pressure Controlled Room. The DPDUs will be designed to show the original design room pressures/pressure differentials and the corresponding actual room pressures/pressure differentials with a clear indication of any deviations. Time related alarm signals will be generated to indicate either unacceptable long term or short term deviations, which will be clearly identified on a Colour HMI Display Unit mounted on the facia of the local Nurses Station Control Panel. An historical logging facility will be provided to record ongoing pressure conditions and alarm events for all DPDUs, which will be housed within the Stainless Steel Nurses Control Panel. The capacity for event recording and time intervals for pressure recording will be proportionally similar to the existing facility provided for Ward 2A BMT area, which is expected to cover a period of approximately 14 months. A 24 hr battery back-up provision will be provided for the Pressure logging facility, with an indication lamp showing mains power failure.

All necessary power supplies for the will be taken from the local KNX small Power supply Network.

In addition to the Controls and associated Power installations in connection with the upgraded Ward 2A HOTCT area, there is a requirement to modify the existing Controls and associated Power installations in connection with the alteration to the existing Ward 2A Bone Marrow Transplant and Ward 2B Day Ward Air Handling Units, where the existing Thermal Wheel Units will be removed and the existing F7/F9 Bag filters replaced with new final F7 Bag Filters and H12 HEPA Filters immediately downstream. Individual monitoring of each filter will be required by means of differential Pressure Sensors, to accurately assess the requirement for the replacement of each individual filter, as the replacement or cleaning periods of both will vary significantly. The Specialist Controls Contractor will also be responsible for the provision of new upgraded Inverter Drive Units for the two upgraded AHU Supply Fan Motor concerned, together with the necessary upgrading of the corresponding Power Supplies to the Inverter Drive Units and the new associated upgraded Supply Fan Motors. Work in connection with making good the existing Controls associated with the proposed removal of the Thermal Wheels should also be allowed for. It should be noted that the general refurbishment works in connection with the two existing AHUs, will be carried out by the original AHU manufacturer (Barkell Ltd – refer to Ventilation section of the Particular Specification for further details).

The provision for monitoring the various Air/Water Temperatures, Pressures Humidifies and alarm events will be recorded on the main BMS Front End facility for the building. Corresponding Sensors and other Controls Devices will be also be provided where indicated on either the Tender Drawings or where additionally noted on the following Controls Schedules below:

BUILDING MANAGEMENT SYSTEM

1. General:

All Automatic Controls works will be carried out by an NHS approved Specialist Controls Contractor, who must also comply with the following requirements.

The Building Management System (BMS) will be designed to control and monitor the complete HVAC Controls system.

The new controls will be fully BACnet compliant and truly fully open protocol. All new installed controls systems will be capable of sitting on and fully interfacing with the client's BOWS (BACnet Operator Works Station).

Each project must be incorporated into the current BMS system architecture within the hospital or NHS facility concerned. Due care and attention must be taken when connecting to the sitewide Ethernet network. The Specialist Controls Contractor must arrange meetings and otherwise properly liaise with the Works Contractor together with the appropriate local NHS IT Department to ascertain the relevant IP Addresses, etc.

The products being supplied as part of this contract must be approved through ASHRAE and BacNet Testing Laboratory (BTL) and this must be evidenced prior to the Controls Contract being awarded. The products being supplied must have the BTL trademark together with the relevant BacNet logo.

The nomenclature or naming convention to be used within the engineering strategy is to follow the IES naming strategy carried out previously on the QEUH Royal Hospital for Children Site. Full details are available by contacting IES direct.

Cognisance must be taken to ensure the following under listed tasks are carried out prior to, during, and after project completion:

2. Network Architecture Drawing:

NHS Energy Team (and on some sites the Hospital Estate Officers) are in possession of a Boardwide/Sitewide system architecture schematic drawing. This drawing MUST be updated with any new or modified projects immediately following completion of the project. Items to be detailed on this drawing are:

- Controls Contractor Name & Address
- Project Ref No.
- Project Description
- Project Location
- Controllers Utilised
- Spare Point Identification & Quantity
- Network IP Address

3. Conformity Document

Prior to the engineering of the project software, a Conformity Document will be produced/shared and tabled at a meeting with the relevant project/estate officer/energy manager. The purpose of this document is to maintain the agreed format of works/graphics/settings etc for each new project installed on the site.

On completion of the project, this document will be signed by the Controls Contractor, NHS Energy Manager and the Site NHS Estates Manager (on the assumption that all information is correct, and works have been carried out to an acceptable standard).

All nomenclature within the control strategies will be in the IES agreed format to allow for future monitoring of set points etc.

This document will confirm and highlight the following:

- Graphical Representations – Font colour, size, format etc
- Project Ref No, Description, IP Address, Location on Network, etc
- Time Schedules, Setpoints, Values, Limits, Alarm Levels etc
- All points utilised and associated units of measurement, etc.

4. Description of Operation Document (Des Ops)

A Des Ops is to be supplied, which will describe the operation of the plant/equipment under the control's strategy. This Des Ops will be agreed with the on-site Estates Operational team together with the relevant Energy Manager. It will be described in laymen's terms and have any associated drawings in place to support the Des Ops.

5. Operating & Maintenance Documentation

On completion of any project or modification, an Operating & Maintenance manual will be produced and issued to the relevant Estate Officer. This manual will consist of the following items/sub-sections:

- Complete set of Controls/Control Panel As-Fitted drawings;
- Full description of operations (as previously agreed with Estate Officers/Consultants);
- Full listing of data sheet documentation (associated with each item of equipment utilised on the project);
- Commissioning Report (detailing all setpoints, alarm levels, time schedules, etc)
- Full set of software drawings and back-up of same (memory stick to be handed over with Operating & Maintenance Manual);
- Conformity Document (as detailed previously);
- DesOps Document;
- Graphical print out of all associated graphical representations shown on the BMS Command Centre(s).

6. Naming Convention

The tenderer must provide consistency of approach through consistent nomenclature in their tender return. Please refer to naming convention below for guidance. NHS GG&C will work with the successful bidder to ensure that an agreed naming convention is used post-award.

The naming convention template is identified below:

BMS NAMING CONVENTION

Plant/Software Point	Datalog Name	IES TAGS
Temperature Sensor	DhwPheDuty1FlowTemp	#Temp #heatExchanger #flow
Enable	DhwPheEnable	#enable #domestic # enable
PHE Output	DhwPheSignal	#heatExchanger
Temperature Sensor	DhwPheDuty2FlowTemp	#run #domestic # heatExchanger
PHE Output	DhwPheSignal	#Temp #heatExchanger #flow
Enable	DhwPheEnable	#run #domestic #heatExchanger
Temperature Sensor	DhwPheStandbyFlowTemp	#enable #domestic #heatExchanger
Enable	DhwPheEnable	#Temp #heatExchanger #domestic
PHE Output	DhwPheSignal	#domestic #heatExchanger #enable
Temperature Sensor	DhwsCommonFlowTemp	#run #domestic #heatExchanger
Temperature Sensor	DhwsCommonReturnTemp	#Temp #domestic #flow
Temperature Sensor	ColdWaterSupplyTemp	#Temp #domestic #return
Enable	DhwsSecPumpEnable	#Temp #water
		#Temp #domestic #enable

Example or Spelling Errors	Common Name	IES TAGS
Boiler 01 Flow Setpoint	Boiler 01 Flow SP	#Boiler #Flow #SP #heat
Boiler 02 Flow stpt	Boiler 02 Flow SP	#Boiler #Flow #SP #heat
Boiler 03 Flow SP	Boiler 03 Flow SP	#Boiler #Flow #SP #heat
Boiler 04 Flow sp	Boiler 04 Flow SP	#Boiler #Flow #SP #heat

Notes:

1. Common Name does not need to use precisely the same text, however it still needs to allow for enough flexibility to differentiate between points on-site i.e. Boiler 01, 02, 03, 04
2. Common Name should contain enough key word text (without spelling errors) that allow the manual or automatic generation of #Tags.
3. Manual Tagging can be time consuming and is easy to miss all eventualities. So automated Tagging derived from Point Name is preferred option, but point name needs to be considered from outset.

7. Command Centre and Web Server

On completion of new (or modified) works, each Command Centre on the network (together with the associated Web Server) must be updated in line with the latest software. Due care and attention must be taken such as not to hinder the operation of ongoing projects when updating these PC's. Estate Officers must be notified of any updates taking place in order to make them aware of any access issues raised by End Users during this time.

8. Design Engineering

Prior to works commencing on the software design for each project, the Controls Contractor must liaise with either the Design Consultant or the relevant Energy Manager/Estates Officer (depending on the design responsibility). The Controls Contractor will obtain the relevant information from this meeting in order to commence with the software design for the project. This design will also form part of the Operating & Maintenance document and will also be incorporated within the Conformity Document.

9. Control Panel Types

Where new control panels serve power to motive equipment (such as pumps, fans etc), these panels will be of the Form 2 type (power/control sections). This will allow access to be gained to the control section of the control panel without the need for isolating the power distribution section. In the case where new BMS controllers are purely replacing existing controllers, then a single enclosure will be acceptable. Normally, the power supply serving this single enclosure will be installed by the Estates Department.

10. Graphics

All new graphical displays created for installation onto the Command Centres and Web Server will follow the standard of the current graphics already installed eg:

- Air Filter Displays: In all cases, Differential Pressure Sensors will be installed in lieu of Differential Pressure Switches; this will enable the graphical representation to show a 'traffic light' indication system. Whereby, Green will show a clean filter, Amber will show a filter nearing the change period & Red will show a filter dirty.
- Valve Actuators: In all cases, where the percentage open of a valve is displayed, it will take the form of a fill box (Blue for Chilled Water and Red for Hot Water).
- Pump Trip Conditions: These will be shown as a flashing Red trip indication when activated.

11. Demonstration/Training

Following completion of new/modified projects, the Controls Contractor will carry out a full demonstration of the new BMS equipment and plant interfaces to both the consultant and relevant Energy Manager/Estates Officer. Demonstrations of how to interact with the graphical displays via the Command Centres will also be reviewed as required.

12. Alarm Handling & Notification

Meetings are required to be arranged with the Design Consultant and/or the Energy Manager/Estates Officers in order to ascertain the alarm requirements for particular projects. Further to this meeting, the Controls Contractor will detail all relevant alarms on the Conformity Document, which will then be reviewed and signed off by the Site Estates Manager & the Energy Manager.

13. Data Logging & Archiving

Data logging will be set up to incorporate all software points for daily archiving, then prepared for exporting into Open Building Information Exchange (oBIX) files. Files will automatically be transmitted to the Client's central B-OWS and also to an outgoing Email account.

WARD 2A HOTCT AHU 1 SYSTEM

CONTROL PANEL

Supply and erect a wall mounting enclosure having split power and control sections sized overall approximately 1200mm high x 600mm wide x 260mm deep each section having dust tight lockable access doors and finished externally with structure powder paint light grey RAL7035.

POWER DISTRIBUTION

- 1 TP&N Main Isolator – Door Interlocking – 4 Pole
- 1 TP & N Mains Distribution Block

SUPPLY UNIT

1	TP MCB
1	Variable Speed Drive – Located adjacent to fan
6	Control Relays
1	Run Lights
1	Trip Lights
1	Duct Frost Trip Light
3	Filter Dirty Lights
1	Off/On/Auto Switch

EXTRACT FANS

1	TP MCB's
1	Variable Speed Drive – Located adjacent to fan
2	Control Relays
1	Run Lights
1	Fault Lights
1	Off/On/Auto Switch

CONTROLS

1	BMS Outstation – Refer to Points Schedule for Details
1	Network Controller
1	System Access & Display Panel
1	Socket Outlet – Service Engineers Equipment
1	230/24 Volt Transformer
3	Control Circuit MCB's
1	Building Fire Alarm Circuit Relay
1	Common Fault Light
1	Panel Live Light
1	Control Circuit Live Light

PANEL WIRING & LABELLING SPECIFICATION

All of the above to be prewired in colour coded LSF cables with all outgoing cables terminating at a Klippon terminal strip. Cable ends to be identified by 'Z' type cable markers and all equipment to be identified using ivory designation labels.

All lights and switches specified are to be virtual with the exception of common fault and panel live lights and are to be viewed and accessed via the System Access & Display Panel.

AUTOMATIC CONTROLS

Supply and erect the following automatic controls (pipeline mounted equipment to be handed to BS Contractor for fitting).

SUPPLY UNIT

1	Variable Speed Drive – Located adjacent to fan
1	Air Flow Proving Switch (DPS)
3	Filter Differential Pressure Sensors (including a HEPA unit)
4	Damper Actuators c/w Auxiliary Switches
1	Duct Frost Thermostat
4	Motorised Control Valves (40/40/50/65mm dia)
5	Duct Temperature Sensors
1	Duct Frost Stat
1	Immersion Police Temperature Sensor

1 Air Static Pressure Sensor

EXTRACT UNIT

1 Variable Speed Drive – Located adjacent to fans

1 Air Flow Proving Switch

1 Filter Differential Pressure Sensor

1 Duct Temperature Sensor

1 Duct Temperature/RH Sensor

1

Air Static Pressure Sensor

WARD 2A HOTCT AHU 1 BMS OUTSTATION POINTS SCHEDULE

Software programme the following inputs /outputs:

PLANT	DO	DI	AO	AI
SUPPLY UNIT				
Fan Motor – Enable/Status/Control	1	2	1	
Fresh Air Supply Pre Filter Differential Pressure Sensor – Status	1			1
Supply Air Secondary Filter Differential Pressure Sensor – Status	1			1
Supply Air HEPA Filter Differential Pressure Sensor – Status	1			1
Fresh Air & Supply Air Dampers – Enable/Status	4	4		
Duct Frost Thermostat – Status		1		
Pre-heater Battery Motorised Control Valve			1	
Cooling Battery Motorised Control Valve			1	
Re-heater Battery Motorised Control Valve			1	
Supply Duct Temperature Sensors (2 No Heating, 1 No Cooling & 1 No FA)				4
Immersion Return Temperature Sensor				1
Air Flow Proving Switch - Status (DPS)		1		
Supply Duct Static Pressure Sensor	1			1
HR (RAC) System Package	1	2	1	
Heat Recovery Duct Control Temperature Sensor				1
HR System Pressurisation Unit-Status		1		
EXTRACT UNIT				
Fan Motor – Enable/Status/Control	1	2	1	
Air Flow Proving Switch (DPS)		1		
Extract Duct Static Pressure Sensor	1			1
Filter Differential Pressure Sensor	1			1
Dampers – Enable/Status	3	3		
Extract Duct Temperature Sensor				1
Duct Temperature/RH Sensor				2
SAFETY				
Building Fire Alarm Circuit - Status		1		
TOTAL POINTS C/F	20	22	12	20

ELECTRICAL INSTALLATION

Carry out the electrical installation using LSF insulated cables, screened where necessary run within a galvanised trunking and conduit containment system. Cables would terminate at local isolators/junction boxes where required with final connections to equipment being made using flexible conduit c/w glands and earth wires.

PLANT WIRING

Wire from the panel to the following.

- | | |
|---|--|
| 1 | Supply Fan Motor – Via Variable Speed Drive |
| 1 | Extract Fan Motor – Via Variable Speed Drive |
| 2 | Air Flow Proving Switches (DPS) |
| 2 | Duct Static Pressure Sensors |

4	Filter Differential Pressure Sensors
7	Damper Actuators
4	Motorised Control Valves (for Heating, Cooling & Heat Recovery)
1	Nurse's Control Panel
1	Immersion Temperature Sensor
1	Duct Temperature/RH Sensor
1	Duct Frost Thermostat
5	Duct Temperature Sensors
1	Heat Recovery System
1	HR System Pressurisation Unit
1	AHU Lighting Circuit
1	Smoke Damper Panel Interface

WARD 2A HOTCT AHU 2 SYSTEM

CONTROL PANEL

Supply and erect a wall mounting enclosure having split power and control sections sized overall approximately 1200mm high x 600mm wide x 260mm deep each section having dust tight lockable access doors and finished externally with structure powder paint light grey RAL7035.

POWER DISTRIBUTION

1	TP&N Main Isolator – Door Interlocking (4 Pole)
1	TP & N Mains Distribution Block

SUPPLY UNIT

1	TP MCB
1	Variable Speed Drive – Located adjacent to fan
6	Control Relays
1	Run Lights
1	Trip Lights
1	Duct Frost Trip Light
3	Filter Dirty Lights
1	Off/On/Auto Switch

EXTRACT FANS

1	TP MCB's
1	Variable Speed Drive – Located adjacent to fan
2	Control Relays
1	Run Lights
1	Fault Lights
1	Off/On/Auto Switch

CONTROLS

1	BMS Outstation – Refer to Points Schedule for Details
1	Network Controller
1	System Access & Display Panel
1	Socket Outlet – Service Engineers Equipment
1	230/24 Volt Transformer
3	Control Circuit MCB's
1	Building Fire Alarm Circuit Relay
1	Common Fault Light
1	Panel Live Light
1	Control Circuit Live Light

PANEL WIRING & LABELLING SPECIFICATION

All of the above to be prewired in colour coded LSF cables with all outgoing cables terminating at a Klippon terminal strip. Cable ends to be identified by 'Z' type cable markers and all equipment to be identified using ivory designation labels.

All lights and switches specified are to be virtual with the exception of common fault and panel live lights and are to be viewed and accessed via the System Access & Display Panel.

AUTOMATIC CONTROLS

Supply and erect the following automatic controls (pipeline mounted equipment to be handed to BS Contractor for fitting).

SUPPLY UNIT

1	Variable Speed Drive – Located adjacent to fan
1	Air Flow Proving Switch (DPS)
3	Filter Differential Pressure Sensors (including a HEPA unit)
4	Damper Actuators c/w Auxiliary Switches
1	Duct Frost Thermostat
4	Motorised Control Valves (40/40/50/65mm dia)
5	Duct Temperature Sensors

1	Duct Frost Stat
1	Immersion Police Temperature Sensor
1	Air Static Pressure Sensor

EXTRACT UNIT

1	Variable Speed Drive – Located adjacent to fans
1	Air Flow Proving Switch
1	Filter Differential Pressure Sensor
1	Duct Temperature Sensor
1	Duct Temperature/RH Sensor
1	Air Static Pressure Sensor

WARD 2A HOTCT AHU 2 BMS OUTSTATION POINTS SCHEDULE

Software programme the following inputs /outputs:

PLANT	DO	DI	AO	AI
SUPPLY UNIT				
Fan Motor – Enable/Status/Control	1	2	1	
Fresh Air Supply Pre Filter Differential Pressure Sensor – Status	1			1
Supply Air Secondary Filter Differential Pressure Sensor – Status	1			1
Supply Air HEPA Filter Differential Pressure Sensor – Status	1			1
Fresh Air & Supply Air Dampers – Enable/Status	4	4		
Duct Frost Thermostat – Status		1		
Pre-heater Battery Motorised Control Valve			1	
Cooling Battery Motorised Control Valve			1	
Re-heater Battery Motorised Control Valve			1	
Supply Duct Temperature Sensors (2 No Heating, 1 No Cooling & 1 No FA)				4
Immersion Return Temperature Sensor				1
Air Flow Proving Switch - Status (DPS)		1		
Supply Duct Static Pressure Sensor	1			1
HR (RAC) System Package	1	2	1	
Heat Recovery Duct Control Temperature Sensor				1
HR System Pressurisation Unit-Status		1		
EXTRACT UNIT				
Fan Motor – Enable/Status/Control	1	2	1	
Air Flow Proving Switch (DPS)		1		
Extract Duct Static Pressure Sensor	1			1
Filter Differential Pressure Sensor	1			1
Dampers – Enable/Status	3	3		
Extract Duct Temperature Sensor				1
Duct Temperature/RH Sensor				2
SAFETY				
Building Fire Alarm Circuit - Status		1		
TOTAL POINTS C/F	20	22	12	20

ELECTRICAL INSTALLATION

Carry out the electrical installation using LSF insulated cables, screened where necessary run within a galvanised trunking and conduit containment system. Cables would terminate at local isolators/junction boxes where required with final connections to equipment being made using flexible conduit c/w glands and earth wires.

PLANT WIRING

Wire from the panel to the following.

1	Supply Fan Motor – Via Variable Speed Drive
1	Extract Fan Motor – Via Variable Speed Drive
2	Air Flow Proving Switches (DPS)
2	Duct Static Pressure Sensors
4	Filter Differential Pressure Sensors
7	Damper Actuators
4	Motorised Control Valves (for Heating, Cooling & Heat Recovery)
1	Nurse's Control Panel
1	Immersion Temperature Sensor
1	Duct Temperature/RH Sensor
1	Duct Frost Thermostat
5	Duct Temperature Sensors
1	Heat Recovery System
1	HR System Pressurisation Unit
1	AHU Lighting Circuit
1	Smoke Damper Panel Interface

WARD 2A HOTCT TEF 01 SYSTEM**CONTROL PANEL**

Supply and erect a wall mounting enclosure having split power and control sections sized overall approximately 600mm high x 400mm wide x 210mm deep each section having dust tight lockable access doors and finished externally with structure powder paint light grey RAL7035.

POWER DISTRIBUTION

1	SP&N Main Isolator – Door Interlocking (Double Pole)
1	SP & N Mains Distribution Block

EXTRACT FAN

1	SP MCB
1	Soft Start Unit – Located adjacent to fan
1	Control Relay
1	Run Light
1	Trip Light
1	On/Off/Auto Switch

CONTROLS

1	BMS Outstation – Refer to Points Schedule for Details
1	System Access & Display Panel
1	Socket Outlet – Service Engineers Equipment
1	230/24 Volt Transformer
3	Control Circuit MCB's
1	Building Fire Alarm Circuit Relay
1	Common Fault Light
1	Panel Live Light
1	Control Circuit Live Light

PANEL WIRING & LABELLING SPECIFICATION

All of the above to be prewired in colour coded LSF cables with all outgoing cables terminating at a Klippon terminal strip. Cable ends to be identified by 'Z' type cable markers and all equipment to be identified using ivory designation labels.

Note: All lights and switches specified are to be virtual with the exception of common fault and panel live lights and are to be viewed and accessed via the System Access & Display Panel.

AUTOMATIC CONTROLS

Supply and erect the following automatic controls (pipeline mounted equipment to be handed to BS Contractor for fitting).

EXTRACT FAN

1	Soft Start Controller – Located adjacent to fan
1	Air Flow Proving Switch
1	Air Static Pressure Sensor

WARD 2A HOTCT TEF 01 SYSTEM BMS OUTSTATION POINTS SCHEDULE

Software programme the following inputs /outputs

PLANT	DO	DI	AO	AI
EXTRACT FAN (TEF 01)				
Motor – Enable/Status/Control	1	2	1	
Air Flow Proving Switch – Status		1		
Duct Static Pressure Sensor	1			1
Dampers – Enable/Status	2	2		
SAFETY				
Building Fire Alarm Circuit – Status		1		
TOTAL POINTS ALLOCATED	4	6	1	1

ELECTRICAL INSTALLATION

Carry out the electrical installation using LSF insulated cables, screened where necessary run within a galvanised trunking and conduit containment system. Cables would terminate at local isolators/junction boxes where required with final connections to equipment being made using flexible conduit ^{c/w} glands and earth wires.

PLANT WIRING

Wire from the panel to the following.

- 1 Extract Fan – Via Soft Start Controller
- 1 Air Flow Proving Switch
- 1 Duct Static Pressure Sensor
- 2 Damper Actuators
- 1 Smoke Damper Panel Interface

WARD 2A HOTCT TEF 02 SYSTEM**CONTROL PANEL**

Supply and erect a wall mounting enclosure having split power and control sections sized overall approximately 600mm high x 400mm wide x 210mm deep each section having dust tight lockable access doors and finished externally with structure powder paint light grey RAL7035.

POWER DISTRIBUTION

- 1 SP&N Main Isolator – Door Interlocking (Double Pole)
- 1 SP & N Mains Distribution Block

EXTRACT FAN

- 1 SP MCB
- 1 Soft Start Unit – Located adjacent to fan
- 1 Control Relay
- 1 Run Light
- 1 Trip Light
- 1 On/Off/Auto Switch

CONTROLS

- 1 BMS Outstation – Refer to Points Schedule for Details
- 1 System Access & Display Panel
- 1 Socket Outlet – Service Engineers Equipment
- 1 230/24 Volt Transformer
- 3 Control Circuit MCB's
- 1 Building Fire Alarm Circuit Relay
- 1 Common Fault Light
- 1 Panel Live Light
- 1 Control Circuit Live Light

PANEL WIRING & LABELLING SPECIFICATION

All of the above to be prewired in colour coded LSF cables with all outgoing cables terminating at a Klippon terminal strip. Cable ends to be identified by 'Z'

type cable markers and all equipment to be identified using ivoryine designation labels.

Note: All lights and switches specified are to be virtual with the exception of common fault and panel live lights and are to be viewed and accessed via the System Access & Display Panel.

AUTOMATIC CONTROLS

Supply and erect the following automatic controls (pipeline mounted equipment to be handed to BS Contractor for fitting).

EXTRACT FAN

- 1 Soft Start Controller – Located adjacent to fan
- 1 Air Flow Proving Switch
- 1 Air Static Pressure Sensor

WARD 2A HOTCT TEF 02 SYSTEM BMS OUTSTATION POINTS SCHEDULE

Software programme the following inputs /outputs

PLANT	DO	DI	AO	AI
EXTRACT FAN (TEF 01)				
Motor – Enable/Status/Control	1	2	1	
Air Flow Proving Switch – Status		1		
Duct Static Pressure Sensor	1			1
Dampers – Enable/Status	2	2		
SAFETY				
Building Fire Alarm Circuit – Status		1		
TOTAL POINTS ALLOCATED	4	6	1	1

ELECTRICAL INSTALLATION

Carry out the electrical installation using LSF insulated cables, screened where necessary run within a galvanised trunking and conduit containment system. Cables would terminate at local isolators/junction boxes where required with final connections to equipment being made using flexible conduit %w glands and earth wires.

PLANT WIRING

Wire from the panel to the following.

- 1 Extract Fan – Via Soft Start Controller
- 1 Air Flow Proving Switch
- 1 Duct Static Pressure Sensor
- 2 Damper Actuators
- 1 Smoke Damper Panel Interface

PRESSURE MONITORING SYSTEM

The new Pressure Monitoring System will be designed to measure air pressures within the various rooms covered together with pressure differentials across the various Bedroom-Ward Corridor, Bedroom-TCT Corridor, Play/Dining Room-Ward Corridor and Contingency Room-Ward Corridor compartments. Room Air Pressure Sensors/probes with Stainless steel mounting plates will be located on the ceilings of the various rooms served. These will connect to an Air Pressure monitoring device provided for each

pressure controlled Bedroom, Play/Dining Room and Contingency Room by means of appropriate PVC Tubing. Each of these Air Pressure Monitoring devices will be interfaced with individual LCD Pressure Display Units (with stainless steel face plates) which will be recessed locally into the walls of the adjacent Corridors. All Air Pressure Monitoring Devices will be located in the an easily accessible part of the adjacent Corridor ceiling void. All Air pressure Monitoring Devices will be interfaced with a new Stainless Steel Nurse's Station Control Panel via appropriate Modbus Tap units. The new Nurse's Station Control Panel will be provided with a facia mounted Colour HMI Display screen, with a minimum size of 175mm. A new Data Logger Unit will be provided as part of this Contract designed to accurately monitor all Pressure Differentials, Room Pressures, etc at set time intervals which must meet the specific operating parameters set by the client, which will generally be in line with the present provision for the Ward 2A BMT, however proportionally uprated to cater for the increased number of rooms served within the new upgraded Ward 2A HOTCT area, in terms of the ability and capacity to record a set amount of Historical Data by the Logger Unit installed within the new Nurse's Control Panel located at the Ward 2A Nurse's station. The new Data Logger will be capable of downloading the historical data in a form that can be readily printed out on standard A4 sheets in an easy to read format for review by Validation and other technical personnel.

The specialist Controls Contractor will be responsible for the final Testing and Commissioning of all Pressure Monitoring Systems, together with the setting to work of the complete new Pressure Monitoring System prior to the client Validation Process.

NURSE'S STATION CONTROL PANEL

- 1 Stainless Steel Surface Mounted Control Panel incorporating LCD display Unit on Facia plate. Similar to Existing Unit presently located at the Ward 2A Nurse's Station c/w with the following:-
- 1 Data Logger Unit for Room Pressures and to provide visual and audible indication of alarm conditions, with mute facility.

1	Main Ventilation Plant On Light
1	Main Ventilation Plant Off Light
1	Common Fault Light
19	Room Air Pressure Monitoring Devices and 6mm O.D Colour Tubing)
38	Ceiling mounted Air Sensors/Probes (connected to above Tubing)

NURSE'S STATION CONTROL PANEL HMI INTERFACE

19	Room Air Pressure Monitoring Devices
19	Room Alarm
2	Ventilation Plant Status

LOCAL ROOM AIR PRESSURE DISPLAY UNITS

19	Wall Mounted Pressure Digital Display Units
19	Pressure Sensor (for differential Pressure)
17	Bedrooms
1	Play/Dining Area
1	Contingency Area

BEDROOM, ETC ROOM RE-HEATERS (LTHW)

20	Heating Control Valves (15mm dia)
20	Room Temperature Sensors
20	Temperature Set Point Adjusters
20	Duct Low Limit

MISCELLANEOUS

19	Gas Tight Room Motorised Isolation Dampers
19	Local manual Open/Closed switch for above Isolation Damper (this Damper will also be capable of being operated from the BMS)

GENERAL SMALL POWER WIRING

The specialist Controls Contractor will allow for providing all necessary Small Power wiring installations required to operate or otherwise serve field mounted equipment such as Outstation Units, Pressure Monitoring Devices, Control Valves, Dampers, Actuators, Remote Display Units, Nurses Control Panel (to also have 48 hour battery back-up provision), etc. It is envisaged that these supplies will be connected to the local KNX infrastructure services as required.

EQUIPOTENTIAL BONDING

Carry out all necessary equipotential bonding to current IET regulations, including all equipotential bonding of metal works and containment systems to AHU, ductwork etc.

COMMUNICATIONS NETWORK

CONTROL PANEL

Supply and erect a wall mounting enclosure suitably sized to accommodate the following:-

- 1 Communications Network Controller
- 1 230/34 Volt Transformer
- 1 Socket Outlet – Service Engineer Equipment
- 3 SP MCB's

All the above to be prewired and labelled as per AHU control panel specification.

ELECTRICAL INSTALLATION

Carry out the installation of the BACnet communications network using an LSF insulated multi-core screened cable interconnecting each of the proposed AHU and ancillary Control Panels housing the BMS controllers to the network controller. The cables to be run on a suitable containment system. An IT data point adjacent to the communications network control panel is to be provided by others.

GRAPHICS

Create and install onto the client's existing BACnet Operators Workstation (B-OWS) colour graphics and user pages giving dynamic information and status of the proposed plant and equipment. Alarms and calendars to be set up in conjunction with client's representatives. All graphics, calendars and alarms are to be created to match those that currently exist for similar plant. The client has a confirmatory document which must be adhered to when graphics are to be installed.

SERVICES

Provide the following services.

- **ENGINEERING**
Provide all working and As Fitted Drawings including Operating & Maintenance Documentation.
- **COMMISSIONING**
Upon completion of the control installation and associated electrical works, carry out a full commissioning of the system.
- **DEMONSTRATION**
Upon completion of the commissioning, carry out a full demonstration of the plant to the client's personnel.

STRIP OUT WORKS**WIRING & CONTAINMENT SYSTEMS**

Identify, make safe then strip out all Power and Controls wiring and associated containment systems (where they do not support other services) and other existing redundant equipment which is effectively being replaced by the new Power and Controls Systems as part of these works. Any controls equipment being made redundant that is connected to the existing BMS/Controls system should be removed from the central supervisory terminal graphics in such a way as to prevent spurious alarms. Upon completion of the stripping out of all necessary cables, containment systems, controls equipment, control panels, switchgear, etc., the Contractor will arrange for all materials to be removed from site and disposed of in a responsible manner.

395.000 THERMAL INSULATION**395.010 GENERAL**

Thermal insulation will be applied to the following:

1. All new Fresh Air/Supply Air ventilation ductwork from external louvres up to the new Ward 2A HOTCT Supply AHUs and thereafter from the Supply AHUs to the various end points of the Supply Ventilation ductwork systems, as generally indicated on the Tender Drawings. All Exhaust/Extract Air from the Ward 2A HOTCT Extract AHUs to the various end points of the Extract Ventilation ductwork systems and from the Extract AHUs to the Penthouse Exhaust Terminal as generally indicated on the Tender Drawings. All thermal insulation on the Supply and Extract Ventilation Ductwork systems will be vapour sealed, insulation systems will all have protective aluminium clad over the vapour seal, within Plantroom areas.
2. All new Domestic Water Services pipework, line fittings, etc, that are located within ceiling/floor/wall voids and other areas covered by SHTM 04-01. All thermal insulation on Domestic Mains Water Services and Domestic Cold Water Services pipework will be vapour sealed. Thermal Insulation will be provided with protective aluminium cladding, over the vapour seal, where this is provided.
3. All new LTHW Heating Services pipework, line fittings, etc. will be fully insulated, with Velcro jackets over valves.
4. All new Chilled Water Services pipework, line fittings, etc. All thermal insulation on Chilled Water pipework will be vapour sealed. Velcro jackets will be fitted over valves. Insulation will all have protective aluminium cladding over the vapour seal.
5. Insulation covering ventilation ductwork, domestic water services heating and chilled water pipework will have a suitable low conductivity value, to ensure that there are no problematic issues accommodating it within the space available.

Thermal insulation on pipework and ductwork within Plantroom areas will be covered with aluminium sheet, in accordance with the specification.

All other thermal insulation will be covered with aluminium foil covering in accordance with the specification.

1.1.1 Project Schedule of Insulating Materials and Finishes

<u>Code</u>	<u>Insulating Materials</u>
1.	Calcium Silicate sections or slabs.
2.	Glass mineral wool pipe sections in 1.2m length with self- seal overlap and factory applied aluminium foil jacket.
3.	Glass mineral wool rigid slabs with factory applied aluminium foil facing or flexible mattress with factory applied aluminium.
4.	Phenolic Foam pipe sections with factory applied aluminium foil jacket.
5.	Phenolic Foam laminate with factory applied aluminium foil facing.

<u>Code</u>	<u>Insulating Materials</u>
A	Factory applied reinforced aluminium foil.
B	Hammerclad Aluminium Cladding.
C	Isogenapak PVC cladding. Isogenpac (Internal use only)
D	Ventureclad External jacketing system.
E	Fibaroll FRP external cladding system

Selection of Insulation & Facings (x denotes suitable alternatives).

All mineral wool and Phenolic foam products to be supplied with factory applied aluminium foil facings.

Services (includes associated fittings, equipment, tanks, vessels etc.)	Location	Insulating Material					Final Covering				
		1) Calcium Silicate	2) Glass Mineral Wool section	3) Glass Mineral Wool Slab or Duct Wrap or Crimp Wrap	4) Phenolic Sections	5) Phenolic	A)Aluminium Foil (Factory applied)	B) Aluminium sheet	C) Isogenopac	D) Ventureclad	E) Fibaroll
		1	2	3	4	5	A	B	C	D	E
Steam Condensate	Plant Rooms	x	x	x				x			

	Occupied	x	x	x				x	x	x	
	Hidden	x	x	x			x				
	External	x	x	x			x	x		x	x
MTHW (Below 100°C) LTHW DHW	Plant Rooms	x	x	x	x	x		x	x		
	Occupied	x	x	x	x	x		x	x	x	
	Hidden	x	x	x	x	x	x				
	External	x	x	x	x	x	x	x		x	x
Chilled and Cold Water Services	Plant Rooms		x		x	x	x	x			
	Occupied		x		x	x	x	x	x	x	
	Hidden		x		x	x	x		x		
	External				x	x		x		x	x
Chilled air conditioning Supply and	Plant Rooms		x	x	x	x	x	x			
	Occupied		x	x	x	x	x	x	x	x	
	Hidden		x	x	x	x	x		x		
Plenum Ducts (rectangular, oval and circular ducting)	External		x	x	x	x		x		x	x
Warm air conditioning and return and plenum ducts (rectangular, oval and circular ducting)	Plant Rooms		x	x	x	x	x	x			
	Occupied		x	x	x	x	x	x	x	x	
	Hidden		x	x	x	x	x		x		
	External			x	x	x		x		x	x
Flue Gas Ducting	Plant Rooms	x	x	x				x			
	Occupied	x	x	x				x			
	Hidden	x	x	x				x			
	External	x	x	x				x		x	x

Preferences to be indicated (x) by specifier for particular projects

1.1.2 Insulation Thickness Tables

In accordance with BS 5422 : 2001

Thickness shown in the tables are based on manufacturer's typical declared thermal conductivity values at the appropriate mean temperature of insulation as follows:-

Insulating material	Mean temperature of insulation (°C)				
	0	+10	+50	+75	+100
	Thermal conductivity (W/.K)				
Phenolic foam (PF)	0.021	0.021	0.023	0.025	*
Glass mineral wool (WM)	0.032	0.032	0.037	0.040	0.044
Nitrile rubber (NR)	0.035	0.037	0.040	0.043	*
Calcium silicate (CS)	*	*	0.050	0.053	0.055

* Not recommended for use at these mean temperatures where.

Mean temperature of insulation = Hot face temperature + Cold face temperature

1.1.2.1 Table 1

Thickness of insulation for chilled and cold water supplies to prevent condensation on a low emissivity outer finish (e.g. Bright Class O Foil) in an ambient still air temperature of 25°C and relative humidity of 80%. (BS 5422: 2001 – Table 8).

		Temperature of Water (°C)					
Steel pipe size (mm)		+10		+5		0	
		Thickness of insulation (mm)					
NB	OD	Pheno lic	Miner al	Pheno lic	Miner al	Pheno lic	Miner al
15	21	15	20	15	25	20	30
20	27	15	25	15	30	20	40
25	34	15	25	20	30	25	40
32	42	15	25	20	30	25	50
40	48	15	30	20	30	25	50
50	60	15	30	20	40	25	50
65	76	20	30	25	40	30	50
80	89	20	30	25	40	30	50
100	114	20	30	25	40	30	50
150	168	20	40	30	50	35	60
200	219	20	40	30	50	40	60
250	273	25	40	30	50	40	65
300	324	25	40	35	60	40	65
Vessels & flat surfaces		30	50	40	65	50	80

1.1.2.2 Table 2

Environmental thickness of insulation for non-domestic heating installations to control heat loss. (BS 5422:2001 – Table 11)

	Hot face temperature of installation (°C)
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		+75		+100		+150	
		Thickness of insulation (mm)					
NB	OD	Phenol ic	Miner al	Phenol ic	Miner al	Pheno lic	Miner al
15	21	15	30	15	40	50	80
20	27	15	40	20	40	60	80
25	34	20	40	20	40	60	100
32	42	20	40	20	50	65	100
40	48	20	40	25	50	65	100
50	60	20	40	25	50	65	100
65	76	25	40	25	50	75	100
80	89	25	50	30	60	75	100
100	114	25	50	30	60	75	105
150	168	25	50	35	60	75	105
200	219	30	50	35	60	80	110
250	273	30	50	35	60	80	110
300	324	30	50	35	60	80	110
Vessels & flat surfaces		30	50	40	65	90	115

1.1.2.3 Table 3

Environmental thickness of insulation for non-domestic hot water services.

(BS 5422:2001 – Table 12)

Steel pipe size (mm)		Water temperature of 60°C	
		Thickness of insulation (mm)	
NB	OD	Phenolic Foam	Mineral Wool
15	21	15	25
20	27	15	30
25	34	20	30
32	42	20	30
40	48	20	35
50	60	20	35

65	76	25	35
80	89	25	40
100	114	25	40
150	168	30	50
200	219	30	50
250	273	30	50
300	324	30	50
Vessels & flat surfaces		35	50

Environmental thickness of insulation for domestic central heating installations (+75°C) and hot water supply systems (60°C) to control heat loss in potentially unheated indoor areas with ambient air temperature of – 1°C.

(Reference BS 5422:2001 – Table 13)

Outside diameter of Copper pipe (mm)	Water Temperature of 60°C/75°C	
	Thickness of insulation (mm)	
	Phenolic Foam	Mineral Wool
10	15	25
12	15	25
15	15	30
22	20	40
28	20	40
35	25	40
42	25	40
54	25	50
Cylinders	35	50

1.1.2.4 Table 5

Environmental thickness of insulation for ductwork carrying warm air. (Reference BS 5422:2001 – Table 10a)

Temperature difference between air inside ductwork and ambient air (°C)		
10	25	50
Environmental thickness of Insulation (mm)		

Phenolic Foam	Mineral Wool	Phenolic Foam	Mineral Wool	Phenolic Foam	Mineral Wool
20	40	25	50	35	65

1.1.2.5 Table 6

Thickness of insulation for condensation control on ductwork carrying chilled air in ambient conditions 25°C, 80% RH.

(Reference BS 5422:2001 – Table 10 – low emissivity finish 0.05)

Minimum air temperature inside the ductwork (°C)							
15		10		5		0	
Thickness of insulation (m)							
Phenol ic	Miner al	Phenol ic	Miner al	Phenol ic	Miner al	Phenol ic	Miner al
20	30	25	50	40	75	50	100

1.1.2.6 Table 7

Minimum thickness of insulation required to give protection against freezing under specified commercial and institutional conditions.

(Reference BS 5422:2001 – Table 15)

Initial water temperature		+2°C		+2°C	
Minimum ambient temperature		-6°C (Indoor unheated areas)		-10°C (Outdoor)	
Evaluation period		12h		12h	
Permitted ice formation		50%		50%	
Pipe size (mm)		Thickness of insulation (mm)			
O.Dia	Bore	Phenolic Foam	Mineral Wool	Phenolic Foam	Mineral Wool
Copper Pipes					
15,0	13,6	23 (25)	78 (80)	68 (70)	413 (420)
22,0	20,2	10 (15)	23 (25)	21 (25)	58 (60)

28,0	26,2	7 (15)	13 (20)	13 (15)	28 (30)
35,0	32,6	5 (15)	10 (20)	9 (15)	18 (20)
42,0	39,6	4 (15)	7 (20)	7 (15)	13 (20)
54,0	51,6	3 (15)	5 (20)	5 (15)	9 (20)
76,1	73,1	2 (15)	4 (20)	4 (15)	6 (20)
108,0	105,0	2 (15)	3 (20)	3 (15)	4 (20)
Steel Pipes					
21,3	16,0	18 (20)	48 (50)	44 (45)	173 (175)
26,9	21,6	10 (15)	21 (25)	20 (20)	52 (60)
33,7	27,2	7 (15)	14 (20)	13 (15)	29 (30)
42,4	35,9	5 (15)	9 (20)	9 (15)	17 (20)
48,3	41,8	4 (15)	7 (20)	7 (15)	13 (20)
60,3	53,0	3 (15)	6 (20)	5 (15)	10 (20)
76,1	68,8	3 (15)	4 (20)	4 (15)	7 (20)
88,9	80,8	2 (15)	4 (20)	3 (15)	6 (20)

Note:

Thicknesses given are minimum calculated specifically against the criteria noted in the table. Adopting these thicknesses may not satisfy other design requirements. Thicknesses shown in brackets are nearest standard thicknesses normally available from manufacturers.

Some of the insulation thicknesses calculated are too large to be applied in practice but are included to highlight the difficulty in protecting small diameter pipes against freezing under extreme conditions. In these cases, to provide the appropriate level of frost protection to certain sizes of pipes, it may be necessary to provide additional heat to the system, for example by controlled periodic circulation of the water or by heat tracing.

Thickness calculations ignore the specific heat capacity and surface resistance of the insulation in order to allow for a common situation where the temperature of the insulation is lower than the initial temperature of the water.

Assumed densities and specific heat capacities of water and pipe materials are:-

Water: 1000 kg/m³ and 4200 J/kg.K

Steel: 7840 kg/m³ and 455 J/kg.K

Copper: 8900 kg/m³ and 390 J/kg.K

1.1.3 Specialist Insulation Contractor

Include for all thermal insulation to be carried out by a Specialist Thermal Insulation Contractor.

396.000 SUPPORTS FOR PLANT, EQUIPMENT, ETC.

396.010 GENERAL

The Mechanical Services Contractor will allow for providing all necessary Secondary Support Steelwork necessary for supporting the Supply and Extract Air Handling Units, Extract Fans Sound Attenuators, Ventilation Ductwork, Heating Services/Chilled Water Services/Domestic Water Services/Soil & Rainwater Drainage/Sprinkler/Medical Gas/Pneumatic Tube System pipework, Containment, Controls Equipment, Control Panels, etc.

Where necessary these supports will be structurally checked by the Client's Structural Engineer on behalf of the client, for stability and general soundness.

The Mechanical Services Contractor will be responsible for providing all appropriate technical details of the plant and equipment concerned to properly assist the Structural Engineer and allow them to make a proper value judgement on the likely acceptability or otherwise of the Mechanical Services Contractor's proposals. The Mechanical Services Contractor will thereafter take full cognisance of the Structural Engineers comments and amend the proposals accordingly, where required/advised.

397.000 O&M RECORD INFORMATION, CLIENT TRAINING DEMONSTRATIONS

Following completion and prior to handover the Sub-Contractor shall demonstrate to the user or his appointed representative, the satisfactory operation of all plant, equipment and controls associated with this project.

The demonstration shall be thorough and shall include demonstration by specialist manufacturers where necessary and the automatic controls specialist. Following satisfactory demonstration of the systems, they shall be handed over to the Employer for Client acceptance.

The Sub-Contractor shall on Practical Completion of the works, provide 2 sets of binder style paper Record Drawings and Operating and Maintenance Instructions for all systems and components provided within the Electrical Services Contract Work with 1 No. copy of the Operating and Maintenance Manuals shall be on CD/DVD in an electronic format (PDF) within each binder style paper manual. Manuals shall be in the format as detailed within an in accordance with BSRIA BG01/07

Record Drawings

Record drawings of the contract works generally shall be provided at a scale to match the design drawings except for the site services layouts which may be produced at a scale no smaller than the tender drawings and plant rooms which must be produced at a scale of 1:50.

During the course of the contract the Sub-Contractor shall keep on site a set of the contract drawings which shall be updated between the contract drawings and the actual installation.

The Record Drawings shall show the complete installation including, the sizes and runs of all conduit and containment, and the precise location of all services which may be buried in the structure or laid solid in the ground.

The position and depth of all underground services shall be clearly indicated. Services buried with a thermal or other protective envelope shall be clearly described.

Operating and Maintenance Instructions

Operating and Maintenance Instructions for the Electrical, Mechanical and Plumbing Contract Works shall comprise full details of all installations and equipment provided by the Sub-Contractor.

The detailed requirements of the Operating and Maintenance Instructions are as described generally below:-

General Technical Description:

This section shall contain, for each service, information on where incoming services enter buildings, details and locations of main plant and equipment etc., an outline of the type of system employed, its component parts, the system controls and the principles of operation.

Operating Instructions:

This section shall contain for each service the item of equipment, details of start up procedures, shut down procedure, isolation procedures, procedures to be followed on fault indication and emergency shut down and/or isolation procedures.

Inspection and Maintenance Instructions

This section shall contain, in outline only, the maintenance requirement for all maintainable items of plant and equipment.

Emergency Procedures:

Instructions shall be included for action required for such circumstances as:-

Fire

General failure of the electrical system

Recommended action on plant/equipment malfunction

Information shall also be included on call out procedures, first aid and electrocution.

Manufacturer's Literature:-

This section shall contain all manufacturers' literature, including Operating and Maintenance information, together with an index of contents listing the equipment item and manufacturer's name, address and telephone number.

Recommended Spares:

This section shall contain, for each equipment item, a list of manufacturer's recommended spares including appropriate reference numbers.

Record Drawings:-

This section shall contain a complete index of Record Drawings as provided indicating the Drawing No., area of the Building and Title.

Commissioning Record Sheets:

This section shall contain copies of all commissioning record sheets with an appropriate index.

Test Certificate and Insurance Inspection Sheets:

This section shall contain copies of all test certificates and insurance inspection sheets together with an appropriate index.

A draft copy of the Operating and Maintenance Instructions shall be submitted to the Employer for approval and, following receipt of such approval, three sets of Operating and Maintenance Instructions, in substantial hard backed binders, shall be provided.

R - DISPOSAL SYSTEMS

R10 RAINWATER PIPEWORK SYSTEMS

PART 1 SYSTEM OBJECTIVES

100.010 PERFORMANCE OBJECTIVES:

- Alterations to existing systems to suit new installations as required and detailed on the (52) Series Drawings

100.011 PERFORMANCE OBJECTIVES:

- The purpose of this specification is that the rainwater pipework / gutter systems and equipment provided in compliance with it, will deliver the whole hospital engineering design philosophies and be compliant with all Department of Health (NHS Estates) documentation including, but not limited to HTM's and HBN's pertinent to the nature of the project.

100.020 DESIGN PARAMETERS:

- Relevant parts of BS EN 12056
- BS 8490 for siphonic roof drainage systems.
- Current Building Regulations Technical Guidance Documents and requirements of the Local Authority

PART 2 SELECTION SCHEDULES FOR REFERENCE SPECIFICATIONS

210.000 PIPELINES AND PIPEWORK

210.010 GENERAL:

- Comply with work section general clauses below
- Fire stopping
 - All components forming the seal system, to be from the same manufacturer
 - Comply with BS 9999, relevant approved technical guidance to Building Regulations and BESA Technical Bulletin TB/032
 - Provide proprietary penetration seal system. All products used, to have third party product certification by a scheme accredited by UKAS.
 - Type
 - Stone mineral wool, soft seal type lamella strip with a proprietary flexible coating, used in conjunction with acoustic intumescent sealant and/or high expansion intumescent sealant to suit the application. For use in all applications including where movement of services needs to be accommodated. Tested and assessed to BS EN 1366-3 and BS EN 1366-4 and classified to BS EN 13501-2.
 - Stone mineral wool ablative coated batt seal with a proprietary flexible coating, used in conjunction with acoustic intumescent sealant and/or high expansion intumescent sealant to suit the application. Tested and assessed to BS EN 1366-3.
 - Services expansion and contraction details
 - All services passing through apertures in masonry walls/concrete floors or drywall partitions/systems.
 - Fire resistance
 - 2 hrs.
- Only use UKAS accredited, third party installer certified specialist contractors. The specialists should

be ASFP members and their certification must cover the passive fire protection element they are installing.

- Install all fire stopping systems in accordance with the manufacturer's written instructions and the test / assessment / certification evidence provided by the installer / manufacturer of the penetration seal.
- Support centres for services passing through penetration seals serving fire barriers to be the same as those covered by the test / assessment / certification evidence provided by the installer / manufacturer of the penetration seal.
- Install and inspect fire stopping systems in accordance with Building Regulations Approved Document B, ASFP Code of Practice TGD 17 and the general best practice guidance given in the ASFP On-site guide to installing fire-stopping.

210.040 CAST/DUCTILE IRON PIPES AND FITTINGS:

- Manufacturer To Match Existing - Ensign etc.
- Fluid conveyed Rain Water
- Cast iron/ductile iron pipes and fittings to BS 416-1
 - Spigot and socket - reference Y10.2350A
- Cast iron/ductile iron pipes to BS 437
 - For flexible joints - reference Y10.2370A
- Cast iron/ductile iron fittings to BS 437
 - For flexible joints - reference Y10.2380A
- Cast iron pipes and fittings to BS EN 877
 - Red epoxy finish - reference Y10.2390A
 - Grey epoxy finish - reference Y10.2390B
- Ductile iron pipes to BS EN 545
 - Flanged joints - reference Y10.2410A
 - Spigot and socket joints - reference Y10.2410B
- Ductile iron pipes for water applications to BS ISO 2531
 - Flanged joints - reference Y10.2425A
 - Spigot and socket joints - reference Y10.2425B
- Preinsulated ductile iron pipes, fittings, accessories and joints to BS ISO 9349
 - Application
 - Waste water / drainage
 - Location
 - Above ground
 - Joints
 - Flanged
 - Spigot and socket
 - Flexible joints for water applications to BS ISO 2531
 - Flexible joints for sewerage applications to ISO 7186
- Jointing materials
 - Flanges to BS EN 1092-2.
 - Flanges BS EN 1092-2 PN
 - Cast iron flanges - reference Y10.3010C
 - Flange jointing rings
 - For cast iron - reference Y10.3020C
 - Use push-fit joints for cast iron pipe.
 - Couplings for cast iron pipes to BS EN 877
 - Stainless steel - reference Y10.3105A
 - Red ductile iron - reference Y10.3105B
 - Grey ductile iron - reference Y10.3105C
 - Black ductile iron - reference Y10.3105D
 - Spigot/socket caulked joints

- Reference Y10.3110A
- Use push-in self anchor joints for ductile iron pipes.
- Flexible couplings, sleeve type
 - For ductile iron pipework to BS EN 545, BS EN 598, BS EN 969 - reference Y10.3170A
- Flexible flange adapters, sleeve type
 - For ductile iron pipework to BS EN 545, BS EN 598, BS EN 969 - reference Y10.3180A
- Internal polyurethane lining
 - Provide internal polyurethane linings for ductile iron pipework in accordance with BS EN 15655.

210.050 PLASTICS PIPES AND FITTINGS:

- Fluid conveyed Rain Water
- Plastics piping systems for water supply
 - Reference Y10.2455A - pipes to
 - BS EN ISO 1452-1
 - BS EN ISO 1452-2
 - BS EN ISO 1452-5
 - Reference Y10.2475A - fittings to
 - BS EN ISO 1452-1
 - BS EN ISO 1452-3
- BS EN ISO 1452-5
- Plastic piping systems, buried and above ground for water and other fluids (not potable water)
 - Pipes, fittings and joints to BS EN 15014 - reference Y10.2442
- PVC-U fittings to BS 4514
- Reference Y10.2490A
 - PP Pipes to BS EN 1451-1 and BS EN 15012 - reference Y10.2545A
 - Fittings to BS EN 1451-1 and BS EN 15012 - reference Y10.2555A
 - Solid wall PVC-U pipes to BS EN 1329-1 and BS 4514 - reference Y10.2580A
 - Structured-wall PVC-U pipes to BS EN 1453-1 - reference Y10.2580F
 - ABS pipes to BS EN 1455-1 - reference Y10.2580B
 - PE pipes to BS EN 1519-1 - reference Y10.2580C
 - SAN + PVC pipes to BS EN 1565-1 - reference Y10.2580D
 - PVC-C pipes to BS EN 1566-1 - reference Y10.2580E
 - GRP systems based on unsaturated polyester (UP) resin to BS ISO 10467 or BS EN 14364
 - PVC-U fittings to BS EN 1329-1 and BS 4514 - reference Y10.2585A
 - ABS fittings to BS EN 1455-1 - reference Y10.2585B
 - PE fittings to BS EN 1519-1 - reference Y10.2585C
 - SAN + PVC fittings to BS EN 1565-1 - reference Y10.2585D
 - PVC-C fittings to BS EN 1566-1 - reference Y10.2585E
 - Structured wall PVC-U pipes to BS EN 1453 - reference Y10.2495A
- Plastic rainwater piping systems comprising pipes, fittings and brackets for above ground external use to BS EN 12200-1
 - Pipe material
 - Solid wall PVC-U.
 - Pipe type / details
 - Circular

210.070 PIPEWORK ACCESSORIES:

- Wall, floor and ceiling masking plates
 - Chromium plated - reference Y10.3190A.
 - Plastic - reference Y10.3190B
- Pipe rings and clips

- Pipework support - reference Y10.4210

210.080 GENERAL WORKMANSHIP:

- Appearance - reference Y10.4010
- Spacing - reference Y10.4020
- Gradients - reference Y10.4030
- Air venting requirements
 - Air bottles - reference Y10.4040A
 - Automatic air vents - reference Y10.4040B
- Drain requirements - reference Y10.4050
- Expansion and contraction - reference Y10.4060
- Pipe fittings
 - Bends/swept tees - reference Y10.4070A
 - Elbows/square tees - reference Y10.4070B
- Pipes through walls and floors - reference Y10.4110
- Protect pipework penetrating fire separating elements in accordance with, Building Regulations, BS 9999 and BESA Technical Bulletin TB/032.
- Pipe sleeves
 - Reference Y10.4120A
 - Insulation carried through - reference Y10.4120B
- Pipe through fire barriers - reference Y10.4125
 - Type
 - Proprietary sleeves
 - Ablative coated batt type
 - Fire resistance
 - 2 hours
 - hrs
- Connect to equipment.
- Use distribution headers.
- Temporary plugs, caps and flanges
 - Reference Y10.4150A.
- Flanged joints general - reference Y10.4160
- Dissimilar metals - reference Y10.4170
- Pipe rings and clips - reference Y10.4180
 - Anchors - reference Y10.4190
- Pipe supports - reference Y10.4205
 - Comply with the manufacturers' installation recommendations for the following proprietary pipe systems:
- Support spacing
 - Tables for steel, copper, iron, PVC and ABS pipes - reference Y10.4220
 - For the following proprietary pipe systems comply with the manufacturers' installation recommendations:
 - Plastic pipe systems.
- Maintenance and renewal - reference Y10.4240
- Non-ferrous components - thoroughly clean and degrease.
- Pipe collars (closers) for plastic pipes where they pass through fire resistant walls and floors.
 - Type
 - Stainless steel collar with fixing brackets with intumescent liner.
 - Pre-assembled wrap for casing within concrete floor or masonry wall.
 - Fire resistance
 - 2 hrs
 - Installation to be in accordance with the manufacturer's instructions and grouted/sealed using the

manufacturer's proprietary compound/sealant.

- Standards
 - Test to BS EN 1366-3 and BS EN 1363-1.
- Test to BS 476-20.

210.110 WORKMANSHIP, CAST/DUCTILE IRON:

- Flanged joints - reference Y10.7010
- Caulked joints - reference Y10.7020
- Flexible joints - reference Y10.7030

210.120 WORKMANSHIP, PLASTIC PIPES:

- Installation of thermoplastic piping for soil and waste discharge inside buildings and buried in ground within the building - reference Y10.8005
- Installation of thermoplastic polybutylene and cross linked polyethylene piping for hot and cold water systems and heating systems - reference Y10.8006
- Solvent welded joints, PVC - reference Y10.8010
- Fusion joints, PE - reference Y10.8020
- Mechanical fittings, PE - reference Y10.8030
- Anchors, PVC - reference Y10.8040
- Jointing polybutylene pipes and fittings - reference Y10.8050
- Plastic pipes and fittings with secondary containment and fittings for underground fuel oil systems - reference Y10.8070.

254.000 IDENTIFICATION - MECHANICAL

254.010 GENERAL:

- Comply with work section general clauses below
 - Requirements - reference Y54.1010
 - New systems - reference Y54.1020
 - Existing systems - reference Y54.1030
 - Colours - reference Y54.1040
 - Performance and durability - reference Y54.1045
- Provide identification - mechanical as specified in work section

254.020 PIPEWORK IDENTIFICATION:

- Reference Y54.2010

254.045 GRAPHICAL SYMBOLS FOR USE ON EQUIPMENT IN ACCORDANCE WITH BS EN 80416:

- Reference Y54.2035

254.070 LABORATORY OUTLETS:

- Type
- Application

254.100 DANGER AND WARNING NOTICES:

- Reference Y54.2090

254.110 SYSTEM IDENTIFICATION INSTALLATION CHARTS:

- Perspex sheet glazing with frame - reference Y54.2100A

290.000 FIXING TO BUILDING FABRIC

290.010 GENERAL:

- Comply with work section general clauses below
 - Preparation - reference Y90.1010
 - Manufacturer's drawings - reference Y90.1020
 - Fixings - reference Y90.1030
 - Loading details - reference Y90.1040
 - Building-in by others - reference Y90.1050
 - Size of fixing - reference Y90.1060
- Greasing of fixings - reference Y90.1070

290.020 FIXINGS:

- Standards - reference Y90.2010
- Plugs - reference Y90.2020
- Screws - reference Y90.2030
- Non-penetrative support systems - reference Y90.2080
 - Manufacturer and reference
 - Or approved equivalent.

290.030 WORKMANSHIP:

- Drilling - reference Y90.3010
- Fixing to timber rails - reference Y90.3050
- Fixing to hollow stud/tile/block wall
 - Reference Y90.3060A
- Fixing to concrete, brickwork or blockwork
 - Reference Y90.3070A
- Fixing to metalwork
 - Reference Y90.3080A
- Fixing to structural steelwork and concrete structures
 - Reference Y90.3090A
- Non-penetrative support systems for roof mounted equipment - reference Y90.3100#

291.000 OFF-SITE PAINTING AND ANTI-CORROSION TREATMENT

291.010 GENERAL

- Comply with work section general clauses below
 - General requirements - reference Y91.1010
- Damaged finishes - reference Y91.1020

291.020 PAINT MATERIALS:

- Paint materials
 - Reference Y91.2010A

- Paint quality - reference Y91.2020

291.030 WORKMANSHIP

- Weather and other conditions - reference Y91.3020
- Cleaning and preparing for painting
 - Steel surfaces - reference Y91.3030A
 - Surfaces - reference Y91.3030B
 - Reference Y91.3030#
- Application off-site - reference Y91.3040
- Application - reference Y91.3050
- Cold galvanizing - reference Y91.3060
- Protection of bright machine parts - reference Y91.3070
- Special protective finishes

PART 3 SPECIFICATION CLAUSES SPECIFIC TO R10

300.000 GENERAL / PRODUCT / MATERIALS

300.005 DRAINAGE SPECIALIST:

- On design and build projects engage a drainage specialist to develop the design, install, commission and set to work a roof drainage system operating under gravity inside the building in accordance with BS EN 12056-3

BS APPENDIX

BS 416-1:2009

Discharge and ventilating pipes and fittings, sand-cast or spun in cast iron. Part 1 Specification for spigot and socket systems

BS 437:2008

Specification for cast iron drain pipes, fittings and their joints for socketed and socketless systems

BS 476-7:1997

Fire tests on building materials and structures. Part 7 Method of test to determine the classification of the surface spread of flame of products

BS 476-20:1987

Fire tests on building materials and structures. Part 20 Method for determination of the fire resistance of elements of construction (general principles)

BS 4514:2001

Unplasticized PVC soil and ventilating pipes of 82.4mm minimum mean outside diameter, and fittings and accessories of 82.4mm and of other sizes. Specification

BS 8490:2007

Guide to siphonic roof drainage systems

BS 9999:2017

Fire safety in the design, management and use of buildings. Code of practice

BS EN 545:2010

Ductile iron pipes, fittings, accessories and their joints for water pipelines. Requirements and test methods

BS EN 598:2007+A1:2009

Ductile iron pipes, fittings, accessories and their joints for sewerage applications. Requirements and test methods

BS EN 877:1999+A1:2006

Cast iron pipes and fittings, their joints and accessories for the evacuation of water from buildings. Requirements, test methods and quality assurance

BS EN 969:2009

Specification for ductile iron pipes, fittings, accessories and their joints for gas pipelines. Requirements and test methods

BS EN 1092-1:2018

Flanges and their joints. Circular flanges for pipes, valves, fittings and accessories, PN designated. Part 1 steel flanges

BS EN 1092-2:1997

Flanges and their joints. Circular flanges for pipes, valves, fittings and accessories, PN designated. Part 2 cast iron flanges

BS EN 1329-1:2014+A1:2018

Plastics piping systems for soil and waste discharge (low and high temperature) within the building structure. Unplasticized poly(vinyl chloride) (PVC-U). Specifications for pipes, fittings and the systems

BS EN 1363-1:2012

Fire resistance tests. General requirements

BS EN 1366-3:2009

Fire resistance tests for service installations. Penetration seals

BS EN 1366-4:2006+A1:2010

Fire resistance tests for service installations. Linear joint seals

BS EN 1451-1:2017

Plastics piping systems for soil and waste discharge (low and high temperature) within the building structure. Part 1 Polypropylene (PP). Specifications for pipes, fittings and the system

BS EN 1453-1:2017

Plastics piping systems with structured-wall pipes for soil and waste discharge (low and high temperature) inside buildings. Unplasticized poly (vinyl chloride) (PVC-U). Part 1 Specifications for pipes and the system

BS EN 1453-1:2017

Plastics piping systems with structured-wall pipes for soil and waste discharge (low and high temperature) inside buildings. Unplasticized poly (vinyl chloride) (PVC-U). Part 1 Specifications for pipes and the system

BS EN 1455-1:2000

Plastics piping systems for soil and waste (low and high temperature) within the building structure. Acrylonitrile-butadiene-styrene (ABS). Part 1 Specifications for pipes, fittings and the system

BS EN 1519-1:2000

Plastics piping systems for soil and waste discharge (low and high temperature) within the building structure. Polyethylene (PE). Part 1 Specifications for pipes, fittings and the system

BS EN 1565-1:2000

Plastics piping systems for soil and waste discharge (low and high temperature) within the building structure. Styrene copolymer blends (SAN + PVC). Part 1 Specifications for pipes, fittings and the system

BS EN 1566-1:2000

Plastics piping systems for soil and waste discharge (low and high temperature) within the building structure. Chlorinated poly(vinyl chloride) (PVC-C). Part 1 Specification for pipes, fittings and the system

BS EN 12056-1:2000

Gravity drainage systems inside buildings. Part 1 General and performance requirements

BS EN 12056-2:2000

Gravity drainage systems inside buildings. Part 2 Sanitary pipework, layout and calculation

BS EN 12056-3:2000

Gravity drainage systems inside buildings. Part 3 Roof drainage, layout and calculation

BS EN 12056-4:2000

Gravity drainage systems inside buildings. Part 4 Wastewater lifting plants. Layout and calculation

BS EN 12056-5:2000

Gravity drainage systems inside buildings. Part 5 Installation and testing, instructions for operation, maintenance and use

BS EN 12200-1:2016

Plastics rainwater piping systems for above ground external use. Unplasticized poly(vinyl

chloride)(PVC-U). Specifications for pipes, fittings and the system

BS EN 13501-2:2016

Fire classification of construction products and building elements. Classification using data from fire resistance tests, excluding ventilation services

BS EN 14364:2013

Plastic piping systems for drainage and sewerage with or without pressure. Glass reinforced thermosetting plastics (GRP) based on unsaturated polyester resin (UP). Specifications for pipes, fittings and joints

BS EN 15012:2007

Plastics piping systems. Soil and waste discharge systems within the building structure. Performance characteristics for pipes, fittings and their joints

BS EN 15014:2007

Plastics piping systems. Buried and above ground systems for water and other fluids under pressure. Performance characteristics for pipes, fittings and their joints

BS EN 15655:2009

Ductile iron pipes, fittings and accessories. Internal polyurethane lining for pipes and fittings. Requirements and test methods

BS EN 80416-1:2009

Basic principles for graphical symbols for use on equipment. Part 1 Creation of symbol originals

BS EN 80416-2:2001

Basic principles for graphical symbols for use on equipment. Part 2 Form and use of arrows

BS EN 80416-3:2002+A1:2011

Basic principles for graphical symbols for use on equipment. Part 3 Guidelines for the application of graphical symbols

BS EN ISO 1452-1:2009

Plastics piping systems for water supply and for buried and above-ground drainage and sewerage under pressure. Unplasticized poly(vinyl chloride) (PVC U). Part 1 General

BS EN ISO 1452-2:2009

Plastics piping systems for water supply and for buried and above-ground drainage and sewerage under pressure. Unplasticized poly(vinyl chloride) (PVC U). Part 2 Pipes

BS EN ISO 1452-3:2010

Plastics piping systems for water supply and for buried and above-ground drainage and sewerage under pressure. Unplasticized poly(vinyl chloride) (PVC U). Part 3 Fittings

BS EN ISO 1452-5:2009

Plastics piping systems for water supply and for buried and above-ground drainage and sewerage under pressure. Unplasticized poly(vinyl chloride) (PVC U). Part 5 Fitness for purpose of the system

BS ISO 2531:2009

Ductile iron pipes, fittings, accessories and their joints for water applications

BS ISO 9349:2017

Ductile iron pipes, fittings, accessories and their joints. Thermal preinsulated products

BS ISO 10467:2018

Plastics piping systems for pressure and non-pressure drainage and sewerage. Glass-reinforced thermosetting plastics (GRP) systems based on unsaturated polyester (UP) resin

ISO 7186:2011

Ductile iron products for sewerage applications

R11 FOUL DRAINAGE ABOVE GROUND

PART 1 SYSTEM OBJECTIVES

100.010 PERFORMANCE OBJECTIVES:

- Alterations to the existing above ground drainage system, generally as detailed on the (52) Series Drawings

100.011 PERFORMANCE OBJECTIVES:

- The purpose of this specification is that the foul drainage above ground systems and equipment provided in compliance with it, will deliver the whole hospital engineering design philosophies and be compliant with all Department of Health (NHS Estates) documentation including, but not limited to HTM's and HBN's pertinent to the nature of the project.

100.020 DESIGN PARAMETERS:

- Relevant parts of BS EN 12056
- Current Building Regulations Technical Guidance Documents and requirements of the Local Authority

100.040 CONTROL REQUIREMENTS:

- Isolations and Liaison with NHS Estates along with wards the will be effected by the isolations will be required by the contractor on a local site level

100.060 SYSTEM DRAWINGS:

- Reference (52) Series Drawings

PART 2 SELECTION SCHEDULES FOR REFERENCE SPECIFICATIONS

210.000 PIPELINES AND PIPEWORK

210.010 GENERAL:

- Comply with work section general clauses below
 - prefabricated pipework - reference Y10.1010
- Fire stopping
 - All components forming the seal system, to be from the same manufacturer
 - Comply with BS 9999, relevant approved technical guidance to Building Regulations and BESA Technical Bulletin TB/032
 - Provide proprietary penetration seal system. All products used, to have third party product certification by a scheme accredited by UKAS.
 - Type
 - Stone mineral wool, soft seal type lamella strip with a proprietary flexible coating, used in conjunction with acoustic intumescent sealant and/or high expansion intumescent sealant to suit the application. For use in all applications including where movement of services needs to be accommodated. Tested and assessed to BS EN 1366-3 and BS EN 1366-4 and classified to BS EN 13501-2.
 - Stone mineral wool ablative coated batt seal with a proprietary flexible coating, used in conjunction with acoustic intumescent sealant and/or high expansion intumescent sealant to suit the application. Tested and assessed to BS EN 1366-3.
 - All services passing through apertures in masonry walls/concrete floors or drywall

partitions/systems.

- Fire resistance
 - 2 hrs.
- Only use UKAS accredited, third party installer certified specialist contractors. The specialists should be ASFP members and their certification must cover the passive fire protection element they are installing.
- Install all fire stopping systems in accordance with the manufacturer's written instructions and the test / assessment / certification evidence provided by the installer / manufacturer of the penetration seal.
- Support centres for services passing through penetration seals serving fire barriers to be the same as those covered by the test / assessment / certification evidence provided by the installer / manufacturer of the penetration seal.
- Install and inspect fire stopping systems in accordance with Building Regulations Approved Document B, ASFP Code of Practice TGD 17 and the general best practice guidance given in the ASFP On-site guide to installing fire-stopping.

210.040 CAST/DUCTILE IRON PIPES AND FITTINGS:

- Type In line with existing systems, Ensign etc.
- Application Above ground drairage systems.
- Manufacturer Ensign or similar to match the existing systems installed
 - Or approved equivalent
- Cast iron/ductile iron pipes and fittings to BS 416-1
 - Spigot and socket - reference Y10.2350A
- Cast iron/ductile iron pipes to BS 437
 - For flexible joints - reference Y10.2370A
- Cast iron/ductile iron fittings to BS 437
 - For flexible joints - reference Y10.2380A
- Cast iron pipes and fittings to BS EN 877
 - Red epoxy finish - reference Y10.2390A
 - Grey epoxy finish - reference Y10.2390B
- Ductile iron pipes to BS EN 545
 - Flanged joints - reference Y10.2410A
 - Spigot and socket joints - reference Y10.2410B
- Ductile iron pipes for water applications to BS ISO 2531
 - Flanged joints - reference Y10.2425A
 - Spigot and socket joints - reference Y10.2425B
- Jointing materials
 - Flanges to BS EN 1092-2.
 - Flanges BS EN 1092-2 PN
 - Cast iron flanges - reference Y10.3010C
 - Flange jointing rings
 - For cast iron - reference Y10.3020C
 - Use push-fit joints for cast iron pipe.
 - Couplings for cast iron pipes to BS EN 877
 - Stainless steel - reference Y10.3105A
 - Red ductile iron - reference Y10.3105B
 - Grey ductile iron - reference Y10.3105C
 - Black ductile iron - reference Y10.3105D
 - Spigot/socket caulked joints
 - Reference Y10.3110A
 - Use push-in self anchor joints for ductile iron pipes.
 - Flexible couplings, sleeve type
 - For ductile iron pipework to BS EN 545, BS EN 598, BS EN 969 - reference Y10.3170A
 - Flexible flange adapters, sleeve type

- For ductile iron pipework to BS EN 545, BS EN 598, BS EN 969 - reference Y10.3180A
- Internal polyurethane lining
 - Provide internal polyurethane linings for ductile iron pipework in accordance with BS EN 15655.

210.050 PLASTICS PIPES AND FITTINGS:

- Plastics piping systems for water supply
 - Reference Y10.2455A - pipes to
 - BS EN ISO 1452-1
 - BS EN ISO 1452-2
 - BS EN ISO 1452-5
 - Reference Y10.2475A - fittings to
 - BS EN ISO 1452-1
 - BS EN ISO 1452-3
- BS EN ISO 1452-5
- Plastic piping systems, buried and above ground for water and other fluids (not potable water)
 - Pipes, fittings and joints to BS EN 15014 - reference Y10.2442
- PVC-U fittings to BS 4514
 - Reference Y10.2490A
- PVC-O to BS ISO 16422
 - Reference Y10.2491A 12666-1
- Compression fittings for polyethylene
- Reference Y10.2510A systems of PVC-U, PP and PE, to relevant parts of BS EN 13476
 - Pipes and fittings with smooth internal and external surface, Type A, to BS EN 13476-2 - reference Y10.2553A
- Pipes and fittings with smooth internal and profiled external surfaces, Type B, to BS EN 13476-3 - reference Y10.2553B
- Plastics piping systems for soil, waste and rainwater discharge within the building structure
 - PP Pipes to BS EN 1451-1 and BS EN 15012 - reference Y10.2545A
 - Fittings to BS EN 1451-1 and BS EN 15012 - reference Y10.2555A
 - Solid wall PVC-U pipes to BS EN 1329-1 and BS 4514 - reference Y10.2580A
 - Structured-wall PVC-U pipes to BS EN 1453-1 - reference Y10.2580F
 - PVC-U fittings to BS EN 1329-1 and BS 4514 - reference Y10.2585A
 - Structured wall PVC-U pipes to BS EN 1453 - reference Y10.2495A
- Plastic rainwater piping systems comprising pipes, fittings and brackets for above ground external use to BS EN 12200-1
 - Pipe material
 - Solid wall PVC-U.
 - Pipe type / details
- Circular
 - Special materials
- Unplasticised PVC pipes to BS EN 1401-1
- Unplasticised PVC pipe fittings to BS EN 1401-1

210.060 OTHER PIPES AND FITTINGS:

210.070 PIPEWORK ACCESSORIES:

- Wall, floor and ceiling masking plates
 - Chromium plated - reference Y10.3190A.
 - Plastic - reference Y10.3190B
- Pipe rings and clips
- Copper pipework

- Use plastic pipe clips.
- Use brass pipe clips.
- Pipework support - reference Y10.4210

210.080 GENERAL WORKMANSHIP:

- Appearance - reference Y10.4010
- Spacing - reference Y10.4020
- Gradients - reference Y10.4030
- Air venting requirements
 - Air bottles - reference Y10.4040A
 - Automatic air vents - reference Y10.4040B
- Drain requirements - reference Y10.4050
- Expansion and contraction - reference Y10.4060
- Pipe fittings
 - Bends/swept tees - reference Y10.4070A
 - Elbows/square tees - reference Y10.4070B
- Pipes through walls and floors - reference Y10.4110
- Protect pipework penetrating fire separating elements in accordance with, Building Regulations, BS 9999 and BESA Technical Bulletin TB/032.
- Pipe sleeves
 - Reference Y10.4120A
 - Insulation carried through - reference Y10.4120B
- Pipe through fire barriers - reference Y10.4125
 - Type
 - Proprietary sleeves
 - Ablative coated batt type
 - Fire resistance
 - 2 hours
 - hrs
- Connect to equipment.
- Use distribution headers.
- Temporary plugs, caps and flanges
 - Reference Y10.4150A.
- Flanged joints general - reference Y10.4160
- Dissimilar metals - reference Y10.4170
- Pipe rings and clips - reference Y10.4180
 - Anchors - reference Y10.4190
- Pipe supports - reference Y10.4205
 - Comply with the manufacturers' installation recommendations for the following proprietary pipe systems:
 - Plastic pipe systems.
 -
- Support spacing
 - Tables for steel, copper, iron, PVC and ABS pipes - reference Y10.4220
 -
- Isolation and regulation
 - Reference Y10.4230A
- Maintenance and renewal - reference Y10.4240
- Clean by removing cement and clean off all pipework and brackets.
- Non-ferrous components - thoroughly clean and degrease.
- Pipe collars (closers) for plastic pipes where they pass through fire resistant walls and floors.
 - Type

- Stainless steel collar with fixing brackets with intumescent liner.
- Pre-assembled wrap for casing within concrete floor or masonry wall.
- Fire resistance
 - 2 hrs
 - hrs
- Installation to be in accordance with the manufacturer's instructions and grouted/sealed using the manufacturer's proprietary compound/sealant.
- Standards
 - Test to BS EN 1366-3 and BS EN 1363-1.
- Test to BS 476-20.

210.100 WORKMANSHIP, COPPER PIPEWORK:

- Compression joints - reference Y10.6030
- Capillary joints - reference Y10.6040
- Anchors
 - Flanges - reference Y10.6060A
- Saddle clamps - reference Y10.6060B

210.110 WORKMANSHIP, CAST/DUCTILE IRON:

- Flanged joints - reference Y10.7010
- Caulked joints - reference Y10.7020
- Flexible joints - reference Y10.7030

210.120 WORKMANSHIP, PLASTIC PIPES:

- Installation of thermoplastic piping for soil and waste discharge inside buildings and buried in ground within the building - reference Y10.8005
- Installation of thermoplastic polybutylene and cross linked polyethylene piping for hot and cold water systems and heating systems - reference Y10.8006
- Solvent welded joints, PVC - reference Y10.8010
- Fusion joints, PE - reference Y10.8020
- Mechanical fittings, PE - reference Y10.8030
- Anchors, PVC - reference Y10.8040
- Jointing polybutylene pipes and fittings - reference Y10.8050
- Plastic pipes and fittings with secondary containment and fittings for underground fuel oil systems - reference Y10.8070.

211.000 PIPELINE ANCILLARIES

211.080 TEST PLUGS:

- Self sealing test points - reference Y11.2670A
- Valve controlled test points - reference Y11.2670B

211.120 TUNDISHES:

- Copper - reference Y11.2690A
- Mild steel, galvanized - reference Y11.2690B

211.160 LOOSE ITEMS:

- Keys for spindle shank valves - reference Y11.3010A
 - Number
- For drain cocks - reference Y11.3010B
- Number

254.000 IDENTIFICATION - MECHANICAL

254.010 GENERAL:

- Comply with work section general clauses below
 - Requirements - reference Y54.1010
 - New systems - reference Y54.1020
 - Existing systems - reference Y54.1030
 - Colours - reference Y54.1040
 - Performance and durability - reference Y54.1045
- Provide identification - mechanical as specified in work section

254.020 PIPEWORK IDENTIFICATION:

- Reference Y54.2010

254.045 GRAPHICAL SYMBOLS FOR USE ON EQUIPMENT IN ACCORDANCE WITH BS EN 80416:

- Reference Y54.2035

254.100 DANGER AND WARNING NOTICES:

- Reference Y54.2090

254.110 SYSTEM IDENTIFICATION INSTALLATION CHARTS:

- Perspex sheet glazing with frame - reference Y54.2100A

290.000 FIXING TO BUILDING FABRIC

290.010 GENERAL:

- Comply with work section general clauses below
 - Preparation - reference Y90.1010
 - Manufacturer's drawings - reference Y90.1020
 - Fixings - reference Y90.1030
 - Loading details - reference Y90.1040
 - Building-in by others - reference Y90.1050
 - Size of fixing - reference Y90.1060
- Greasing of fixings - reference Y90.1070

290.020 FIXINGS:

- Standards - reference Y90.2010
- Plugs - reference Y90.2020
- Screws - reference Y90.2030

- Non-penetrative support systems - reference Y90.2080

290.030 WORKMANSHIP:

- Drilling - reference Y90.3010
- Fixing to timber rails - reference Y90.3050
- Fixing to hollow stud/tile/block wall
 - Reference Y90.3060A
- Fixing to concrete, brickwork or blockwork
 - Reference Y90.3070A
- Fixing to metalwork
 - Reference Y90.3080A
- Fixing to structural steelwork and concrete structures
 - Reference Y90.3090A
- Non-penetrative support systems for roof mounted equipment - reference Y90.3100#

291.000 OFF-SITE PAINTING AND ANTI-CORROSION TREATMENT

291.010 GENERAL

- Comply with work section general clauses below
 - General requirements - reference Y91.1010
- Damaged finishes - reference Y91.1020

291.020 PAINT MATERIALS:

- Paint materials
 - Reference Y91.2010A
- Paint quality - reference Y91.2020

291.030 WORKMANSHIP

- Weather and other conditions - reference Y91.3020
- Cleaning and preparing for painting
 - Steel surfaces - reference Y91.3030A
 - Surfaces - reference Y91.3030B
 - Reference Y91.3030#
- Application off-site - reference Y91.3040
- Application - reference Y91.3050
- Cold galvanizing - reference Y91.3060
- Protection of bright machine parts - reference Y91.3070

BS APPENDIX

BS 416-1:2009

Discharge and ventilating pipes and fittings, sand-cast or spun in cast iron. Part 1 Specification for spigot and socket systems

BS 437:2008

Specification for cast iron drain pipes, fittings and their joints for socketed and socketless systems

BS 476-7:1997

Fire tests on building materials and structures. Part 7 Method of test to determine the classification of the surface spread of flame of products

BS 476-20:1987

Fire tests on building materials and structures. Part 20 Method for determination of the fire resistance of elements of construction (general principles)

BS 4514:2001

Unplasticized PVC soil and ventilating pipes of 82.4mm minimum mean outside diameter, and fittings and accessories of 82.4mm and of other sizes. Specification

BS 9999:2017

Fire safety in the design, management and use of buildings. Code of practice

BS EN 545:2010

Ductile iron pipes, fittings, accessories and their joints for water pipelines. Requirements and test methods

BS EN 598:2007+A1:2009

Ductile iron pipes, fittings, accessories and their joints for sewerage applications. Requirements and test methods

BS EN 877:1999+A1:2006

Cast iron pipes and fittings, their joints and accessories for the evacuation of water from buildings. Requirements, test methods and quality assurance

BS EN 969:2009

Specification for ductile iron pipes, fittings, accessories and their joints for gas pipelines. Requirements and test methods

BS EN 1092-1:2018

Flanges and their joints. Circular flanges for pipes, valves, fittings and accessories, PN designated. Part 1 steel flanges

BS EN 1092-2:1997

Flanges and their joints. Circular flanges for pipes, valves, fittings and accessories, PN designated. Part 2 cast iron flanges

BS EN 1092-3:2003

Flanges and their joints. Circular flanges for pipes, valves, fittings and accessories, PN designated. Part 3 copper alloy flanges

BS EN 1092-4:2002

Flanges and their joints. Circular flanges for pipes, valves, fittings and accessories, PN designated. Part 4

aluminium alloy flanges

BS EN 1329-1:2014+A1:2018

Plastics piping systems for soil and waste discharge (low and high temperature) within the building structure. Unplasticized poly(vinyl chloride) (PVC-U). Specifications for pipes, fittings and the systems

BS EN 1363-1:2012

Fire resistance tests. General requirements

BS EN 1366-3:2009

Fire resistance tests for service installations. Penetration seals

BS EN 1366-4:2006+A1:2010

Fire resistance tests for service installations. Linear joint seals

BS EN 1401-1:2009

Plastics piping systems for non-pressure underground drainage and sewerage. Unplasticized poly(vinyl chloride) (PVC-U). Part 1 Specifications for pipes, fittings and the system

BS EN 1451-1:2017

Plastics piping systems for soil and waste discharge (low and high temperature) within the building structure. Part 1 Polypropylene (PP). Specifications for pipes, fittings and the system

BS EN 1453-1:2017

Plastics piping systems with structured-wall pipes for soil and waste discharge (low and high temperature) inside buildings. Unplasticized poly (vinyl chloride) (PVC-U). Part 1 Specifications for pipes and the system

BS EN 1453-1:2017

Plastics piping systems with structured-wall pipes for soil and waste discharge (low and high temperature) inside buildings. Unplasticized poly (vinyl chloride) (PVC-U). Part 1 Specifications for pipes and the system

BS EN 12056-1:2000

Gravity drainage systems inside buildings. Part 1 General and performance requirements

BS EN 12056-2:2000

Gravity drainage systems inside buildings. Part 2 Sanitary pipework, layout and calculation

BS EN 12056-3:2000

Gravity drainage systems inside buildings. Part 3 Roof drainage, layout and calculation

BS EN 12056-4:2000

Gravity drainage systems inside buildings. Part 4 Wastewater lifting plants. Layout and calculation

BS EN 12056-5:2000

Gravity drainage systems inside buildings. Part 5 Installation and testing, instructions for operation, maintenance and use

BS EN 12200-1:2016

Plastics rainwater piping systems for above ground external use. Unplasticized poly(vinyl chloride)(PVC-U). Specifications for pipes, fittings and the system

BS EN 13476-1:2018

Plastics piping systems for non-pressure underground drainage and sewerage. Structured-wall piping systems of unplasticized poly(vinyl chloride) (PVC-U), polypropylene (PP) and polyethylene (PE). Part 1 General requirements and performance characteristics

BS EN 13476-2:2018

Plastics piping systems for non-pressure underground drainage and sewerage. Structured-wall piping systems of unplasticized poly(vinyl chloride) (PVC-U), polypropylene (PP) and polyethylene (PE). Specifications for pipes and fittings with smooth internal and external surface and the system, Type A

BS EN 13476-3:2018

Plastics piping systems for non-pressure underground drainage and sewerage. Structured-wall piping systems of unplasticized poly(vinyl chloride) (PVC-U), polypropylene (PP) and polyethylene (PE). Part 3 Specifications for pipes and fittings with smooth internal and profiled external surface and the system, Type B

BS EN 13501-2:2016

Fire classification of construction products and building elements. Classification using data from fire resistance tests, excluding ventilation services

BS EN 15012:2007

Plastics piping systems. Soil and waste discharge systems within the building structure. Performance characteristics for pipes, fittings and their joints

BS EN 15014:2007

Plastics piping systems. Buried and above ground systems for water and other fluids under pressure. Performance characteristics for pipes, fittings and their joints

BS EN 15655:2009

Ductile iron pipes, fittings and accessories. Internal polyurethane lining for pipes and fittings. Requirements and test methods

BS EN 80416-1:2009

Basic principles for graphical symbols for use on equipment. Part 1 Creation of symbol originals

BS EN 80416-2:2001

Basic principles for graphical symbols for use on equipment. Part 2 Form and use of arrows

BS EN 80416-3:2002+A1:2011

Basic principles for graphical symbols for use on equipment. Part 3 Guidelines for the application of graphical symbols

BS EN ISO 1452-1:2009

Plastics piping systems for water supply and for buried and above-ground drainage and sewerage under pressure. Unplasticized poly(vinyl chloride) (PVC U). Part 1 General

BS EN ISO 1452-2:2009

Plastics piping systems for water supply and for buried and above-ground drainage and sewerage under pressure. Unplasticized poly(vinyl chloride) (PVC U). Part 2 Pipes

BS EN ISO 1452-3:2010

Plastics piping systems for water supply and for buried and above-ground drainage and sewerage under pressure. Unplasticized poly(vinyl chloride) (PVC U). Part 3 Fittings

BS EN ISO 1452-5:2009

Plastics piping systems for water supply and for buried and above-ground drainage and sewerage under pressure. Unplasticized poly(vinyl chloride) (PVC U). Part 5 Fitness for purpose of the system

BS ISO 2531:2009

Ductile iron pipes, fittings, accessories and their joints for water applications

BS ISO 16422:2014

Pipes and joints made of oriented unplasticized poly(vinyl chloride) (PVC-O) for the conveyance of water under pressure. Specifications

S - PIPEWORK and DUCTWORK SYSTEMS

PART 1 SYSTEM OBJECTIVES

100.060 SYSTEM DRAWINGS:

- (53), (55) and (56) Series Drawings

PART 2 SELECTION SCHEDULES FOR REFERENCE SPECIFICATIONS

210.000 PIPELINES AND PIPEWORK

210.010 GENERAL:

- Comply with work section general clauses below
 - prefabricated pipework - reference Y10.1010
 - Supply pre-insulated underground pipeline as schedule reference Pre-insulated Pipework
 - Location As detailed on the drawings
- Fire stopping
 - All components forming the seal system, to be from the same manufacturer
 - Comply with BS 9999, relevant approved technical guidance to Building Regulations and BESA Technical Bulletin TB/032
 - Provide proprietary penetration seal system. All products used, to have third party product certification by a scheme accredited by UKAS.
 - Type
 - Stone mineral wool, soft seal type lamella strip with a proprietary flexible coating, used in conjunction with acoustic intumescent sealant and/or high expansion intumescent sealant to suit the application. For use in all applications including where movement of services needs to be accommodated. Tested and assessed to BS EN 1366-3 and BS EN 1366-4 and classified to BS EN 13501-2.
 - Stone mineral wool ablative coated batt seal with a proprietary flexible coating, used in conjunction with acoustic intumescent sealant and/or high expansion intumescent sealant to suit the application. Tested and assessed to BS EN 1366-3.
 - All services passing through apertures in masonry walls/concrete floors or drywall partitions/systems.
 - Fire resistance
 - 2 hrs.
 - Only use UKAS accredited, third party installer certified specialist contractors. The specialists should be ASFP members and their certification must cover the passive fire protection element they are installing.
 - Install all fire stopping systems in accordance with the manufacturer's written instructions and the test / assessment / certification evidence provided by the installer / manufacturer of the penetration seal.
 - Support centres for services passing through penetration seals serving fire barriers to be the same as those covered by the test / assessment / certification evidence provided by the installer / manufacturer of the penetration seal.
 - Install and inspect fire stopping systems in accordance with Building Regulations Approved Document B, ASFP Code of Practice TGD 17 and the general best practice guidance given in the ASFP On-site guide to installing fire-stopping.

210.015 STAINLESS STEEL PIPES AND FITTINGS:

- Manufacturer and reference Gervberit 316 Grade

- Welded stainless steel tubes for general purpose
 - Light gauge to BS EN 10312 - reference Y10.2220 for push and press-fit systems
 - Size range - nominal diameter (DN) up to and including 150mm
 - Size range - nominal diameter (DN)
 - Wall thickness - to be suitable for the application duty / testing requirements
 - Wall thickness in accordance with BS EN 10312
 - Table 2 - Series 2 (1mm - 3mm depending on OD)
 - To BS EN 10217-7 - reference Y10.2250B for general purpose use.
 - To ASTM A312 (dimensions determined by ANSI B36.19) for general use.
 - Joints - up to and including 50mm - screwed.
 - Joints - up to and including 50mm - welded and flanged.
 - Joints - 65mm and above - welded and flanged.
- Seamless stainless steel tubes for general purpose
 - To BS EN 10216-5 - reference Y10.2250A
 - To ASTM A312 (dimensions determined by ANSI B36.19)
 - Size - nominal diameter (DN) 200mm and above
 - Wall thickness - to be suitable for the application duty / testing requirements.
 - Grade of steel for general purpose
 - 316
- Seamless stainless steel tubes and fittings to BS 4825 for food and chemical industry applications - reference Y10.2230 and Y10.2240.
 - Size range - nominal diameter (DN)
 - Wall thickness - to be suitable for the application duty / testing requirements.
 - Wall thickness Minimum of 1mm
 - Grade of steel
 - 316S11
 - 316S13
 - 316S31
 - 316S33
- Stainless steel push-fit fittings - reference Y10.2257
- Stainless steel fittings, grooved for mechanical joints
 - Reference Y10.2255A
 - Reference Y10.2255#
- Mechanical joints, grooved stainless steel pipes reference Y10.3152A
- Light gauge stainless steel for push-fit and press-fit systems to BS EN 10312 - reference Y10.2220
- Light gauge stainless steel for push-fit and press-fit systems reference Y10.2221
- Use press fitting jointing system for stainless steel pipe for pressure purposes.
 - Jointing equipment for press fitting jointing system - reference Y10.3125
 - Press fittings for stainless steel pipe - reference Y10.3130#

210.025 MALABLE IRON / STEEL PIPES AND FITTINGS: PIPE-IN-PIPE:

- Application LTHW and Chilled Water Applications
 - Carbon steel pipes to BS EN 10253-1 or BS EN 10253-2
 - Heavy, black - reference Y10.2010A
 - Medium, black - reference Y10.2010B
 - Reference Y10.2010#
 - Carbon steel fittings to BS EN 10253-1 or BS EN 10253-2
 - Heavy weight - reference Y10.2060A
 - Medium weight - reference Y10.2060B
 - Malleable cast iron fittings, screwed
 - Black - reference Y10.2070A

- Jointing materials
 - Screwed joints to relevant parts of BS EN 10226
 - Paste and hemp and PTFE tape - reference Y10.3030A
 - PTFE tape - reference Y10.3030B
 - Where chemical cleaning is required - reference Y10.3030C
 - Union connections
 - Railroad pattern - spherical seating bronze to iron.
 - Navy pattern - spherical seating bronze to bronze.
 - Welding rods
- Reference Y10.3050A
- Outer pipe
 - Carbon steel pipes to BS EN 10255
 - Heavy, black - reference Y10.2010A
 - Medium, black - reference Y10.2010B
 - Carbon steel fittings to BS EN 10253-1 or BS EN 10253-2
 - Heavy weight - reference Y10.2060A
 - Medium weight - reference Y10.2060B
 - Malleable cast iron fittings, screwed
 - Black - reference Y10.2070A
 - Jointing materials
 - Screwed joints to BS 21 and BS EN 10226-1.
 - Paste and hemp and PTFE tape - reference Y10.3030A
 - PTFE tape - reference Y10.3030B
 - Where chemical cleaning is required - reference Y10.3030C
 - Union connections
 - Railroad pattern - spherical seating bronze to iron.
 - Navy pattern - spherical seating bronze to bronze.
 - Welding rods
- Reference Y10.3050A

210.060 OTHER PIPES AND FITTINGS:

210.090 WORKMANSHIP, STEEL PIPEWORK:

- Welding, general
 - Class 1 - reference Y10.5010A
 - Class 2 - reference Y10.5010B
- Welded joints - reference Y10.5020
- Painting welded joints - reference Y10.5030
- Flanged joints - reference Y10.5040
- Screwed joints - reference Y10.5050
- Mechanical joints - reference Y10.5060
- Anchors
 - U-bolts - reference Y10.5070A
- Flanges - reference Y10.5070B
- Pipework painting - reference Y10.5090
- Installation of stainless steel pipework
 - Compression joints - reference Y10.5100
 - Mechanical joints - Y10.5060

210.100 WORKMANSHIP, COPPER PIPEWORK:

- Compression joints - reference Y10.6030
- Capillary joints - reference Y10.6040
- Anchors
 - Flanges - reference Y10.6060A
- Saddle clamps - reference Y10.6060B

211.000 PIPELINE ANCILLARIES

211.010 GENERAL:

- Comply with work section general clauses below
 - Safety and relief valves, bursting discs, self-operated, application and standards - reference Y11.1010
- For applicable valves comply with BS EN 16668 for all essential safety requirements of the Pressure Equipment (Safety) Regulations 2016. Valves excluded from conformance to this standard in the Regulations shall meet "sound engineering practice" by conformity to the relevant product standard.
- Face to face and centre to face dimension of PN and Class designated flanged metal valves to be in accordance with BS EN 558
- In addition to the particular valve type standard, valves to be used in, or connected to, water supply pipe systems, above or below ground carrying water intended for human consumption to comply with the relevant parts of BS EN 1074 and BS 5163 as appropriate to the application.
 - BS EN 1074-1 - General requirements
 - BS EN 1074-2 - Isolating valves
 - BS EN 1074-3 - Check valves
 - BS EN 1074-4 - Air valves
 - BS EN 1074-5 - Control valves
 - BS EN 1074-6 - Hydrants
- Valves and components of valves specified are as defined in BS EN 736-1 and BS EN 736-2.
- Testing of valves
 - Pressure test metallic valves at manufacturer's works, in accordance with BS EN 12266-1 or BS ISO 5208 in conjunction with given specific requirements of the valve product or performance standard.
 - Undertake supplementary tests below in accordance with BS EN 12266-2 in conjunction with given specific requirements of the valve product or performance standard
 - Obturator strength
 - Back seat tightness
 - Operability
 - Anti-static design at 12V
 - Anti-static design at 100V
 - Fire tested design
 - Flow resistance
 - Pressure test thermoplastic valves at manufacturer's works, in accordance with BS ISO 9393-1 in conjunction with given specific requirements of the valve product or performance standard

211.030 STOP VALVES:

- Service fluid
- Water
- PN to suit system maximum working pressure.
- WRAS approved for water services applications.
- Comply with BS EN 1074-1 and BS EN 1074-2 in addition to the particular valve type standard, for valves for water supply applications carrying water for human consumption.
- Kitemark certified.
- Pipe material
 - To suit copper tube.

- To suit steel tube.
- Copper alloy globe type stop valves (stop cocks) to BS EN 1213 for potable water supplies
 - Compression ends for copper - reference Y11.2015A
 - Capillary - reference Y11.2015C
 - Threaded - reference Y11.2015D
- Copper alloy gate valves for general use to BS 5154
 - Screwed to BS EN ISO 228-1, or ISO 7-1 - reference Y11.2020A
 - Compression to BS EN 1254-2 - reference Y11.2020B
 - Flanged to BS EN 1092-3 - reference Y11.2020C
 - Loose nut/union end - reference Y11.2020D
- Cast iron gate valves for general use to BS EN 1171
 - Grey cast iron flanged to BS EN 1092-2 - reference Y11.2030A
- Copper alloy globe valves for general use to BS 5154
 - Screwed to relevant parts of BS EN 10226 - reference Y11.2040A
 - Flanged to BS EN 1092-3 - reference Y11.2040B
 - Compression to BS EN 1254-2 - reference Y11.2040C
 - Compression to BS EN 1254-3 - reference Y11.2040D
- Cast iron globe valves for general use to BS EN 13789
 - Grey cast iron flanged to BS EN 1092-2 - reference Y11.2050A
- Steel parallel slide for steam and other high temperature / pressure applications to BS EN 1984
 - Reference Y11.2060A
- Steel wedge type gate valve for general use to BS EN 1984
 - Flanged to BS EN 1092-1 - reference Y11.2070A
 - Threaded - reference Y11.2070D
 - Auxiliary connections
- Ball valves
 - Application, standard and material
 - Potable water - copper alloy to BS EN 13828, PN 10 and distribution temperature of 65 °C with occasional excursions up to 90 °C permitted for a period of 1 hour maximum.
 - General purpose heating, cooling and other applications - copper alloy to BS EN 13547.
 - Steam and high temperature / pressure applications - steel to BS ISO 7121 - reference Y11.2160#.
 - Screw driver/key operated
 - Screwed to relevant parts of BS EN 10226 - reference Y11.2080A
 - Compression to BS EN 1254-2 - reference Y11.2080B
 - Lever operated
 - Screwed to relevant parts of BS EN 10226 - reference Y11.2080C
 - Compression to BS EN 1254-2 - reference Y11.2080D
 - Lockshield
 - Screwed to relevant parts of BS EN 10226 - reference Y11.2080E
 - Compression to BS EN 1254-2 - reference Y11.2080F
- Servicing valves, for water services for maintenance of fittings / appliances, copper alloy to BS 6675
 - Handwheel operated
 - Screwed ends - reference Y11.2085A
 - Compression ends - reference Y11.2085B
 - Capillary ends - reference Y11.2085C
 - Lever operated
 - Screwed ends - reference Y11.2085D
 - Compression ends - reference Y11.2085E
 - Capillary ends - reference Y11.2085F
 - Screw driver operated
 - Screwed ends - reference Y11.2085G
 - Compression ends - reference Y11.2085H
 - Capillary ends - reference Y11.2085I

- Butterfly valves for general use to BS EN 593
 - Semi-lugged between flanges to BS EN 1092-2
 - Lever operated - reference Y11.2090A
 - Gear operated - reference Y11.2090B
 - Between mechanical joints
 - Lever operated - reference Y11.2090C
 - Gear operated - reference Y11.2090D
 - Fully-lugged to BS EN 593 - reference Y11.2090E
 - Lever operated.
- Gear operated.
- Cast iron gate type for waterworks purposes to relevant parts of BS 5163
- Key operated type A - reference Y11.2110A
- Closed bottom taper plug valves for gas installations for buildings to BS EN 331.

211.050 DOUBLE REGULATING VALVES:

- Service fluid
- Water
- WRAS approved.
- Kitemark certified.
- Pipe material
 - To suit copper tube.
 - To suit steel tube.
- Butterfly type to BS EN 593
 - Between flanges to BS EN 1092-2
 - Lever operated - reference Y11.2210A
 - Gear operated - reference Y11.2210B
 - Between mechanical joints
 - Lever operated - reference Y11.2210C
 - Gear operated - reference Y11.2210D
- Globe valves to BS 7350, section 3.1.
 - Copper alloy
 - Screwed to relevant parts of BS EN 10226 - reference Y11.2220A
 - Flanged to BS EN 1092-2 - reference Y11.2220B
 - Cast iron
- Flanged to BS EN 1092-2 - reference Y11.2220C

211.060 FLOW MEASUREMENT VALVES:

- Service fluid
- Water
- WRAS approved.
- Kitemark certified.
- Pipe material
 - To suit copper tube.
 - To suit steel tube.
- Flow measurement devices to BS 7350
 - Section 3.2 Type 3
 - Copper alloy
 - Screwed to relevant parts of BS EN 10226 - reference Y11.2230A
 - Flanged to BS EN 1092-3 - reference Y11.2230B
 - Cast iron
 - Flanged to BS EN 1092-2 - reference Y11.2230C

- Section 3.2 Type 4
 - Copper alloy
 - Screwed to relevant parts of BS EN 10226 - reference Y11.2230E
 - Flanged to BS EN 1092-3 - reference Y11.2230F
 - Cast iron - reference Y11.2230G
 - Variable orifice valve
- Fixed orifice valve

211.065 PRESSURE INDEPENDENT CONTROL VALVES (PICV'S):

- Select, install and commission valves to provide the functions of flow limitation, modulating or on/off control and differential pressure control within a single valve body.
- Commission valves in accordance with the manufacturer's recommendations and Commissioning Specialists Association TM18.
- The valve manufacturer shall provide test results for each type and size of PICV to be used on the project in accordance with BSRIA Test Method for Pressure Independent Control Valves BTS 1/2012.
- Incorporate a flushing drain in the pipework between the terminal unit and the PICV.
- Type
 - Full stroke constant k_v where the control and flow setting functions are separated within the valve and the full stroke of the valve is available for control.
 - Full stroke variable k_v where the control valve section has a constant unchangeable stroke distance but its k_v can be varied by means of an inlet port with an adjustable opening size.
 - Stroke limited variable k_v where the control valve and flow setting devices are combined in a single component.
 - Globe.
 - Rotary, characterised ball.
 -
- Valve characteristic/control function
 - On/off.
 - Linear (modulating).
 - Equal percentage (modulating).
- Application
 - Heating terminal units
 - Cooling terminal units
- Heating and cooling terminal units
- Manufacturer and reference
 - Or approved equivalent.
- Duties
 - To suit terminal unit design flow rates as detailed in equipment schedules
- Duties and details as schedule reference Motorised Control Valvesd
 - Relevant parts of BS EN 60534
 - Valve leakage class to BS EN 60534-4 when shut off.
 - IV.
 -
 -
 -
- Maximum pressure differential (kPa)
- Minimum operating pressure differential for PICV operation (kPa)
- Materials
 - Body - DZR brass.
 - Globe or ball - brass.
 - Stem - brass.
 - O-Ring/diagram - EPDM rubber.

- Springs - stainless steel.
-
- Features
- Facility to measure pressure drop across valves at commissioning.
- Actuator
 - TRV actuator for radiators.
 - TRV with capillary sensor for radiators and radiant panels.
 - Thermo - electric on/off.
 - 0-10V proportional electric for modulating control.
- 3 point floating control.
- Prefabricated packaged valve assembly requirements
 - Type of heating/cooling terminal:
 - Fan coil units - heating and cooling.
 - Fan coil units - cooling only.
 - Chilled beams - heating and cooling.
 - Chilled beams - cooling only.
 - Chilled ceiling panels.
 - Radiators
 - Radiant panels
 -
- Components required:
 - PICV.
 - Ball type isolation valves on flow and return.
 - Flushing by-pass with 3-port valve.
 - Flushing blow down drain valve.
 - Flow measurement venturi for commissioning verification.
 -
- Component to be pre-assembled and tested at the manufacturer's works, test pressure (kPa)
-
- Labeling requirements

211.070 FLOW REGULATORS AND COMBINATION VALVES:

- Service fluid
- Water
- WRAS approved.
- Kitemark certified.
- Pipe material
 - To suit copper tube.
- To suit steel tube.

211.075 HEAT METERS:

- Manufacturer and reference Kamstrup - Ultrasonic
 - Or approved equivalent.
- Standards
 - Meters - BS EN 1434-1, BS EN 1434-2, BS EN 1434-3, BS EN 1434-4, BS EN 1434-5
 - Heat meter installation commissioning, operational monitoring and maintenance - BS EN 1434-6
 - Provide heat meters with integrator, flow sensor, matched pair of temperature sensors and interconnecting cables calibrated as a single unit at manufacturer's works. Installations to be in accordance with manufacturer's recommendations.
 - RHI compliant heat meters and their installation shall meet the requirements of the following:
 - The Renewable Heat Incentive Scheme Regulations 2018 as amended.
 - The most recent version of Ofgem Renewable Heat Incentive Guidance Volume One: Eligibility and

How to Apply.

- Annex MI-004 of the EU Measuring Instruments Directive (MID) 2004/22/EC refer to Directive 2014/32/EU from 20th April 2016.
- Commissioning to be carried out by the manufacturer.
- Metering installation arrangement for RHI eligibility
 - Standard metering
 - Multiple metering
- Meter accuracy class for RHI eligibility as defined in Annex MI-004 of the MID/BS EN 1434-1
 - Class 2.
- For RHI installation with a capacity of 45Wth and below the installation shall be undertaken by a Microgeneration Certification Scheme (MCS) certified installer.
- For RHI installation of a capacity of 1MWth and above or when the installation is classed as a multiple metering arrangement or steam is to be metered, provide an independent report on metering as defined by Ofgem.
- Arrangement
 - In-line.
- Service fluid
 - Water.
 - Water/Glycol mix (% Glycol)

211.080 TEST PLUGS:

- Self sealing test points - reference Y11.2670A
- Valve controlled test points - reference Y11.2670B

211.090 RADIATOR VALVES TO BS 2767:

- Manufacturer and reference Herz Valves
- Kitemark certified.
- Type 4 - reference Y11.2260A
 - Finish
- Natural.

211.100 PIPELINE STRAINERS:

- Bronze (Y type)
 - Screwed to relevant parts of BS EN 10226 - reference Y11.2680A
 - Flanged to BS EN 1092-3 - reference Y11.2680B
 - Compression to BS EN 1254-2
Reference Y11.2680C
- Cast iron/ductile iron
 - Y type - flanged to BS EN 1092-2 - reference Y11.2680D
 - Flanged suction diffuser type reference Y11.2680G
 - Cast iron body with ductile iron cover and cast iron guide vanes (PN16)
 - Ductile iron body and cover, and ductile guide vanes (PN25)
- Ductile iron grooved ends
 - Y type - reference Y11.2680E
 - Suction diffuser strainer - reference Y11.2680F

211.110 THERMOSTATIC RADIATOR VALVES TO BS EN 215:

- Application Remote with capillary for ceiling mounted radiant panels
 - Manufacturer and reference Herz Valves
- Kitemark certified.

- Table A.1 - Series D - reference Y11.2270A
 - Pattern
 - Straight
 - Angle
- Table A.2 - Series F - reference Y11.2270B
 - Pattern
 - Straight
 - Angle
- Table A.3 - Series S - reference Y11.2270C
 - Pattern
 - Straight
 - Angle
- Table A.4 - Series GB - reference Y11.2270D
 - Pattern
 - Straight
 - Angle
- Tamper proof Table A.1 - Series D - reference Y11.2270E
 - Pattern
 - Straight
 - Angle
- Tamper proof Table A.2 - reference Y11.2270F
 - Pattern
 - Straight
 - Angle
- Tamper proof Table A.3 - reference Y11.2270G
 - Pattern
 - Straight
 - Angle
- Tamper proof Table A.4 - reference Y11.2270H
 - Pattern
 - Straight
- Angle

211.120 TUNDISHES:

- Copper - reference Y11.2690A

211.140 GAUGES:

- General - reference Y11.2700A
 - 150mm black stoved enamel finish
 - Flush panel mounting - reference Y11.2700B
 - Direct mounting - reference Y11.2700C
- 100mm - finish
- Temperature gauges general - reference Y11.2710A
 - Mercury in steel - reference Y11.2710B
 - Vapour pressure to BS EN 13190
 - Direct mounting - reference Y11.2710C
- Pressure and altitude gauges - reference Y11.2720
- Vacuum gauges - reference Y11.2730
- Differential pressure gauges
 - Hardwood - reference Y11.2750A

211.150 CONTROL VALVES:

- WRAS approved.
- Kitemark certified.
- Ball control valves
 - Open/close - reference Y11.2315A
 - Two way - reference Y11.2315B
 - Three way - reference Y11.2315C

211.160 LOOSE ITEMS:

- Keys for spindle shank valves - reference Y11.3010A
 - Number
- For drain cocks - reference Y11.3010B
- Number

211.170 CHECK VALVES:

- WRAS approved.
- Kitemark certified.
- Service fluid
- Water.
- Pipe material
 - To suit copper tube.
 - To suit steel tube.
- Copper alloy check type to BS 5154
 - Swing type screwed to relevant parts of BS EN 10226 - reference Y11.2320A
 - Swing type flanged to BS EN 1092-3 - reference Y11.2320B
- Steel and cast iron check valves to BS EN 16767
 - Swing check
 - Flanged - reference Y11.2330A
 - Grooved for mechanical joints.
 - Wafer body - reference Y11.2330B
 - Lift check
 - Flanged - reference Y11.2330C
 - Wafer body - reference Y11.2330D
 - Body material
 - Grey cast iron
 - Malleable cast iron
 - SG cast iron
 - Steel
- Wafer flange fitting type
- Reference Y11.2340A
- Steel globe stop and check type to BS EN 13709 - reference Y11.2370#
- Device to prevent contamination of water by backflow to BS EN 14451
 - Combined check and anti-vacuum - reference Y11.2385A
- Anti-back syphonage valve, combined check and anti-vacuum type
 - Reference Y11.2390A
- Anti-back syphonage valve, hose union anti-vacuum type
- Reference Y11.2391A

211.180 WORKMANSHIP:

- Installation - reference Y11.4010

- Location - reference Y11.4020
 - Positions
- Location of thermostatic radiator valves - reference Y11.4025
- Positioning of components
 - Flow/pressure measurement valves - reference Y11.4030
 - Double regulating variable orifice valves - reference Y11.4040
 - Install control ball valves in accordance with manufacturer's recommendations.
 - Control components
 - Reference Y11.4050A
- Provide outlets of vent cocks with discharge pipes.
- Valve stuffing boxes - reference Y11.4070
- Discharge connections
 - Safety and Relief valves - reference Y11.4080A
 - Vent cocks - reference Y11.4080B
 - Air bottles - reference Y11.4080C
 - Automatic air vents - reference Y11.4080D
- Expansion devices - reference Y11.4090
- Expansion compensators - reference Y11.4100
- Flexible connections installation - reference Y11.4110
- Terminal unit connections - install hose connections strictly in accordance with manufacturer's instructions.

211.210 DRAIN COCKS:

- WRAS approved.
- Kitemark certified.
- Throughway gland cock type
 - Reference Y11.2440A
- Screwdown to BS 2879, type 1 - reference Y11.2450
- Ball type - reference Y11.2460

211.220 VENT COCKS:

- Kitemark certified.
- Two way gland cock type - reference Y11.2470
- Ball type - reference Y11.2480
- Three way gland cock type - reference Y11.2490
- Plug valve type
 - Wrench operated - reference Y11.2500A
 - Gear operated - reference Y11.2500B

211.230 AUTOMATIC AIR VENTS:

- Application At high points on LTHW systems
 - Manufacturer and reference Spirotech - Spirotop AAV's
- Float type
 - Reference Y11.2510A

211.260 EXPANSION ARRANGEMENTS/DEVICES AND FLEXIBLE CONNECTIONS/HOSES:

Expansion Bellows and Flexible Hose Compensatorsps

- Steel
 - Reference Y11.2610A

- Galvanized after manufacture.
- Copper - reference Y11.2620
- Expansion compensators
 - Axial bellows
 - Screwed to relevant parts of BS EN 10226 - reference Y11.2630A
 - Flanged to BS EN 1092-1 - reference Y11.2630B
 - Articulated bellows
 - Screwed to relevant parts of BS EN 10226 - reference Y11.2630D
 - Flanged to BS EN 1092-1 - reference Y11.2630E
 - Slip-type axial, grooved and expansion compensators
 - Reference Y11.2630J
 - Multiple grooved couplings type compensators
 - Reference Y11.2630K
- Hose compensators
 - Screwed to relevant parts of BS EN 10226 - reference Y11.2640A
 - Flanged to BS EN 1092-1 - reference Y11.2640B
 - Standard
 - Corrugated metal hoses to comply with BS EN 14585-1 and PD CEN/TR 14585-3
- Flexible connections for noise and vibration attenuation
 - EPDM rubber, up to 100°C
 - Flanged to BS EN 1092-1 - reference Y11.2650A
 - Screwed to relevant parts of BS EN 10226 - reference Y11.2650B
 - Grooved flexible mechanical joints for noise and vibration attenuation
 - Install 3 grooved flexible mechanical joints after the source of vibration and before the first change in pipe direction. Installation to be strictly in accordance with the manufacturer's instructions.
 - Convoluted stainless steel, above 100°C
 - Flanged to BS EN 1092-1 - reference Y11.2650C
 - EPDM rubber, up to 70°C
 - Flanged to BS EN 1092-1 - reference Y11.2650D
 - Screwed to relevant parts BS EN 10226 - reference Y11.2650E
 - Chlorobutyl rubber, up to 100°C
 - Flanged to BS EN 1092-1 - reference Y11.2650F
 - Screwed to relevant parts of BS EN 10226 - reference Y11.2650G
 - Chlorobutyl rubber, up to 60°C
 - Flanged to BS EN 1092-1 - reference Y11.2650H
 - Screwed to relevant parts of BS EN 10226 - reference Y11.2650I
- Terminal heating and cooling unit connections
 - Heating services
 - Stainless steel - reference Y11.2660A
 - Stainless steel with quick release couplings - reference Y11.2660B
 - Rubber - reference Y11.2660C
 - Chilled water services
 - Stainless steel - reference Y11.2660D
 - Stainless steel with quick release couplings - reference Y11.2660E
 - Rubber - reference Y11.2660F
 - Corrugated metal hoses to comply with BS EN 14585-1 and PD CEN/TR 14585-3
- Flexible hose assemblies for drinking water installations to connect sanitary tap ware, heaters and similar appliances with maximum operating temperature 70°C to be in accordance with BS EN 13618. Flexible hose assemblies intended for use as integral parts of appliances, to be in accordance with BS EN 61770
- Hose and hose assemblies for saturated steam and hot water condensate.
 - Application
 - Standard - BS EN ISO 6134

- Type 1 - low pressure, maximum working pressure 6 bar
- Type 2 - high pressure, maximum working pressure 18 bar
- Incorporate an oil-resistant cover

225.000 CLEANING AND CHEMICAL TREATMENT

225.010 GENERAL:

- Comply with work section general clauses below
 - Conditions for cleaning and chemical treatment - reference Y25.1010
 - Method statement - reference Y25.1015
- Comply with Approved Codes of Practice and associated technical guidance published by HSE on the requirements of the Health and Safety at Work etc. Act 1974 and the Control of Substances Hazardous to Health Regulations 2002 as amended, that apply to the risk from exposure to legionella bacteria.

225.020 CLEANING AND CHEMICAL TREATMENT SPECIALIST:

- Reference Y25.2010
 - Use one of the following specialists Phoenix Commissioning, COTS, Contract Engineering, or NHS current term maintenance contractor that looks after the QUEH and RHC Building/Systems
- On closed systems the specialist shall, in addition to specific requirements detailed elsewhere in this specification or drawings, undertake the following:
 - Obtain relevant information on the closed system to be treated.
 - Evaluate which treatment options will achieve the corrosion control and water quality objectives, taking account of regulatory issues and product selection constraints.
 - Follow up the treatment programme with proper monitoring of chemical, microbiological and physical parameters, ideally including monitoring of corrosion rates.
- On open evaporation cooling systems the specialist shall, in addition to specific requirements detailed elsewhere in this specification or drawings, review the design and confirm the system can be operated and maintained in accordance with HSE L8 Approved Code of Practice and Guidance - Legionnaire's' Disease: The control of legionella bacteria in water systems and associated technical guidance in HSG274 Part 1: The control of legionella bacteria in evaporative cooling systems.

225.040 PRELIMINARY CHECKS:

- Reference Y25.2030A
- Systems applicable Domestic Water Systems, LTHW, Chilled Water Systems

225.050 PROCEDURAL PRECAUTIONS:

- Reference Y25.2040A
- Including taking samples - reference Y25.2040B

225.060 CHEMICAL INJECTION AND DOSING METHODS:

- Water treatment methods
 - Reference Y25.2050#
 - Water treatment methods for hot water heating closed circuit recirculating systems - reference Y25.2050A
 - Water treatment methods for chilled and condenser water closed circuit recirculating systems - reference Y25.2050B
 - Water treatment methods for cooling tower hot water heating closed circuit recirculating systems - reference Y25.2050C
- Method of introducing chemicals into closed systems - reference Y25.2060A

- Method of introducing chemicals into open recirculating systems - reference Y25.2060B
- Packaged plant - reference Y25.2060C
- Dosing for closed systems - reference Y25.2060D
- Dosing pot capacity to be sized by water treatment specialist to suit system capacity and chemicals used.
- Dosing for open systems - reference Y25.2060E
- Dosing chemicals - reference Y25.2065

225.065 CORROSION TEST COUPON RACKS:

- Type
 - Serpentine, incorporating isolation valves on both sides of the rack and built-in flow control to hold the water flow through the rig at the ASTM recommended velocity of 0.6m/s to 1.8m/s.
- Standard
- ASTM D2688

225.090 FLUSHING:

- Application
 - Heating, cooling and other closed pipework systems
 - BSRIA Guide BG 29/2012 - Pre-commission Cleaning of Pipework Systems - reference Y25.3010B
 - System filling
 - Temporary connection from mains in compliance with
 - England and Wales - The Water Supply (Water Fittings) Regulations 1999 as amended, the Water Act 2014 and The Construction Products Regulations 2013.
 - Scotland - The Water Supply (Water Fittings) Byelaws 2014.
 - Northern Ireland - The Water Supply (Water Fittings) Regulations 2009.
 - Temporary connection from fire hydrant pipework.
 - By installation of temporary tank and pump arrangement.
 - Flush system until discharge water is visually clear.
- Services supplying water for domestic use - reference Y25.3010D

225.100 PURGING:

- Testing and purging gas pipework from the outlet of the Emergency Control Valve (ECV) fitted on the end of the gas service that is owned by the Gas Transporter and the inlet connection to the gas appliance.
 - Industrial and commercial installation - reference Y25.3020A
- Small low pressure industrial and commercial installations (having a volume not exceeding 1m³) - reference Y25.3020B

225.110 CHEMICAL CLEANING AND SOLIDS REMOVAL:

- BSRIA Application Guide 29/2012: Pre-commission Cleaning of Pipework Systems.
 - Inhibited acid - reference Y25.3030A
 - Formulated products - reference Y25.3030B
- Cleaning and chemical treatment regime - reference Y25.3035

225.120 DISINFECTION:

- General - reference Y25.3040
- Hot and cold water systems - reference Y25.3050

225.150 DOCUMENTATION:

- Reference Y25.3090

230.000 AIR DUCTLINES AND ANCILLARIES

230.010 GENERAL:

- Comply with work section general clauses below
 - Ductwork installation standards - reference Y30.1010
 - Ductwork dimensions - reference Y30.1020
- Electrical bonding terminal - reference Y30.1030
- Location Refer to (57) Series Drawings
- Fire stopping
 - All components forming the seal system to be from the same manufacturer. All products used, to have third party product certification by a scheme accredited by UKAS.
 - Only use UKAS accredited, third party installer certified specialist contractors. The specialists should be ASFP members and their certification must cover the passive fire protection element they are installing.
 - Install all fire stopping systems in accordance with the manufacturer's written instructions and the test / assessment / certification evidence provided by the installer / manufacturer of the penetration seal.
 - Support centres for services passing through penetration seals serving fire barriers to be the same as those covered by the test / assessment / certification evidence provided by the installer / manufacturer of the penetration seal.
 - Install and inspect fire stopping systems in accordance with Building Regulations Approved Document B, ASFP Code of Practice TGD 17 and general best practice guidance given in the ASFP On-site guide to installing fire-stopping.

230.020 INSTALLER SELECTION:

- Use a member of the BESA (Building Engineering Services Association) specialising in manufacturing and installing ductwork.
- Where post installation cleaning is specified, appoint a specialist cleaning contractor to undertake the work in accordance with BESA TR/19, and supply and install any additional cleaning openings to suit their selected specific methods of cleaning and to suit the practical site conditions relative to the fabric of the building and position of other services.
- Existing systems that require inspection and cleaning prior to modification or re-commissioning (including kitchen extract systems).
 - Employ a specialist, approved in accordance with Loss Prevention Standard LPS 2084, to undertake the following:

230.030 DUCTWORK AND FITTINGS:

- Type Refer to (57) Series Drawings
- Application Supply and Extract Ventilation systems as detailed
 - Electrical bonding terminal - reference Y30.1030
- Design Information
 - Pressure classification
 - Class A, positive - reference Y30.2010A
 - Class A, negative - reference Y30.2010B
 - Cleanliness quality class to BS EN 15780 and BESA TR/19
 - High.
 - Prior to final commissioning, in addition to a visual assessment of the internal surfaces, undertake Preferred Vacuum Test (PVT) to establish dust accumulation level is within the acceptable level for the

cleanliness quality class listed in Table 2 (A.4) in BESA TR/19.

- Protection Delivery and Installation (PDI) level to BS EN 15780 and BESA TR/19
- Advanced (including post installation cleaning) - reference Y30.4090C
- Reference Y30.4090#
- Post installation cleaning for advance level of PDI
 - To be undertaken by a ductwork cleaning specialist.
 - Dry method - reference Y30.4090D
 - Wet method - reference Y30.4090E
 - Medium pressure ductwork - reference Y30.2030B
 - Low pressure ductwork - reference Y30.2030C
- Ductwork strength and air leakage testing, circular sheet metal ductwork - reference Y30.2035
- Ductwork strength and air leakage testing, rectangular sheet metal ductwork - reference Y30.2036.

230.040 SHEET METAL DUCTWORK TO DW/144:

- Material
 - Zinc coated. Hot-dip galvanised steel to BS EN 10346.
 - Pre-coated steel.
- Protective finishes
 - Galvanizing.
 - Metal spraying.
 - Paint.
- Construction
 - Rectangular.
 - Circular.
 - Man access and safety bars - reference Y30.2070

230.070 FIRE RESISTING / SMOKE EXTRACT DUCTWORK AND METHOD OF MAINTAINING FIRE INTEGRITY:

- Type and method of fire rating 2 Hour
- Fire protection material Specialist Coatings - Paint and Applied Materials
- Ventilation systems to be protected Refer to (57) Series Drawing for locations and Specific Ductwork that is to be fire rated
- Install and inspect fire resisting duct systems in accordance with Building Regulations and ASFP Code of Practice TGD 18.
- The installation shall be fully in accordance with the test certification.
- Supply fire resisting ductwork as schedule reference Fire Rated Ductwork
- Supply fire resisting ductwork as below
 - Duct type
 - Fire outside duct Type A
 - Application
 - Fire protection of supply and extract ventilation ductwork
 - Fire resistance when tested to the requirements of BS EN 1366-1, BS EN 1366-8 or BS EN 1366-9 and classified in accordance with BS EN 13501-3 for ventilation ducts or BS EN 13501-4 for smoke control ducts using BS EN "EI" nomenclature by UKAS accredited certification body.
 - Integrity 120 mins
 - Fire rating when tested to the requirements of BS 476-24 by a UKAS accredited certification body.
 - Thermal insulation requirements
 - As detailed in Y 50 / D1.9.10.
 - Minimum thickness to control heat loss and heat gain in accordance with Building Regulations.
- Pressure class of ductwork to BESA DW/144: Classs
 - Smoke and heat control duct systems to BS EN 12101-7

- BS 9999 for general fire safety
- BS EN 1363-1 Fire resistance tests. General requirements
- BS EN 1366-1 Fire resistance tests for service installations. Ventilation ducts
- BS EN 1366-9 Fire resistance tests for service installations. Single compartment smoke extraction ducts
- BS EN 13501-3 Classification using data from fire resistance tests on products and elements used in building service installations: fire resisting ducts and fire dampers
- BS EN 13501-4 Classification using data from fire resistance tests on components of smoke control systems
- Fire protection with fire dampers or automatically actuated fire and smoke dampers triggered by smoke detectors - reference Y30.2110A
- Fire protection with fire resisting enclosures
- Reference Y30.2110B
- Fire resisting ductwork tested to BS EN 1366 - reference Y30.2110E
 - Fire resisting and smoke / heat control ductwork tested to BS EN 1366 - reference Y30.2110F
- The manufacturer/installer shall be assessed and registered in accordance with BS EN ISO 9001
- Systems/materials shall be listed within the Loss Prevention Certification Board (LPCB) Red Book.
- Systems/materials used shall have third party accreditation by a UKAS accredited certification body.

230.080 INSULATED DUCTWORK:

- Type Supply and Extract systems
 - Application for heat recovery and acoustic issues
- External thermal/acoustic insulation
 - Reference Y30.2121

230.090 SUPPORTS:

- Hangers and supports
 - Reference Y30.2140A
- Support of air terminal units
 - Reference Y30.2150A

230.100 ACCESSORIES:

- Construction and finishes - reference Y30.3010
- Inspection/servicing access openings
 - Metal ductwork - reference Y30.3020A
 - BESA TR/19 - reference Y30.3020D
- Test holes
 - Metal ductwork - reference Y30.3030A
- Holes for controls/instruments - metal ductwork - reference Y30.3040
- Installation of instruments and controls - reference Y30.3042
- Cleaning access
 - Basic level of PDI - reference Y30.3050A
 - Intermediate level of PDI - reference Y30.3050B
 - Advanced level of PDI with post installation cleaning - reference Y30.3050C
- Flexible joint connections
 - Reference Y30.3110A

230.110 REGULATING DAMPERS - METAL DUCTWORK:

- Type Fire Stop Dampers and Isolation Dampers
- Manufacturer and reference Halton and Actionair

- Or approved equivalent.
- Acoustic testing requirements to BS EN ISO 5135
- Balancing dampers
 - Steel single-blade dampers - reference Y30.3060A
 - Steel multi-blade dampers - reference Y30.3060B
- Control dampers
 - Steel single-blade dampers - reference Y30.3060C
- Steel multi-blade dampers - reference Y30.3060D

230.150 COMBINATION SMOKE AND FIRE DAMPERS:

- Type Refer to (50) Series and (57) Series Drawings
- Application Fire Smoke Dampers
- Manufacturer and reference Actionair
- Control mode To Suit Existing - Refer to Entropic
- General - reference Y30.3089
- Steel single-blade - reference Y30.3090A
- Steel multi-blade - reference Y30.3090B
- Combination smoke control / fire dampers to be in accordance with BS EN 12101-8 tested to BS EN 1366-10 and BS EN 1366-2 and classified in accordance with BS EN 13501-4.

230.180 AIR DUCTLINES & ANCILLARIES WORKMANSHIP:

- General - reference Y30.4010
- Ductwork supports - reference Y30.4020
- Component support on pre-insulated aluminium ductwork
 - Reference Y30.4025
- Duct support for vapour seal continuity
 - Reference Y30.4030A
- External ductwork
 - Construction
 - Galvanised steel to BESA DW/144 Section 26, protected from the elements by a watertight membrane installed immediately after the ductwork has been installed.
 - Galvanised steel to BESA DW/144 Section 26 not protected by a watertight membrane.
 - Insulation
 - Refer to Thermal Insulation specification clauses / schedule.
 - Protective finish
 - Painting
 - Aluminium cladding.
 - Laminating foil / film jacketing system
 - External ductwork supports - reference Y30.4040
 - As shown on drawings
- Ductwork floor support - reference Y30.4050
- Drainage of ductwork - reference Y30.4060
- Connections to building openings
 - Metal ductwork, comply with DW/144, Appendix K.
- Weather proofing
 - Flashing plate and cowl - reference Y30.4100A
 - Ductwork sleeves
 - Flanged - reference Y30.4110B
- Fire rated ductwork sleeves
 - Provide as indicated on drawing.
- Installation of control equipment

- Reference Y30.4130
- Positions
 - Position components as indicated and in accordance with manufacturer's instructions as shown on the following drawings
 - Contract drawings.
 - Manufacturer's drawings.
 - Specialist supplier's drawings.
 - Specialist contractor's drawings.
- Instrument connections
 - Reference Y30.4140
- Damper access - reference Y30.4160

241.000 FANS

241.010 GENERAL:

- Comply with general clauses below
 - Standards
 - Reference Y41.1000
 - Design duties, fan selection, efficiency and EC ecodesign requirements for fans and ventilation units.
 - Reference Y41.1010
 - Protection
 - Reference Y41.1020
- Supply fans as schedule reference Fans Referecne AHU specification and Schedules
 - Location Level 4 new Plant Room
- Ensure all electrical equipment supplied and installed is suitable for power supply indicated.
- Provide details of electrical input, starting and performance characteristics of all motors above 750W to an agreed format.
- Where appropriate ensure motors and drives are supplied complete with keys and keyways.
- Supply fans as schedule reference (50) Series Drawing

241.020 FAN AND MOTOR:

- Application
 - Included in air handling unit reference AHU AHU/01 and AHU/02 Supply and AHU/01 and AHU/02 Extract
 - Manufacturer and reference
 - Select fans from Quality Assured firms.
 - Fully Eurovent Certified as an assembly and for individual components
 - Or approved equivalent.
- Electrical supply to BS EN 60038
 - Single-phase.
 - 3-phase.
 - 3-phase and neutral. BS EN 10143
 - Construct casing from mild steel coated with epoxy polyester finish.
- Motor
 - Type
 - Asynchronous induction with Variable Speed Drive (VSD).
 - Permanent-Magnet Synchronous, with Variable Speed Drive (VSD).
 - Magnet free synchronous reluctance with VSD.
 - EC Permanent-Magnet Synchronous with integral AC to DC converter and electronic controls with 0-10V control input.
 - EC Permanent-Magnet Synchronous with integral AC to DC converter and electronic controls with

- 0-10V control input and integral PID controller to enable sensors to be connected directly to the motor.
- Standards - reference Y92.1010
- General - reference Y92.2020
 - Provide protected enclosures against external mechanical impacts in accordance with BS EN 62262
 - IK 08.
- On belt driven fan fit motors on slide rails - reference Y92.2030
- Motor efficiency
 - Efficiency class - IE2 - reference Y92.2025A
 - Efficiency class - IE3 - reference Y92.2025B
 - Efficiency class - IE4 - reference Y92.2025C
- Degree of protection in accordance with BS EN 60034-5
 - IP55.
 - Method of motor cooling in accordance with BS EN 60034-6
- Surge suppressors
 - Manufacturer fitted - reference Y92.1040A
- Motor operating conditions
 - Standard operating conditions
 - Non standard operating conditions (above 1000m with air conditions exceeding 40°C and 50%
- Motors - over temperature protection
 - Thermistors - reference Y92.2060A
 - Reference Y92.2060#
- Drives
 - Indirect drives
 - Toothed belt - reference Y92.2070A
 - Flat belt - reference Y92.2070B
 - Direct coupled drives
 - Reference Y92.2080A
 - Variable speed drives (VSDs)
 - Frequency converters (VSD) tailor made for HVAC application
 - Located in control panel or exposed wall or frame mounted - reference Y72.2190A
 - Located in motor control centre - reference Y72.2190B
 - Reference Y72.2190#
 - Demarcation of responsibilities and location of VSD
 - Integrated with pump motor, supplied and selected by pump manufacturer to suit design duty
 - Supplied and selected by the controls specialist to suit plant duty and provided as part of local plant controls for integration with BMS
 - Located remote from motor
 - Guards
 - Reference Y92.2090A
 - Motor mounting classification - reference Y92.2100#

241.050 WORKMANSHIP

- Location - reference Y41.4010
- Attitude - reference Y41.4020
- Alignment - reference Y41.4030
- Testing - reference Y41.4040
- Drain connections - reference Y41.4050

250.000 THERMAL INSULATION

250.010 GENERAL:

- Comply with work section general clauses reference below
 - Temperature range - reference Y50.1010
 - Standards - reference Y50.1020
 - Materials - reference Y50.1030
 - Pre-insulated equipment - reference Y50.1032
 - Protection applied in situ - reference Y50.1034
 - European classification for reaction to fire performance - reference Y50.1035A
 - European classification for reaction to fire performance - reference Y50.1035#
 - Spread of flame - reference Y50.1050A
 - Spread of flame - reference Y50.1050#
 - Smoke emission characteristics - reference Y50.1055
 - Electrical bonding terminal - reference Y50.1080
- Inspection and testing - reference Y50.1090
- Make good any sections that are cut during inspection for thickness and compliance with specification.
- Insulation thicknesses
 - Reference Y50.2289

250.020 INSTALLER SELECTION:

- Use a contractor specialising in the supply and installation of thermal insulation.
- Use thermal insulation materials supplied by a manufacturer assessed and registered in accordance with BS EN ISO 9001.
- Use thermal insulation materials supplied by a manufacturer assessed and registered in accordance with BS EN ISO 14001.
- Use thermal insulation materials supplied by a manufacturer assessed and registered in accordance with BS OHSAS 18001

250.030 MINERAL WOOL THERMAL INSULATION - PIPEWORK:

- Reference Y50.1035A
- Spread of flame as BS 476-7
 - Reference Y50.1050A
- Smoke emission characteristics
 - Reference Y50.1055
- Electrical bonding terminal - reference Y50.1080
- Inspection and testing - reference Y50.1090
- Materials
 - Standard - BS EN 14303.
- Thermal conductivity - reference Y50.2010
- Thermal performance life expectancy
 - For plant design life - reference Y50.2015A
 - Details - reference Y50.2015B
- Restrictions on use of materials - reference Y50.2020
- Mineral wool pipe insulation
 - Foil faced - Rock mineral wool reference Y50.2030A
 - Canvas covered - Rock mineral wool reference Y50.2030B
 - Foil faced - Glass mineral wool reference Y50.2030C
 - Canvas covered - Glass mineral wool reference Y50.2030D
 - Vapour barrier permeance
- Vapour barrier coatings
 - Bitumen - reference Y50.2180A
 - Vinyl - reference Y50.2180B

- Solvent polymers- reference Y50.2180C
- Bitumen emulsion- reference Y50.2180D
- Adhesives - reference Y50.2190
- Protection
 - Application
 - Self-adhesive multi-layer laminate covering - reference Y50.2200A
 - Roofing felt - reference Y50.2200B
 - Flat aluminium-zinc coated steel - reference Y50.2200C
 - Ribbed aluminium-zinc coated steel - reference Y50.2200D
 - Aluminium sheeting - reference Y50.2200E
 - Canvas - reference Y50.2200G
 - Canvas with aluminium bands - reference Y50.2200H
 - Reinforcement
- Valve and flange insulation
 - Application
- Thickness table
 - Insulation thickness calculation methods, Building Regulations - reference Y50.2286
 - Insulation thickness calculation methods, ECA Enhanced - reference Y50.2287
 - Insulation thickness tables - reference Y50.2289
 - Non-domestic hot water supply services Building Regulations (rock mineral wool) - reference Y50.2290
 - Non-domestic hot water supply services Building Regulations (glass mineral wool) - reference Y50.2295
 - Non-domestic hot water supply services ECA Enhanced - reference Y50.2307
 - Non-domestic heating installations, Building Regulations (rock mineral wool) - reference Y50.2310
 - Non-domestic heating installations, Building Regulations (glass mineral wool) - reference Y50.2315
 - Non-domestic heating installations, ECA Enhanced - reference Y50.2327
 - Domestic central heating and hot water system, Building Regulations - reference Y50.2330
 - Domestic central heating and hot water systems, ECA Enhanced - reference Y50.2331
 - Cooled water supplies, Building Regulations and condensation control on cooled and cold water supplies rock mineral wool - reference Y50.2395
 - Cooled water supplies, Building Regulations and condensation control on cooled and cold water supplies glass mineral wool - reference Y50.2396
 - Protection against freezing rock mineral wool - reference Y50.2420
 - Protection against freezing glass mineral wool - reference Y50.2421
- Thickness of insulation
- Thickness of insulation for refrigeration pipework and equipment to BS 5422 - reference Y50.2495#
- Thickness of insulation for process pipework and equipment to BS 5422 - reference Y50.2490#

250.040 CLOSED CELL MATERIALS THERMAL INSULATION - PIPEWORK:

- Reference Y50.1035A
- Spread of flame as BS 476-7
 - Reference Y50.1050A
 - Smoke emission characteristics
- Electrical bonding terminal - reference Y50.1080
- Inspection and testing - reference Y50.1090
- Materials
- Thermal conductivity - reference Y50.2010
- Thermal performance life expectancy
 - For plant design life - reference Y50.2015A
 - Details - reference Y50.2015B
- Restrictions on use of materials - reference Y50.2020

- Closed cell rigid phenolic preformed sections
 - Foil faced - reference Y50.2110A
- High density rigid phenolic pipe and duct insulation - Reference Y50.2130A
- Closed cell nitrile rubber preformed flexible sections
 - Reference Y50.2140A
- Vapour barrier permeance
 - Reference Y50.2170
- Vapour barrier coatings
 - Bitumen - reference Y50.2180A
 - Vinyl - reference Y50.2180B
 - Solvent polymers- reference Y50.2180C
 - Bitumen emulsion- reference Y50.2180D
- Adhesives - reference Y50.2190
- Protection
 - Application
 - Self-adhesive multi-layer laminate covering - reference Y50.2200A
 Roofing felt - reference Y50.2200B
 - Flat aluminium-zinc coated steel - reference Y50.2200C
 - Ribbed aluminium-zinc coated steel - reference Y50.2200D
 - Aluminium sheeting - reference Y50.2200E
 - Canvas - reference Y50.2200G
 - Canvas with aluminium bands - reference Y50.2200H
 - Reinforcement
- Valve and flange insulation
 - Application
- Thickness table
 - Insulation thickness calculation methods, Building Regulations - reference Y50.2286
 - Insulation thickness calculation methods, ECA Enhanced - reference Y50.2287
 - Insulation thickness tables - reference Y50.2289
 - Non-domestic hot water service area - reference
 - Non-domestic hot water service area, Building Regulations - phenolic foam - reference Y50.2305
 - Non-domestic hot water service area, Building Regulations - nitrile rubber - reference Y50.2306
 - Non-domestic hot water supply services, ECA Enhanced maximum permitted heat losses - reference Y50.2307
 - Non-domestic heating installations, Building Regulations - phenolic foam - reference Y50.2325
 - Non-domestic heating installations, Building Regulations - nitrile rubber - reference Y50.2326
 - Non-domestic heating installations, ECA Enhanced maximum permitted heat losses - reference Y50.2327
 - Domestic central heating and hot water systems, ECA Enhanced maximum permitted heat losses - reference Y50.2331
 - Domestic central heating and hot water systems, Building Regulations - phenolic foam - reference Y50.2336
 - Domestic central heating and hot water systems, Building regulations - nitrile rubber - reference Y50.2337
 - Cooled water supplies, Building Regulations and condensation control on cooled and cold water supplies - phenolic foam - reference Y50.2411
 - Cooled water supplies, Building Regulations and condensation control on cooled and cold water supplies - nitrile rubber - reference Y50.2412
 - Protection against freezing
 - Phenolic foam - reference Y50.2430
 - Nitrile rubber - reference Y50.2440
- Thickness of insulation
- Thickness of insulation for refrigeration pipework to BS 5422 - reference Y50.2495#

250.060 MINERAL WOOL THERMAL INSULATION - DUCTWORK: Performance

- Reference Y50.1035A
- Spread of flame as BS 476-7
 - Reference Y50.1050A
- Smoke emission characteristics
 - Reference Y50.1055
 - Electrical bonding terminal - reference Y50.1080
- Inspection and testing - reference Y50.1090
- Materials
- Thermal conductivity - reference Y50.2010
- Thermal performance life expectancy
 - For plant design life - reference Y50.2015A
 - Details - reference Y50.2015B
- Restrictions on use of materials - reference Y50.2020
- Mineral wool duct insulation
 - Rigid
 - Foil faced - Rock mineral wool reference Y50.2040A
 - Foil faced - Glass mineral wool reference Y50.2040B
 - Flexible
 - Foil faced - Rock mineral wool reference Y50.2050A
 - Foil faced - Glass mineral wool reference Y50.2050B
 - Lamella duct insulation
 - Foil faced - Rock mineral wool reference Y50.2060A
 - Foil faced - Glass mineral wool reference Y50.2060C
 - Kraft paper - Rock mineral wool reference Y50.2060B
 - Kraft paper - Glass mineral wool reference Y50.2060D
 - Crimped mat ductwork insulation - reference Y50.2065
 - Metal mesh faced mattresses for the insulation of high temperature ducts, tanks, vessels and other equipment
 - Galvanized mesh
 - One face - reference Y50.2070A
 - Both faces - reference Y50.2070B
 - Stainless steel mesh
 - One face - reference Y50.2070C
 - Both faces - reference Y50.2070D
- Fire protection insulation
 - Flat ductwork
 - Mitred joints - reference Y50.2080A
 - Butted joints - reference Y50.2080B
 - Circular ductwork
 - Section - reference Y50.2080C
 - PSM - reference Y50.2080D
 - Wired mattress - reference Y50.2080E
- Vapour barrier coatings
 - Bitumen - reference Y50.2180A
 - Vinyl - reference Y50.2180B
 - Solvent polymers- reference Y50.2180C
 - Bitumen emulsion- reference Y50.2180D
- Adhesives - reference Y50.2190
- Protection
 - Application

- Self-adhesive multi-layer laminate covering - reference Y50.2200A
- Roofing felt - reference Y50.2200B
- Flat aluminium-zinc coated steel - reference Y50.2200C
- Ribbed aluminium-zinc coated steel - reference Y50.2200D
- Aluminium sheeting - reference Y50.2200E
- Canvas - reference Y50.2200G
- Canvas with aluminium bands - reference Y50.2200H
- Reinforcement
- Thickness table
 - Insulation thickness calculation methods, Building Regulations - reference Y50.2286
 - Insulation thickness tables - reference Y50.2289
 - Insulation thickness on ductwork, Building Regulations - reference Y50.2456
 - Condensation control on chilled air ductwork, rock mineral wool - reference Y50.2460
 - Condensation control on chilled air ductwork, glass mineral wool - reference Y50.2461
- Thickness of insulation

250.070 CLOSED CELL MATERIALS THERMAL INSULATION - DUCTWORK:

- Type
- Application
 - Manufacturer and reference
- Temperature of fluid in ducts (°C)
 - European Classification for Reaction to Fire Performance
 - Reference Y50.1035A
- Spread of flame as BS 476-7
 - Reference Y50.1050A
- Smoke emission characteristics
 - Reference Y50.1055
 - Electrical bonding terminal - reference Y50.1080
- Inspection and testing - reference Y50.1090
- Materials
- Thermal conductivity - reference Y50.2010
- Thermal performance life expectancy
 - For plant design life - reference Y50.2015A
 - Details - reference Y50.2015B
- Restrictions on use of materials - reference Y50.2020
- Closed cell rigid phenolic foam (PF) slab
 - Obtain written confirmation from the manufacturer that the material is CFC and HCFC free.
 - Foil faced - reference Y50.2120A
 - Reference Y50.2120B
- High density phenolic pipe and duct support foam
 - Reference Y50.2130A
 - Obtain written confirmation from the manufacturer that the material is CFC and HCFC free.
- Closed cell nitrile rubber elastomeric sheet
 - Reference Y50.2140A
- Vapour barrier coatings
 - Bitumen - reference Y50.2180A
 - Vinyl - reference Y50.2180B
 - Solvent polymers- reference Y50.2180C
 - Bitumen emulsion- reference Y50.2180D
- Adhesives - reference Y50.2190
- Protection
 - Application

- Self-adhesive multi-layer laminate covering - reference Y50.2200A
- Roofing felt - reference Y50.2200B
- Flat aluminium-zinc coated steel - reference Y50.2200C
- Ribbed aluminium-zinc coated steel - reference Y50.2200D
- Aluminium sheeting - reference Y50.2200E
- Canvas - reference Y50.2200G
- Canvas with aluminium bands - reference Y50.2200H
- Reinforcement
- Thickness table
 - Insulation thickness calculation methods, Building Regulations - reference Y50.2286
 - Insulation thickness tables - reference Y50.2289
 - Insulation thickness on ductwork, Building Regulations - reference Y50.2456
 - Condensation control on chilled air ductwork - phenolic foam - reference Y50.2470
 - Condensation control on chilled air ductwork - closed cell FEF nitrile foam - reference Y50.2475
- Thickness of insulation

250.080 THERMAL INSULATION - PLANT: Performance

- Reference Y50.1035A
- Spread of flame as BS 476-7
 - Reference Y50.1050A
- Smoke emission characteristics
 - Reference Y50.1055
 - Electrical bonding terminal - reference Y50.1080
- Inspection and testing - reference Y50.1090
- Materials
- Thermal conductivity - reference Y50.2010
- Thermal performance life expectancy
 - For plant design life - reference Y50.2015A
 - Details - reference Y50.2015B
- Restrictions on use of materials - reference Y50.2020
- Mineral fibre duct insulation
 - Rigid
 - Foil faced - reference Y50.2040A
 - Flexible
 - Foil faced - reference Y50.2050A
 - Lamella duct insulation
 - Foil faced - reference Y50.2060A
 - Kraft paper - reference Y50.2060B
 - Metal mesh faced mattresses
 - Galvanized mesh
 - One face - reference Y50.2070A
 - Both faces - reference Y50.2070B
 - Stainless steel mesh
 - One face - reference Y50.2070C
 - Both faces - reference Y50.2070D
- Mineral fibre insulation for hot water storage vessels
 - Resin bonded slabs
 - To comply with Building Regulations, Non-domestic Building Services Compliance Guide - reference Y50.2308
- Closed cell rigid phenolic foam (PF) slab
 - Obtain written confirmation from the manufacturer that the material is CFC and HCFC free.

- Foil faced - reference Y50.2120A
- Reference Y50.2120B
- High density phenolic pipe and duct support foam
 - Reference Y50.2130A
 - Obtain written confirmation from the manufacturer that the material is CFC and HCFC free.
- Closed cell nitrile and EPDM rubber elastomeric sheet and preformed sections.
 - Reference Y50.2140A
- Vapour barrier coatings
 - Bitumen - reference Y50.2180A
 - Vinyl - reference Y50.2180B
 - Solvent polymers- reference Y50.2180C
 - Bitumen emulsion- reference Y50.2180D
- Adhesives - reference Y50.2190
- Protection
 - Application
 - Self-adhesive multi-layer laminate covering - reference Y50.2200A
 - Roofing felt - reference Y50.2200B
 - Flat aluminium-zinc coated steel - reference Y50.2200C
 - Ribbed aluminium-zinc coated steel - reference Y50.2200D
 - Aluminium sheeting - reference Y50.2200E
 - Canvas - reference Y50.2200G
 - Canvas with aluminium bands - reference Y50.2200H
 - Reinforcement
- Protection for heat exchangers and other vessels
 - Aluminium
 - Reference Y50.2230A
 - With chest covers - reference Y50.2230B
 - Aluminium-zinc coated steel
 - Multi-layer laminate - reference Y50.2230E
- Mineral wool insulation for boiler flues
 - With aluminium casing - reference Y50.2240A
- Supply pre-insulated boiler flues
- Supply cylinder jackets
- Pumps and other irregular shapes - reference Y50.2280
- Thickness of insulation
 - Unless specified otherwise elsewhere, the thicknesses for flat surfaces or irregular shaped plant items shall not be less than that for the largest pipe size given in the thickness tables below
 - Insulation thickness calculation methods, Building Regulations - reference Y50.2286
 - Insulation thickness tables - reference Y50.2289
 - Non-domestic hot water supply services (Building Regulations)
 - Rock mineral wool - reference Y50.2290
 - Glass mineral wool - reference Y50.2295
 - Non-domestic heating installations (Building Regulations)
 - Rock mineral wool - reference Y50.2310
 - Glass mineral wool - reference Y50.2315
 - Domestic central heating and hot water systems, Building Regulations (rock mineral wool) - reference Y50.2330
 - Steam and condensate systems, mineral wool - reference Y50.2340
 - Cooled water supplies, Building Regulations and condensation control on cooled and cold water supplies rock mineral wool - reference Y50.2395
 - Protection against freezing
 - Mineral wool - reference Y50.2420
 - Phenolic foam - reference Y50.2430

- Nitrile rubber - reference Y50.2440
- Insulation thickness on ductwork, Building Regulations - reference Y50.2456
- Condensation control on chilled air ductwork
 - Rock mineral wool - reference Y50.2460
 - Phenolic foam - reference Y50.2470
 - Closed cell nitrile foam - reference Y50.2475
- Thickness of insulation to BS 5422 for process pipework and equipment- reference Y50.2490#.
- Thickness of insulation to BS 5422 for refrigeration pipework and equipment -reference Y50.2495#
- Thickness of insulation

250.090 WORKMANSHIP PIPEWORK INSULATION:

- General - reference Y50.3010
- Installation of foil faced mineral wool insulation - reference Y50.3020
- Installation of foil faced phenolic foam insulation - reference Y50.3030
- Installation of closed cell nitrile rubber insulation - reference Y50.3050
- Installation of protection
 - Polyisobutylene (PIB) - reference Y50.3120
 - Self-adhesive multi-layer laminate covering - reference Y50.3125
 - Sheet metal finish
 - Reference Y50.3130A
 - Canvas - reference Y50.3150
 - Roofing felt - reference Y50.3160
 - Aluminium sheeting - reference Y50.3170
 - Aluminium-zinc coated steel - reference Y50.3180
 - Rigid PVC - reference Y50.3190
- Flanges and valves - reference Y50.3210
- Installation where insulation is carried through pipeline support
 - Reference Y50.3230A
 - Closed cell insulation - reference Y50.3230B
- Liquid vapour barriers - reference Y50.3260
- Integrity of vapour barriers - reference Y50.3270

250.100 WORKMANSHIP DUCTWORK INSULATION:

- General - reference Y50.3010
- Installation of foil faced rigid or slotted slab insulation - reference Y50.3060
- Installation of foil faced flexible insulation - reference Y50.3070
- Installation of foil faced lamella insulation - reference Y50.3080
- Installation of protection
 - Polyisobutylene (PIB) - reference Y50.3120
 - Self-adhesive multi-layer laminate covering - reference Y50.3125.
 - Sheet metal finish
 - Reference Y50.3140A
 - Canvas - reference Y50.3150
 - Roofing felt - reference Y50.3160
 - Aluminium sheeting - reference Y50.3170
 - Aluminium-zinc coated steel - reference Y50.3180
 - Rigid PVC - reference Y50.3190
- Installation where insulation is carried through ductwork support - reference Y50.3250
- Liquid vapour barriers - reference Y50.3260
- Integrity of vapour barriers - reference Y50.3270

250.110 WORKMANSHIP EQUIPMENT INSULATION:

- General - reference Y50.3010
- Installation of insulation on tanks - reference Y50.3090
- Installation of mineral wool insulation on vessels - reference Y50.3100
- Installation of phenolic foam insulation on vessels - reference Y50.3110
- Installation of protection
 - Polyisobutylene (PIB) - reference Y50.3120
 - Self-adhesive multi-layer laminate covering - reference Y50.3125
 - Sheet metal finish
 - Reference Y50.3140A
 - Canvas - reference Y50.3150
 - Roofing felt - reference Y50.3160
 - Aluminium sheeting - reference Y50.3170
 - Aluminium-zinc coated steel - reference Y50.3180
 - Rigid PVC - reference Y50.3190
- Liquid vapour barriers - reference Y50.3260
- Integrity of vapour barriers - reference Y50.3270

251.000 TESTING AND COMMISSIONING OF MECHANICAL SERVICES**251.010 GENERAL:**

- Carry out testing and commissioning as specified in section SHTM 03-01

251.020 SPECIALIST:

- Use a commissioning specialist who is a member of The Commissioning Specialists Association (CSA).
- Or approved equivalent

251.030 STATIC TESTING:

- Carry out air pressure and leakage testing on air ductwork in accordance with specification section covering air ductlines and ancillaries.
- Carry out pressure / leakage testing of builders work air shafts, voids and floor plenums where they are used for supply ventilation - reference Y51.2015
- Pressure testing
 - General - reference Y51.2010
 - Hot and cold water supply systems, water circulating systems (LTHW, MTHW, HTHW, chilled and condenser water) and steam and condense lines - reference Y51.2020
 - Underground pipework
 - Test pre-insulated bonded steel pipe systems for district heating in accordance with BS EN 13941.
 - Test pre-insulated non bonded pipe systems in accordance with the system manufacturer's recommendations.
 - Test pre-insulated bonded flexible pipe systems in accordance with the system manufacturer's recommendations.
 - Underground cold water supply mains - reference Y51.2040
 - Fire risers - reference Y51.2050
 - Refrigerant pipework
 - Strength pressure test - reference Y51.2055A
 - Leak test - reference Y51.2055B
 - Deep vacuum test - reference Y51.2055C

- Gas pipework
 - Pressure testing - reference Y51.2060
- Oil pipework - reference Y51.2065
- Piped medical gases - reference Y51.2070
- Condense and overflow systems - reference Y51.2075
- Soil, waste, ventilation, anti-syphon and rainwater pipework - reference Y51.2080
- Underslab drainage - reference Y51.2090
- Vacuum testing - reference Y51.2100
- Provide an air compressor and subject the pipework to sectional testing by air at low pressure (not exceeding 0.5 bars) before commencing any flushing or testing with water.
- On completion of all cleaning, flushing and air testing operations, recharge each system with clean water and subject them to sectional hydraulic tests of one and a half times the working pressure.
- There is to be no loss of pressure for a period of not less than 30 minutes for each test.

251.040 COMMISSIONING:

- Commissioning codes - reference Y51.3020
- Commissioning
 - Water distribution
 - Including BSRIA pre-commissioning check list
 - Reference Y51.3030
 - Air distribution
 - Including BSRIA pre-commissioning check list
 - Reference Y51.3040
 - Automatic control systems - reference Y51.3070
- Instruments and gauges
 - Reference Y51.3090A
- Commissioning records
 - Distribution
 - For air systems
 - To BSRIA Guide BG 49/2015 - reference Y51.3100A
 - For water systems
 - To BSRIA Guide BG 2/2010 - reference Y51.3100B
- BMS commissioning
 - Control system specification details required for commissioning - reference Y51.3110
 - Pre-commissioning - reference Y51.3120
 - Plant ready for control system commissioning
 - Reference Y51.3130A
 - Control system requirements for plant commissioning - reference Y51.3140
 - Commissioning of building services as required by Scottish Technical Handbook Section 6.7.
 - Commissioning - reference Y51.3150

251.050 PERFORMANCE TESTING:

- System performance testing - reference Y51.4010
- Testing of residential ventilation systems - reference Y51.4015
- Where applicable, on ventilation facilities correct the measured air flow rate when ambient measuring conditions are different from standard conditions in accordance with PD CEN/TS 17153.
- Specific Fan Power Validation tests
 - After fitting clean filters, air handling systems to be commissioned under validation load. Measure the specific fan power SFP of each system for calculation of the building "as constructed" CO₂ emission rate.
 - Details

- Environmental tests for HVAC systems
 - Artificial loads - reference Y51.4020A
 - Ambient Air Quality - reference Y51.4020B
- Recorders - reference Y51.4030
 - Seven day space temperature recorders
 - Number
 - For (weeks) Two
 - Relative humidity recorders
 - Number
 - For (weeks) Two coils
-

252.000 VIBRATION ISOLATION MOUNTINGS

252.010 GENERAL:

- Comply with work section general clauses below
 - Design intent - reference Y52.1010
 - Spring anti vibration mountings - reference Y52.1020
 - Locking facility - reference Y52.1040
- Supply plant and pipework vibration isolation as schedule reference

252.020 MAT AND PAD MOUNTINGS:

- Duty
- Configured mat mountings
 - Neoprene/composite fibre/synthetic rubber
 - Reference Y52.2010A
 - Natural rubber - reference Y52.2010B
 - High temperature synthetic rubber
 - Reference Y52.2010C
- Resilient mat mountings
 - Cast in base - reference Y52.2010D
- Pad mountings
- Composite synthetic rubber - reference Y52.2010E

252.030 MOUNTINGS:

- Turret compression mountings
 - Synthetic rubber - reference Y52.2020A
 - Lockable facility - reference Y52.1040
 - Neoprene - reference Y52.2020B
 - Lockable facility - reference Y52.1040
- Spring compression mountings - reference Y52.2030
 - Lockable facility - reference Y52.1040
- Captive spring mountings - reference Y52.2040

252.040 EQUIPMENT HANGINGS:

- Spring compression hangers - reference Y52.2060
 - Lockable facility - reference Y52.1040
- Combined turret/spring compression hangers
 - Synthetic rubber - reference Y52.2070A

- Lockable facility - reference Y52.1040
- Neoprene - reference Y52.2070B
- Lockable facility - reference Y52.1040

252.050 PIPEWORK HANGERS:

- Spring compression hangers - reference Y52.2060
 - Lockable facility - reference Y52.1040
- Combined turret/spring compression hangers
 - Synthetic rubber - reference Y52.2070A
 - Lockable facility - reference Y52.1040
 - Neoprene - reference Y52.2070B
 - Lockable facility - reference Y52.1040

252.060 HORIZONTALLY RESTRAINED SPRING MOUNTINGS:

- Horizontally restrained spring mountings
 - Reference Y52.2080
 - Lockable facility - reference Y52.1040

252.070 INERTIA BASES:

- Manufacturer and reference.
- Reinforced concrete - reference Y52.2090A
 - Lockable facility - reference Y52.1040
- Welded steel frame - reference Y52.2090B
- Lockable facility - reference Y52.1040

252.080 VIBRATION ISOLATION HOSES:

- Vibration isolation hoses - reference Y52.2100
-

252.090 PIPEWORK NOISE VIBRATION ISOLATION:

- Natural corkwood - reference Y52.2110A
- Reconstituted corkwood granules - reference Y52.2110B
- Rubber matting - reference Y52.2110C

252.100 WORKMANSHIP:

- Horizontally restrained spring mountings - reference Y52.3040

252.110 PIPE, WALL AND RISER SEALS:

- Sponge foam packing - reference Y52.2120A
- Mineral fibre packing - reference Y52.2120B

254.000 IDENTIFICATION - MECHANICAL

254.010 GENERAL:

- Comply with work section general clauses below

- Requirements - reference Y54.1010
- New systems - reference Y54.1020
- Existing systems - reference Y54.1030
- Colours - reference Y54.1040
- Performance and durability - reference Y54.1045

254.020 PIPEWORK IDENTIFICATION:

- Reference Y54.2010

254.030 DUCTWORK IDENTIFICATION:

- Reference Y54.2020

254.040 PLANT AND EQUIPMENT IDENTIFICATION:

- Type Generally in line with current NHS GGC convention and Asset Registers
- Application Client to confirm exact details
 - Lettering
 - Laminated plates, multi-coloured with outer layer removed for lettering - reference Y54.2030B

254.045 GRAPHICAL SYMBOLS FOR USE ON EQUIPMENT IN ACCORDANCE WITH BS EN 80416:

- Reference Y54.2035

254.050 VALVE AND COCK IDENTIFICATION:

- Reference Y54.2040

254.070 LABORATORY OUTLETS:

- Type
- Application

254.080 AIR VOLUME REGULATING AND CONTROL DAMPER IDENTIFICATION:

- Reference Y54.2070

254.090 INSTRUMENT IDENTIFICATION:

- Reference Y54.2080

254.100 DANGER AND WARNING NOTICES:

- Reference Y54.2090

290.000 FIXING TO BUILDING FABRIC

290.010 GENERAL:

- Comply with work section general clauses below
 - Preparation - reference Y90.1010
 - Manufacturer's drawings - reference Y90.1020
 - Fixings - reference Y90.1030

- Loading details - reference Y90.1040
- Building-in by others - reference Y90.1050
- Size of fixing - reference Y90.1060
- Greasing of fixings - reference Y90.1070

290.020 FIXINGS:

- Standards - reference Y90.2010
- Plugs - reference Y90.2020
- Screws - reference Y90.2030
- Non-penetrative support systems - reference Y90.2080
 - Manufacturer and reference
 - Or approved equivalent.

290.030 WORKMANSHIP:

- Drilling - reference Y90.3010
- Fixing to timber rails - reference Y90.3050
- Fixing to hollow stud/tile/block wall
 - Reference Y90.3060A
- Fixing to concrete, brickwork or blockwork
 - Reference Y90.3070A
- Fixing to metalwork
 - Reference Y90.3080A
- Fixing to structural steelwork and concrete structures
 - Reference Y90.3090A
- Non-penetrative support systems for roof mounted equipment - reference Y90.3100#

291.000 OFF-SITE PAINTING AND ANTI-CORROSION TREATMENT

291.010 GENERAL

- Comply with work section general clauses below
 - General requirements - reference Y91.1010
- Damaged finishes - reference Y91.1020

291.020 PAINT MATERIALS:

- Paint materials
 - Reference Y91.2010A
- Paint quality - reference Y91.2020

291.030 WORKMANSHIP

- Weather and other conditions - reference Y91.3020
- Cleaning and preparing for painting
 - Steel surfaces - reference Y91.3030A
 - Surfaces - reference Y91.3030B
 - Reference Y91.3030#
- Application off-site - reference Y91.3040
- Application - reference Y91.3050
- Cold galvanizing - reference Y91.3060
- Protection of bright machine parts - reference Y91.3070

BS APPENDIX

BS 476-3:2004

Fire tests on building materials and structures. Part 3 Classification and method of test for external fire exposure to roofs

BS 476-4:1970

Fire tests on building materials and structures. Part 4 Non-combustibility test for materials

BS 476-6:1989+A1:2009

Fire tests on building materials and structures. Part 6 Method of test for fire propagation for products

BS 476-7:1997

Fire tests on building materials and structures. Part 7 Method of test to determine the classification of the surface spread of flame of products

BS 476-10:2009

Fire tests on building materials and structures. Part 10 Guide to principles, selection, role and application of fire testing and their outputs

BS 476-11:1982

Fire tests on the building materials and structures. Part 11 Method for assessing the heat emission from building materials

BS 476-12:1991

Fire tests on building materials and structures. Part 12 Method of test for ignitability of products by direct flame impingement

BS 476-13:1987, ISO 5657:1986

Fire tests on building materials and structures. Part 13 Method of measuring the ignitability of products subjected to thermal irradiance

BS 476-20:1987

Fire tests on building materials and structures. Part 20 Method for determination of the fire resistance of elements of construction (general principles)

BS 476-20:1987

Fire tests on building materials and structures. Part 20 Method for determination of the fire resistance of elements of construction (general principles)

BS 476-21:1987

Fire tests on building materials and structures. Methods for determination of the fire resistance of loadbearing elements of construction

BS 476-22:1987

Fire tests on building materials and structures. Part 22 Method for determination of the fire resistance of non-loadbearing elements of construction

BS 476-24:1987, ISO 6944:1985

Fire tests on building materials and structures. Part 24 Method for determination of the fire resistance of ventilation ducts

BS 476-31.1:1983

Fire tests on building materials and structures. Part 31.1 Methods for measuring smoke penetration through doorsets and shutter assemblies. Method of measurement under ambient temperature conditions

BS 476-32:1989

Fire tests on building materials and structures. Part 32 Guide to full scale fire tests within buildings

BS 476-33:1993, ISO 9705:1993

Fire tests on building materials and structures. Part 33 Full-scale room test for surface products

BS 2767:1991

Specification for manually operated copper alloy valves for radiators

BS 2879:1980

Specification for draining taps (screw-down pattern)

BS 4825-1:1991+A2:2009

Stainless steel tubes and fittings for the food industry and other hygienic applications. Part 1 Specification for tubes

Partially replaced by BS EN 10357:2013

BS 4825-2:1991+A2:2009

Stainless steel tubes and fittings for the food industry and other hygienic applications. Part 2 Specification for bends and tees

BS 4825-3:1991+A2:2009

Stainless steel tubes and fittings for the food industry and other hygienic applications. Part 3 Specification for clamp type couplings

BS 4825-4:1991+A1:2009

Stainless steel tubes and fittings for the food industry and other hygienic applications. Part 4 Specification for threaded (IDF type) coupling

BS 4825-5:1991+A1:2009

Stainless steel tubes and fittings for the food industry and other hygienic applications. Part 5 Specification for recessed ring joint type couplings

BS 5154:1991

Specification for copper alloy globe, globe stop and check, check and gate valves.

Partially replaced by BS EN 12288

BS 5163-1:2004

Valves for waterworks purposes. Part 1 Predominantly key-operated cast iron gate valves. Code of practice

BS 5163-2:2004

Valves for waterworks purposes. Part 2 Stem caps for use on isolating valves and associated water control apparatus. Specification

BS 5422:2009

Method for specifying thermal insulating materials for pipes, tanks, vessels, ductwork and equipment operating within the temperature range -40°C to +700°C

BS 6675:1986

Specification for servicing valves (copper alloy) for water services

BS 7350:1990

Specification for double regulating globe valves and flow measurement devices for heating and chilled water systems

BS 9999:2017

Fire safety in the design, management and use of buildings. Code of practice

BS EN 215-1:1991

Thermostatic radiator valves. Part 1 Requirements and test methods

BS EN 215:2004

Thermostatic radiator valves. Requirements and test methods

BS EN 331:2015

Manually operated ball valves and closed bottom taper plug valves for gas installations for buildings

BS EN 558:2017

Industrial valves. Face-to-face and centre-to-face dimensions of metal valves for use in flanged pipe systems. PN and Class designated valves

BS EN 593:2017

Industrial valves. Metallic butterfly valves for general purposes.

BS EN 736-1:2018

Valves. Terminology. Definition of types of valves

BS EN 736-2:2016

Valves. Terminology. Definition of components of valves

BS EN 1074-1:2000

Valves for water supply. Fitness for purpose requirements and appropriate verification tests. General requirements

BS EN 1074-1:2000

Valves for water supply. Fitness for purpose requirements and appropriate verification tests. General requirements

BS EN 1074-2:2000

Valves for water supply. Fitness for purpose requirements and appropriate verification tests. Isolating valves

BS EN 1074-2:2000

Valves for water supply. Fitness for purpose requirements and appropriate verification tests. Isolating valves

BS EN 1074-3:2000

Valves for water supply. Fitness for purpose requirements and appropriate verification tests. Check valves

BS EN 1074-4:2000

Valves for water supply. Fitness for purpose requirements and appropriate verification tests. Air valves

BS EN 1074-5:2001

Valves for water supply. Fitness for purpose requirements and appropriate verification tests. Control valves

BS EN 1074-6:2008

Valves for water supply. Fitness for purpose requirements and appropriate verification tests. Hydrants

BS EN 1092-1:2018

Flanges and their joints. Circular flanges for pipes, valves, fittings and accessories, PN designated. Part 1 steel flanges

BS EN 1092-2:1997

Flanges and their joints. Circular flanges for pipes, valves, fittings and accessories, PN designated. Part 2 cast iron flanges

BS EN 1092-3:2003

Flanges and their joints. Circular flanges for pipes, valves, fittings and accessories, PN designated. Part 3 copper alloy flanges

BS EN 1092-4:2002

Flanges and their joints. Circular flanges for pipes, valves, fittings and accessories, PN designated. Part 4 aluminium alloy flanges

BS EN 1171:2015

Industrial valves. Cast iron gate valves

BS EN 1213:2000

Building valves. Copper alloy stopvalves for potable water supply in buildings. Tests and requirements

BS EN 1254-2:1998

Copper and copper alloys. Plumbing fittings. Part 2 fittings with compression ends for use with copper tubes

BS EN 1254-3:1998

Copper and copper alloys. Plumbing fittings. Part 3 Fittings with compression ends for use with plastics pipes

BS EN 1363-1:2012

Fire resistance tests. General requirements

BS EN 1366-1:2014

Fire resistance tests for service installations. Ventilation ducts

BS EN 1366-1:2014

Fire resistance tests for service installations. Ventilation ducts

BS EN 1366-2:2015

Fire resistance tests for service installations. Part 2 Fire dampers

BS EN 1366-3:2009

Fire resistance tests for service installations. Penetration seals

BS EN 1366-3:2009

Fire resistance tests for service installations. Penetration seals

BS EN 1366-4:2006+A1:2010

Fire resistance tests for service installations. Linear joint seals

BS EN 1366-4:2006+A1:2010

Fire resistance tests for service installations. Linear joint seals

BS EN 1366-5:2010

Fire resistance tests for service installations. Service ducts and shafts

BS EN 1366-6:2004

Fire resistance tests for service installations. Part 6 Raised access and hollow core floors

BS EN 1366-7:2004

Fire resistance tests for service installations. Part 7 Conveyor systems and their closures

BS EN 1366-8:2004

Fire resistance tests for service installations. Part 8 Smoke extraction ducts

BS EN 1366-8:2004

Fire resistance tests for service installations. Part 8 Smoke extraction ducts

BS EN 1366-9:2008

Fire resistance tests for service installations. Single compartment smoke extraction ducts

BS EN 1366-9:2008

Fire resistance tests for service installations. Single compartment smoke extraction ducts

BS EN 1366-10:2011+A1:2017

Fire resistance tests for service installations. Part 10 Smoke control dampers

BS EN 1366-12:2014

Fire resistance tests for service installations. Non-mechanical fire barrier for ventilation ductwork

BS EN 1434-1:2015+A1:2018

Thermal energy meters. General requirements

BS EN 1434-1:2015+A1:2018

Thermal energy meters. General requirements

BS EN 1434-2:2015+A1:2018

Thermal energy meters. Constructional requirements

BS EN 1434-2:2015+A1:2018

Thermal energy meters. Constructional requirements

BS EN 1434-3:2015

Heat Meters. Data exchange and interfaces

BS EN 1434-3:2015

Heat Meters. Data exchange and interfaces

BS EN 1434-4:2015+A1:2018

Thermal energy meters. Pattern approval tests

BS EN 1434-4:2015+A1:2018

Thermal energy meters. Pattern approval tests

BS EN 1434-5:2015+A1:2019

Thermal energy meters. Initial verification tests

BS EN 1434-5:2015+A1:2019

Thermal energy meters. Initial verification tests

BS EN 1434-6:2015+A1:2019

Thermal energy meters. Installation, commissioning, operational monitoring and maintenance

BS EN 1434-6:2015+A1:2019

Thermal energy meters. Installation, commissioning, operational monitoring and maintenance

BS EN 1984:2010

Industrial valves. Steel gate valves

BS EN 10143:2006

Continuously hot-dip coated steel sheet and strip. Tolerances on dimensions and shape

BS EN 10216-1:2013

Seamless steel tubes for pressure purposes. Technical delivery conditions. Part 1 Non-alloy steel tubes with specified room temperature properties

BS EN 10216-1:2013

Seamless steel tubes for pressure purposes. Technical delivery conditions. Part 1 Non-alloy steel tubes with specified room temperature properties

BS EN 10216-2:2013

Seamless steel tubes for pressure purposes. Technical delivery conditions. Part 2 Non-alloy and alloy steel tubes with specified elevated temperature properties

BS EN 10216-2:2013

Seamless steel tubes for pressure purposes. Technical delivery conditions. Part 2 Non-alloy and alloy

steel tubes with specified elevated temperature properties

BS EN 10216-3:2013

Seamless steel tubes for pressure purposes. Technical delivery conditions. Part 3 Alloy fine grain steel tubes

BS EN 10216-3:2013

Seamless steel tubes for pressure purposes. Technical delivery conditions. Part 3 Alloy fine grain steel tubes

BS EN 10216-4:2013

Seamless steel tubes for pressure purposes. Technical delivery conditions. Part 4 Non-alloy and alloy steel tubes with specified low temperature properties

BS EN 10216-4:2013

Seamless steel tubes for pressure purposes. Technical delivery conditions. Part 4 Non-alloy and alloy steel tubes with specified low temperature properties

BS EN 10216-5:2013

Seamless steel tubes for pressure purposes. Technical delivery conditions. Part 5 Stainless steel tubes

BS EN 10216-5:2013

Seamless steel tubes for pressure purposes. Technical delivery conditions. Part 5 Stainless steel tubes

BS EN 10217-1:2002

Welded steel tubes for pressure purposes. Technical delivery conditions. Part 1 Non-alloy steel tubes with specified room temperature properties

BS EN 10217-1:2002

Welded steel tubes for pressure purposes. Technical delivery conditions. Part 1 Non-alloy steel tubes with specified room temperature properties

BS EN 10217-2:2002+A1:2005

Welded steel tubes for pressure purposes. Technical delivery conditions. Part 2 Electric welded non-alloy and alloy steel tubes with specified elevated temperature properties

BS EN 10217-2:2002+A1:2005

Welded steel tubes for pressure purposes. Technical delivery conditions. Part 2 Electric welded non-alloy and alloy steel tubes with specified elevated temperature properties

BS EN 10217-3:2002

Welded steel tubes for pressure purposes. Technical delivery conditions. Part 3 Alloy fine grain steel tubes

BS EN 10217-3:2002

Welded steel tubes for pressure purposes. Technical delivery conditions. Part 3 Alloy fine grain steel tubes

BS EN 10217-4:2002

Welded steel tubes for pressure purposes. Technical delivery conditions. Part 4 Electric welded non-alloy steel tubes with specified low temperature properties

BS EN 10217-4:2002

Welded steel tubes for pressure purposes. Technical delivery conditions. Part 4 Electric welded non-alloy steel tubes with specified low temperature properties

BS EN 10217-5:2002

Welded steel tubes for pressure purposes. Technical delivery conditions. Part 5 Submerged arc welded non-alloy and alloy steel tubes with specified elevated temperature properties

BS EN 10217-5:2002

Welded steel tubes for pressure purposes. Technical delivery conditions. Part 5 Submerged arc welded non-alloy and alloy steel tubes with specified elevated temperature properties

BS EN 10217-6:2002

Welded steel tubes for pressure purposes. Technical delivery conditions. Part 6 Submerged arc welded non-alloy steel tubes with specified low temperature properties

BS EN 10217-6:2002

Welded steel tubes for pressure purposes. Technical delivery conditions. Part 6 Submerged arc welded non-alloy steel tubes with specified low temperature properties

BS EN 10217-7:2014

Welded steel tubes for pressure purposes. Technical delivery conditions. Part 7 Stainless steel tubes

BS EN 10217-7:2014

Welded steel tubes for pressure purposes. Technical delivery conditions. Part 7 Stainless steel tubes

BS EN 10226-1:2004

Pipe threads where pressure tight joints are made on the threads. Taper external threads and parallel internal threads. Part 1 dimensions, tolerances and designation

BS EN 10226-2:2005

Pipe threads where pressure tight joints are made on the threads. Taper external threads and taper internal threads. Dimensions, tolerances and designation

BS EN 10226-3:2005

Pipes threads where pressure-tight joints are made on the threads. Verification by means of limit gauges

BS EN 10253-1:1999

Butt-welding pipe fittings. Part 1 Wrought carbon steel for general use and without specific inspection requirements

BS EN 10253-2:2007

Butt-welding pipe fittings. Part 2 Non alloy and ferritic alloy steels with specific inspection requirements

BS EN 10253-3:2008

Butt-welding pipe fittings. Wrought austenitic and austenitic-ferritic (duplex) stainless steels without specific inspection requirements

BS EN 10253-4:2008

Butt-welding pipe fittings. Wrought austenitic and austenitic-ferritic (duplex) stainless steels with specific inspection requirements

BS EN 10255:2004

Non-alloy steel tubes suitable for welding and threading. Technical delivery conditions

BS EN 10312:2002

Welded stainless steel tubes for the conveyance of aqueous liquids including water for human consumption. Technical delivery conditions

BS EN 10346:2015

Continuously hot-dip coated steel flat products for cold forming. Technical delivery conditions

BS EN 12101-3:2015

Smoke and heat control systems. Specification for powered smoke and heat control ventilators (Fans)

BS EN 12101-7:2011

Smoke and heat control systems. Part 7 Smoke duct sections

BS EN 12101-8:2011

Smoke and heat control systems. Part 8 Smoke control dampers

BS EN 12266-1:2012

Industrial valves. Testing of valves. Pressure tests, test procedures and acceptance criteria. Mandatory requirements

BS EN 12266-2:2012

Industrial valves. Testing of metallic valves. Tests, test procedures and acceptance criteria. Supplementary requirements

BS EN 13190:2001

Thermal insulation products for buildings. Factory made products of phenolic foam (PF). Specification

BS EN 13501-2:2016

Fire classification of construction products and building elements. Classification using data from fire resistance tests, excluding ventilation services

BS EN 13501-3:2005+A1:2009

Fire classification of construction products and building elements. Part 3 Classification using data from fire resistance tests on products and elements used in building service installations: fire resisting ducts and fire dampers

BS EN 13501-4:2016

Fire classification of construction products and building elements. Classification using data from fire resistance tests on components of smoke control systems

BS EN 13547:2013

Industrial valves. Copper alloy ball valves

BS EN 13618:2016

Flexible hose assemblies in drinking water installations. Functional requirements and test methods

BS EN 13709:2010

Industrial valves. Steel globe and globe stop and check valves

BS EN 13789:2010

Industrial valves. Cast iron globe valves

BS EN 13828:2003

Building valves. Manually operated copper alloy and stainless steel ball valves for potable water supply in buildings. Tests and requirements

BS EN 13941:2009+A1:2010

Design and installation of pre-insulated bonded pipe systems for district heating

BS EN 14303:2015

Thermal insulation products for building equipment and industrial installations. Factory made mineral wool products (MW). Specification.

BS EN 14451:2005

Devices to prevent pollution by backflow of potable water. In-line anti-vacuum valves DN 8 to DN 80. Family D, type A

BS EN 14585-1:2006

Corrugated metal hose assemblies for pressure applications. Requirements

BS EN 15780:2011

Ventilation for buildings. Ductwork. Cleanliness of ventilation systems

BS EN 16668:2016+A1:2018

Industrial valves. Requirements and testing for metallic valves as pressure accessories

BS EN 16767:2016

Industrial valves. Steel and cast iron check valves

BS EN 60034-5:2001

Rotating electrical machines. Part 5 Degrees of protection provided by the integral design of rotating electrical machines (IP code). Classification

BS EN 60034-6:1994, IEC 60034-6:1991

Rotating electrical machines. Part 6 Methods of cooling (IC Code)

BS EN 60038:2011

CENELEC standard voltages

BS EN 60534-1:2005

Industrial-process control valves. Control valve terminology and general considerations

BS EN 60534-2-1:2011

Industrial-process control valves. Flow capacity. Sizing equations for fluid flow under installed conditions

BS EN 60534-2-3:2016

Industrial-process control valves. Flow capacity. Test procedures

BS EN 60534-2-4:2009

Industrial-process control valves. Flow capacity. Inherent flow characteristics and rangeability

BS EN 60534-2-5:2003

Industrial-process control valves. Flow capacity. Sizing equations for fluid flow through multistage control valves with interstage recovery

BS EN 60534-3-1:2000, IEC 60534-3-1:2000

Industrial-process control valves. Dimensions. Face-to-face dimensions for flanged, two-way, globe-type, straight pattern and centre-to-face dimensions for flanged, two-way, globe-type, angle pattern control valves

BS EN 60534-3-2:2001, IEC 60534-3-2:2001

Industrial-process control valves. Dimensions. Face-to-face dimensions for rotary control valves except

butterfly valves

BS EN 60534-3-3:1998, IEC 60534-3-3:1998

Industrial-process control valves. Dimensions. End-to-end dimensions for butt-weld, two-way, globe-type, straight pattern control valves

BS EN 60534-4:2006

Industrial-process control valves. Inspection and routine testing

BS EN 60534-5:2004

Industrial-process control valves. Marking

BS EN 60534-6-1:1998, IEC 60534-6-1:1997

Industrial-process control valves. Mounting details for attachment of positioners to control valves. Positioner mounting on linear actuators

BS EN 60534-6-2:2001, IEC 60534-6-2:2000

Industrial-process control valves. Mounting details for attachment of positioners to control valves. Positioner mounting on rotary actuators

BS EN 60534-7:2010

Industrial-process control valves. Control valve data sheet

BS EN 60534-8-1:2005

Industrial-process control valves. Noise considerations. Laboratory measurement of noise generated by aerodynamic flow through control valves

BS EN 60534-8-2:2011

Industrial-process control valves. Noise considerations. Laboratory measurement of noise generated by hydrodynamic flow through control valves

BS EN 60534-8-3:2011

Industrial-process control valves. Noise considerations. Control valve aerodynamic noise prediction method

BS EN 60534-8-4:2015

Industrial-process control valve. Noise considerations. Prediction of noise generated by hydrodynamic flow

BS EN 60534-9:2007

Industrial-process control valves. Test procedure for response measurements from step inputs

BS EN 61770:2009+A11:2018

Electric appliances connected to the water mains. Avoidance of backsiphonage and failure of hose-sets

BS EN 62262:2002

Degrees of protection provided by enclosures for electrical equipment against external mechanical impacts (IK code)

BS EN 80416-1:2009

Basic principles for graphical symbols for use on equipment. Part 1 Creation of symbol originals

BS EN 80416-2:2001

Basic principles for graphical symbols for use on equipment. Part 2 Form and use of arrows

BS EN 80416-3:2002+A1:2011

Basic principles for graphical symbols for use on equipment. Part 3 Guidelines for the application of graphical symbols

BS EN ISO 228-1:2003

Pipe threads where pressure-tight joints are not made on the threads. Part 1 Dimensions, tolerances and designation

BS EN ISO 5135:1999

Acoustics. Determination of sound power levels of noise from air-terminal devices, air-terminal units, dampers and valves by measurement in a reverberation room

BS EN ISO 6134:2017

Rubber hoses and hose assemblies for saturated steam. Specification

BS EN ISO 9001:2015

Quality management systems. Requirements

BS ISO 5208:2015

Industrial valves. Pressure testing of metallic valves

BS ISO 7121:2016

Steel ball valves for general-purpose industrial applications

BS ISO 9393-1:2004

Thermoplastics valves for industrial applications. Pressure test methods and requirements. General

ISO 7-1:1994

Pipe threads where pressure-tight joints are made on the threads. Part 1 Dimensions, tolerances and designation

T - COOLING DISTRIBUTION

PRIMARY / SECONDARY COOLING DISTRIBUTION

PART 1 SYSTEM OBJECTIVES

100.010 PERFORMANCE OBJECTIVES

- New Chilled Water Distribution System – Reference (55) Series Drawings.38

100.011 PERFORMANCE OBJECTIVES

The purpose of this specification is that the primary/secondary cooling distribution systems, plant and equipment provided in compliance with it, will deliver the whole hospital engineering design philosophies and be compliant with all Department of Health (NHS Estates) documentation including, but not limited to SHTM's and SHBN's pertinent to the nature of the project.

100.030 SYSTEM DESCRIPTION

- Alteration and extension to existing systems as required to allow for new Chilled Water Distribution systems as required for the project

100.060 SYSTEM DRAWINGS

Refer to the (55) Series Drawings

PART 2 SELECTION SCHEDULES FOR REFERENCE SPECIFICATIONS

210.000 PIPELINES AND PIPEWORK

210.010 GENERAL:

- Comply with work section general clauses below
 - prefabricated pipework - reference Y10.1010
- Fire stopping
 - All components forming the seal system, to be from the same manufacturer
 - Comply with BS 9999, relevant approved technical guidance to Building Regulations and BESA Technical Bulletin TB/032
 - Provide proprietary penetration seal system. All products used, to have third party product certification by a scheme accredited by UKAS.
 - Type
 - Stone mineral wool, soft seal type lamella strip with a proprietary flexible coating, used in conjunction with acoustic intumescent sealant and/or high expansion intumescent sealant to suit the application. For use in all applications including where movement of services needs to be accommodated. Tested and assessed to BS EN 1366-3 and BS EN 1366-4 and classified to BS EN 13501-2.
 - Stone mineral wool ablative coated batt seal with a proprietary flexible coating, used in conjunction with acoustic intumescent sealant and/or high expansion intumescent sealant to suit the application. Tested and assessed to BS EN 1366-3.
 - All services passing through apertures in masonry walls/concrete floors or drywall partitions/systems.
 - Fire resistance
 - 2 hrs.
- Only use UKAS accredited, third party installer certified specialist contractors. The specialists should

be ASFP members and their certification must cover the passive fire protection element they are installing.

- Install all fire stopping systems in accordance with the manufacturer's written instructions and the test / assessment / certification evidence provided by the installer / manufacturer of the penetration seal.
- Support centres for services passing through penetration seals serving fire barriers to be the same as those covered by the test / assessment / certification evidence provided by the installer / manufacturer of the penetration seal.
- Install and inspect fire stopping systems in accordance with Building Regulations Approved Document B, ASFP Code of Practice TGD 17 and the general best practice guidance given in the ASFP On-site guide to installing fire-stopping.

210.020 CARBON STEEL PIPES AND FITTINGS:

- Welded carbon steel tubes
 - To BS EN 10225, heavy, black - reference Y10.2010A
 - Size - nominal diameter (DN) up to and including 150mm.
 - Size - nominal diameter (DN)
 - To BS EN 10225, medium, black - reference Y10.2010B
 - Size - nominal diameter (DN) up to and including 150mm.
 - Size - nominal diameter (DN)
 - To BS EN 10217-1 - reference Y10.2050
 - Size - nominal diameter (DN) 200mm and above.
 - Size - nominal diameter (DN)
 - Wall thickness - to be suitable for the application duty / testing requirements.
 - Wall thickness
 - Joints - up to and including 50mm - screwed.
 - Joints - up to and including 50mm - welded and flanged.
 - Joints - 65mm and above - welded and flanged.
 - Heavy black, grooved ends to BS EN 10255 - reference Y10.2010E
 - Medium, black, grooved ends to BS EN 10255 - reference Y10.2010F
 - Medium, galvanized, grooved ends - reference Y10.2010H
- Seamless carbon steel tubes
 - To BS EN 10225, heavy, black - reference Y10.2010A
 - Size - nominal diameter (DN) up to and including 150mm.
 - Size - nominal diameter (DN)
 - To BS EN 10225, medium, black - reference Y10.2010B
 - Size - nominal diameter (DN) up to and including 150mm.
 - Size - nominal diameter (DN)
 - To BS EN 10216-1 - reference Y10.2030
 - Size - nominal diameter (DN) 200mm and above.
 - Size - nominal diameter (DN)
 - Wall thickness - to be suitable for the application duty / testing requirements.
 - Wall thickness
 - Joints - up to and including 50mm - screwed.
 - Joints - up to and including 50mm - welded and flanged.
 - Joints - 65mm and above - welded and flanged.
 - Joints - grooved ends for mechanical joints.
 - Carbon steel pipes for push-fit and press-fit systems
- Light gauge galvanised - reference Y10.2012A
- Butt welding carbon steel fittings.
 - To BS EN 10253-1 for general use without specific inspection requirements - reference Y10.2060A
 - To BS EN 10253-2 with specific inspection requirements for use on applications covered by the Pressure Equipment (Safety) Regulations 2016 - reference Y10.2060B
- Malleable cast iron fittings, screwed

- Black - reference Y10.2070A
- Galvanised - reference Y10.2070B
- Steel threaded pipe fittings
 - Type
 - Seamless fittings manufactured from seamless tube, forging or rolled bar.
 - Fabricated fittings manufactured from welded tube or where welding forms part of the fabrication of the fitting.
 - Reference Y10.2090
 - Fittings, grooved for mechanical joints
 - Galvanised cast iron - reference Y10.2080E
 - Painted steel - reference Y10.2080F
 - Special materials
- Jointing materials
 - Circular flanges
 - Flanges to BS EN 1092-1 and BS ISO 7005-1
 - PN
 - Class
 - Welding flanges - reference Y10.3010A
 - Screwed flanges - reference Y10.3010B
 - Jointing rings for circular flanges
 - Non-metallic flat for flanges to BS EN 1092-1 - reference Y10.3020A
 - Metallic for flanges to BS EN 1092-1 - reference Y10.3020B
 - Screwed joints to relevant parts of BS EN 10226
 - Paste and hemp and PTFE tape - reference Y10.3030A
 - PTFE tape - reference Y10.3030B
 - Where chemical cleaning is required - reference Y10.3030C
 - Union connections
 - Railroad pattern - spherical seating bronze to iron.
 - Navy pattern - spherical seating bronze to bronze.
 - Welding rods
 - Reference Y10.3050A

210.060 OTHER PIPES AND FITTINGS:

210.080 GENERAL WORKMANSHIP:

- Appearance - reference Y10.4010
- Spacing - reference Y10.4020
- Gradients - reference Y10.4030
- Air venting requirements
 - Air bottles - reference Y10.4040A
 - Automatic air vents - reference Y10.4040B
- Drain requirements - reference Y10.4050
- Expansion and contraction - reference Y10.4060
- Pipe fittings
 - Bends/swept tees - reference Y10.4070A
 - Elbows/square tees - reference Y10.4070B
- Pipes through walls and floors - reference Y10.4110
- Protect pipework penetrating fire separating elements in accordance with, Building Regulations, BS 9999 and BESA Technical Bulletin TB/032.
- Pipe sleeves
 - Reference Y10.4120A
 - Insulation carried through - reference Y10.4120B
- Pipe through fire barriers - reference Y10.4125

- Type
 - Proprietary sleeves
 - Ablative coated batt type
- Fire resistance
 - 2 hours
 - hrs
- Connect to equipment.
- Use distribution headers.
- Temporary plugs, caps and flanges
 - Reference Y10.4150A.
- Flanged joints general - reference Y10.4160
- Dissimilar metals - reference Y10.4170
- Pipe rings and clips - reference Y10.4180
 - Anchors - reference Y10.4190
- Pipe supports - reference Y10.4205
 - Comply with the manufacturers' installation recommendations for the following proprietary pipe systems:
 -
- Isolation and regulation
 - Reference Y10.4230A
- Maintenance and renewal - reference Y10.4240
- Clean by removing cement and clean off all pipework and brackets.
- Non-ferrous components - thoroughly clean and degrease.
- Pipe collars (closers) for plastic pipes where they pass through fire resistant walls and floors.
 - Type
 - Stainless steel collar with fixing brackets with intumescent liner.
 - Pre-assembled wrap for casing within concrete floor or masonry wall.
 - Fire resistance
 - 2 hrs
 - Installation to be in accordance with the manufacturer's instructions and grouted/sealed using the manufacturer's proprietary compound/sealant.
 - Standards
 - Test to BS EN 1366-3 and BS EN 1363-1.
 - Test to BS 476-20.

210.090 WORKMANSHIP, STEEL PIPEWORK:

- Welding, general
 - Class 1 - reference Y10.5010A
 - Class 2 - reference Y10.5010B
- Welded joints - reference Y10.5020
- Painting welded joints - reference Y10.5030
- Flanged joints - reference Y10.5040
- Screwed joints - reference Y10.5050
- Mechanical joints - reference Y10.5060
- Anchors
 - U-bolts - reference Y10.5070A
- Flanges - reference Y10.5070B
- Pipework painting - reference Y10.5090
- Installation of stainless steel pipework
 - Compression joints - reference Y10.5100
 - Mechanical joints - Y10.5060

211.000 PIPELINE ANCILLARIES**211.010 GENERAL:**

- Comply with work section general clauses below
 - Safety and relief valves, bursting discs, self-operated, application and standards - reference Y11.1010
- For applicable valves comply with BS EN 16668 for all essential safety requirements of the Pressure Equipment (Safety) Regulations 2016. Valves excluded from conformance to this standard in the Regulations shall meet "sound engineering practice" by conformity to the relevant product standard.
- Face to face and centre to face dimension of PN and Class designated flanged metal valves to be in accordance with BS EN 558
- In addition to the particular valve type standard, valves to be used in, or connected to, water supply pipe systems, above or below ground carrying water intended for human consumption to comply with the relevant parts of BS EN 1074 and BS 5163 as appropriate to the application.
 - BS EN 1074-1 - General requirements
 - BS EN 1074-2 - Isolating valves
 - BS EN 1074-3 - Check valves
 - BS EN 1074-4 - Air valves
 - BS EN 1074-5 - Control valves
 - BS EN 1074-6 - Hydrants
- Valves and components of valves specified are as defined in BS EN 736-1 and BS EN 736-2.
- Testing of valves
 - Pressure test metallic valves at manufacturer's works, in accordance with BS EN 12266-1 or BS ISO 5208 in conjunction with given specific requirements of the valve product or performance standard.
 - Undertake supplementary tests below in accordance with BS EN 12266-2 in conjunction with given specific requirements of the valve product or performance standard
 - Obturator strength
 - Back seat tightness
 - Operability
 - Anti-static design at 12V
 - Anti-static design at 100V
 - Fire tested design
- Flow resistance

211.030 STOP VALVES:

- Service fluid
- Water
- PN to suit system maximum working pressure.
- WRAS approved for water services applications.
- Comply with BS EN 1074-1 and BS EN 1074-2 in addition to the particular valve type standard, for valves for water supply applications carrying water for human consumption.
- Kitemark certified.
- Pipe material
 - To suit copper tube.
 - To suit plastic tube.
 - To suit steel tube.
- Copper alloy globe type stop valves (stop cocks) to BS EN 1213 for potable water supplies
 - Compression ends for copper - reference Y11.2015A
 - Compression ends for plastics - reference Y11.2015B
 - Capillary - reference Y11.2015C
 - Threaded - reference Y11.2015D
- Copper alloy gate valves for general use to BS 5154
 - Screwed to BS EN ISO 228-1, or ISO 7-1 - reference Y11.2020A
 - Compression to BS EN 1254-2 - reference Y11.2020B

- Flanged to BS EN 1092-3 - reference Y11.2020C
- Loose nut/union end - reference Y11.2020D
- Cast iron gate valves for general use to BS EN 1171
 - Grey cast iron flanged to BS EN 1092-2 - reference Y11.2030A
- Copper alloy globe valves for general use to BS 5154
 - Screwed to relevant parts of BS EN 10226 - reference Y11.2040A
 - Flanged to BS EN 1092-3 - reference Y11.2040B
 - Compression to BS EN 1254-2 - reference Y11.2040C
 - Compression to BS EN 1254-3 - reference Y11.2040D
- Cast iron globe valves for general use to BS EN 13789
 - Grey cast iron flanged to BS EN 1092-2 - reference Y11.2050A
- Steel parallel slide for steam and other high temperature / pressure applications to BS EN 1984
 - Reference Y11.2060A
- Steel wedge type gate valve for general use to BS EN 1984
 - Flanged to BS EN 1092-1 - reference Y11.2070A
 - Threaded - reference Y11.2070D
 - Auxiliary connections
- Ball valves
 - Application, standard and material
 - Potable water - copper alloy to BS EN 13828, PN 10 and distribution temperature of 65 °C with occasional excursions up to 90 °C permitted for a period of 1 hour maximum.
 - General purpose heating, cooling and other applications - copper alloy to BS EN 13547.
 - Steam and high temperature / pressure applications - steel to BS ISO 7121 - reference Y11.2160#.
 - Gas - to BS EN 331.
 - Screw driver/key operated
 - Screwed to relevant parts of BS EN 10226 - reference Y11.2080A
 - Compression to BS EN 1254-2 - reference Y11.2080B
 - Lever operated
 - Screwed to relevant parts of BS EN 10226 - reference Y11.2080C
 - Compression to BS EN 1254-2 - reference Y11.2080D
 - Lockshield
 - Screwed to relevant parts of BS EN 10226 - reference Y11.2080E
 - Compression to BS EN 1254-2 - reference Y11.2080F
- Servicing valves, for water services for maintenance of fittings / appliances, copper alloy to BS 6675
 - Handwheel operated
 - Screwed ends - reference Y11.2085A
 - Compression ends - reference Y11.2085B
 - Capillary ends - reference Y11.2085C
 - Lever operated
 - Screwed ends - reference Y11.2085D
 - Compression ends - reference Y11.2085E
 - Capillary ends - reference Y11.2085F
 - Screw driver operated
 - Screwed ends - reference Y11.2085G
 - Compression ends - reference Y11.2085H
 - Capillary ends - reference Y11.2085I
- Butterfly valves for general use to BS EN 593
 - Semi-lugged between flanges to BS EN 1092-2
 - Lever operated - reference Y11.2090A
 - Gear operated - reference Y11.2090B
 - Between mechanical joints
 - Lever operated - reference Y11.2090C
 - Gear operated - reference Y11.2090D

- Fully-lugged to BS EN 593 - reference Y11.2090E
 - Lever operated.
- Gear operated.
- Cast iron gate type for waterworks purposes to relevant parts of BS 5163
- Key operated type A - reference Y11.2110A
- Closed bottom taper plug valves for gas installations for buildings to BS EN 331.

211.040 REGULATING VALVES:

- Service fluid
- Water
- WRAS approved.
- Kitemark certified.
 - Pipe material
- To suit steel tube.

211.050 DOUBLE REGULATING VALVES:

- Service fluid
- Water
- WRAS approved.
- Kitemark certified.
 - Pipe material
 - To suit steel tube.
- Butterfly type to BS EN 593
 - Between flanges to BS EN 1092-2
 - Lever operated - reference Y11.2210A
 - Gear operated - reference Y11.2210B
 - Between mechanical joints
 - Lever operated - reference Y11.2210C
 - Gear operated - reference Y11.2210D
- Globe valves to BS 7350, section 3.1.
 - Copper alloy
 - Screwed to relevant parts of BS EN 10226 - reference Y11.2220A
 - Flanged to BS EN 1092-2 - reference Y11.2220B
 - Cast iron
- Flanged to BS EN 1092-2 - reference Y11.2220C

211.060 FLOW MEASUREMENT VALVES:

- Service fluid
- Water
- WRAS approved.
- Kitemark certified.
 - Pipe material
 - To suit steel tube.
- Flow measurement devices to BS 7350
 - Section 3.2 Type 3
 - Copper alloy
 - Screwed to relevant parts of BS EN 10226 - reference Y11.2230A
 - Flanged to BS EN 1092-3 - reference Y11.2230B
 - Cast iron
 - Flanged to BS EN 1092-2 - reference Y11.2230C
 - Section 3.2 Type 4

- Copper alloy
 - Screwed to relevant parts of BS EN 10226 - reference Y11.2230E
 - Flanged to BS EN 1092-3 - reference Y11.2230F
- Cast iron - reference Y11.2230G
- Variable orifice valve
- Fixed orifice valve

211.080 TEST PLUGS:

- Self sealing test points - reference Y11.2670A
- Valve controlled test points - reference Y11.2670B

211.100 PIPELINE STRAINERS:

- Bronze (Y type)
 - Screwed to relevant parts of BS EN 10226 - reference Y11.2680A
 - Flanged to BS EN 1092-3 - reference Y11.2680B
 - Compression to BS EN 1254-2
Reference Y11.2680C
- Cast iron/ductile iron
 - Y type - flanged to BS EN 1092-2 - reference Y11.2680D
 - Flanged suction diffuser type reference Y11.2680G
 - Cast iron body with ductile iron cover and cast iron guide vanes (PN16)
 - Ductile iron body and cover, and ductile guide vanes (PN25)
- Ductile iron grooved ends
 - Y type - reference Y11.2680E
 - Suction diffuser strainer - reference Y11.2680F

211.120 TUNDISHES:

- Copper - reference Y11.2690A
- Mild steel, galvanized - reference Y11.2690B

211.140 GAUGES:

- Manufacturer and referencet
- General - reference Y11.2700A
 - 150mm black stoved enamel finish
 - Flush panel mounting - reference Y11.2700B
 - Direct mounting - reference Y11.2700C
- 100mm - finish
- Temperature gauges general - reference Y11.2710A
 - Mercury in steel - reference Y11.2710B
 - Vapour pressure to BS EN 13190
 - Direct mounting - reference Y11.2710C
- Pressure and altitude gauges - reference Y11.2720
- Vacuum gauges - reference Y11.2730
- Differential pressure gaugess
 - Hardwood - reference Y11.2750A

211.150 CONTROL VALVES:

- WRAS approved.
- Kitemark certified.

- Ball control valves
 - Open/close - reference Y11.2315A
 - Two way - reference Y11.2315B
 - Three way - reference Y11.2315C

211.170 CHECK VALVES:

- WRAS approved.
- Kitemark certified.
- Service fluid
 - Water. (°C)
- Copper alloy check type to BS 5154
 - Swing type screwed to relevant parts of BS EN 10226 - reference Y11.2320A
 - Swing type flanged to BS EN 1092-3 - reference Y11.2320B
- Steel and cast iron check valves to BS EN 16767
 - Swing check
 - Flanged - reference Y11.2330A
 - Grooved for mechanical joints.
 - Wafer body - reference Y11.2330B
 - Lift check
 - Flanged - reference Y11.2330C
 - Wafer body - reference Y11.2330D
 - Body material
 - Grey cast iron
 - Malleable cast iron
 - SG cast iron
 - Steel
- Wafer flange fitting type
- Reference Y11.2340A
- Steel globe stop and check type to BS EN 13709 - reference Y11.2370#
- Device to prevent contamination of water by backflow to BS EN 14451
 - Combined check and anti-vacuum - reference Y11.2385A
- Anti-back syphonage valve, combined check and anti-vacuum type
 - Reference Y11.2390A
- Anti-back syphonage valve, hose union anti-vacuum type
- Reference Y11.2391A

211.180 WORKMANSHIP:

- Installation - reference Y11.4010
- Location - reference Y11.4020
- Positioning of components
 - Flow/pressure measurement valves - reference Y11.4030
 - Double regulating variable orifice valves - reference Y11.4040
 - Install control ball valves in accordance with manufacturer's recommendations.
 - Control components
 - Reference Y11.4050A
- Provide outlets of vent cocks with discharge pipes.
- Valve stuffing boxes - reference Y11.4070
- Discharge connections
 - Safety and Relief valves - reference Y11.4080A
 - Vent cocks - reference Y11.4080B
 - Air bottles - reference Y11.4080C

- Automatic air vents - reference Y11.4080D
- Expansion devices - reference Y11.4090
- Expansion compensators - reference Y11.4100
- Flexible connections installation - reference Y11.4110
- Terminal unit connections - install hose connections strictly in accordance with manufacturer's instructions.

211.210 DRAIN COCKS:

- WRAS approved.
- Kitemark certified.
- Throughway gland cock type
 - Reference Y11.2440A
- Screwdown to BS 2879, type 1 - reference Y11.2450
- Ball type - reference Y11.2460

211.220 VENT COCKS:

- Ball type - reference Y11.2480
- Three way gland cock type - reference Y11.2490
- Plug valve type
 - Wrench operated - reference Y11.2500A
 - Gear operated - reference Y11.2500B

211.230 AUTOMATIC AIR VENTS:

- Float type
 - Reference Y11.2510A

250.000 THERMAL INSULATION

250.010 GENERAL:

- Comply with work section general clauses reference below
 - Temperature range - reference Y50.1010
 - Standards - reference Y50.1020
 - Materials - reference Y50.1030
 - Pre-insulated equipment - reference Y50.1032
 - Protection applied in situ - reference Y50.1034
 - European classification for reaction to fire performance - reference Y50.1035A
 - European classification for reaction to fire performance - reference Y50.1035#
 - Spread of flame - reference Y50.1050A
 - Spread of flame - reference Y50.1050#
 - Smoke emission characteristics - reference Y50.1055
 - Electrical bonding terminal - reference Y50.1080
- Inspection and testing - reference Y50.1090
- Make good any sections that are cut during inspection for thickness and compliance with specification.
- Insulation thicknesses
 - Reference Y50.2289

250.020 INSTALLER SELECTION:

- Use a contractor specialising in the supply and installation of thermal insulation.
- Use thermal insulation materials supplied by a manufacturer assessed and registered in accordance with BS EN ISO 9001.
- Use thermal insulation materials supplied by a manufacturer assessed and registered in accordance with BS EN ISO 14001.
- Use thermal insulation materials supplied by a manufacturer assessed and registered in accordance with BS OHSAS 18001

250.030 MINERAL WOOL THERMAL INSULATION - PIPEWORK:

- Temperature of fluid in pipes (°C)
- European Classification for Reaction to Fire Performance
 - Reference Y50.1035A
- Spread of flame as BS 476-7
 - Reference Y50.1050A
- Smoke emission characteristics
 - Reference Y50.1055
- Electrical bonding terminal - reference Y50.1080
- Inspection and testing - reference Y50.1090
- Materials
 - Standard - BS EN 14303.
- Thermal conductivity - reference Y50.2010
- Thermal performance life expectancy
 - For plant design life - reference Y50.2015A
 - Details - reference Y50.2015B
- Restrictions on use of materials - reference Y50.2020
- Mineral wool pipe insulation
 - Foil faced - Rock mineral wool reference Y50.2030A
 - Canvas covered - Rock mineral wool reference Y50.2030B
 - Foil faced - Glass mineral wool reference Y50.2030C
 - Canvas covered - Glass mineral wool reference Y50.2030D
 - Vapour barrier permeance
- Vapour barrier coatings
 - Bitumen - reference Y50.2180A
 - Vinyl - reference Y50.2180B
 - Solvent polymers- reference Y50.2180C
 - Bitumen emulsion- reference Y50.2180D
- Adhesives - reference Y50.2190
- Protection
 - Application
 - Self-adhesive multi-layer laminate covering - reference Y50.2200A
 - Roofing felt - reference Y50.2200B
 - Flat aluminium-zinc coated steel - reference Y50.2200C
 - Ribbed aluminium-zinc coated steel - reference Y50.2200D
 - Aluminium sheeting - reference Y50.2200E
 - Canvas - reference Y50.2200G
 - Canvas with aluminium bands - reference Y50.2200H
 - Reinforcement
- Valve and flange insulation
 - Application
- Thickness table
 - Insulation thickness calculation methods, Building Regulations - reference Y50.2286

- Insulation thickness calculation methods, ECA Enhanced - reference Y50.2287
- Insulation thickness tables - reference Y50.2289
- Non-domestic hot water supply services Building Regulations (rock mineral wool) - reference Y50.2290
- Non-domestic hot water supply services Building Regulations (glass mineral wool) - reference Y50.2295
- Non-domestic hot water supply services ECA Enhanced - reference Y50.2307
- Non-domestic heating installations, Building Regulations (rock mineral wool) - reference Y50.2310
- Non-domestic heating installations, Building Regulations (glass mineral wool) - reference Y50.2315
- Non-domestic heating installations, ECA Enhanced - reference Y50.2327
- Domestic central heating and hot water system, Building Regulations - reference Y50.2330
- Domestic central heating and hot water systems, ECA Enhanced - reference Y50.2331
- Cooled water supplies, Building Regulations and condensation control on cooled and cold water supplies rock mineral wool - reference Y50.2395
- Cooled water supplies, Building Regulations and condensation control on cooled and cold water supplies glass mineral wool - reference Y50.2396
- Protection against freezing rock mineral wool - reference Y50.2420
- Protection against freezing glass mineral wool - reference Y50.2421
- Thickness of insulation
- Thickness of insulation for refrigeration pipework and equipment to BS 5422 - reference Y50.2495#
- Thickness of insulation for process pipework and equipment to BS 5422 - reference Y50.2490#

250.040 CLOSED CELL MATERIALS THERMAL INSULATION - PIPEWORK:

- Reference Y50.1035A
- Spread of flame as BS 476-7
 - Reference Y50.1050A
 - Smoke emission characteristics
- Electrical bonding terminal - reference Y50.1080
- Inspection and testing - reference Y50.1090
- Materials
- Thermal conductivity - reference Y50.2010
- Thermal performance life expectancy
 - For plant design life - reference Y50.2015A
 - Details - reference Y50.2015B
- Restrictions on use of materials - reference Y50.2020
- Closed cell rigid phenolic preformed sections
 - Foil faced - reference Y50.2110A
- High density rigid phenolic pipe and duct insulation - Reference Y50.2130A
- Closed cell nitrile rubber preformed flexible sections
 - Reference Y50.2140A
- Vapour barrier permeance
 - Reference Y50.2170
- Vapour barrier coatings
 - Bitumen - reference Y50.2180A
 - Vinyl - reference Y50.2180B
 - Solvent polymers- reference Y50.2180C
 - Bitumen emulsion- reference Y50.2180D
- Adhesives - reference Y50.2190
- Protection
 - Application
 - Self-adhesive multi-layer laminate covering - reference Y50.2200A
 - Roofing felt - reference Y50.2200B

- Flat aluminium-zinc coated steel - reference Y50.2200C
- Ribbed aluminium-zinc coated steel - reference Y50.2200D
- Aluminium sheeting - reference Y50.2200E
- Canvas - reference Y50.2200G
- Canvas with aluminium bands - reference Y50.2200H
- Reinforcement
- Valve and flange insulation
 - Application
- Thickness table
 - Insulation thickness calculation methods, Building Regulations - reference Y50.2286
 - Insulation thickness calculation methods, ECA Enhanced - reference Y50.2287
 - Insulation thickness tables - reference Y50.2289
 - Non-domestic hot water service area - reference
 - Non-domestic hot water service area, Building Regulations - phenolic foam - reference Y50.2305
 - Non-domestic hot water service area, Building Regulations - nitrile rubber - reference Y50.2306
 - Non-domestic hot water supply services, ECA Enhanced maximum permitted heat losses - reference Y50.2307
 - Non-domestic heating installations, Building Regulations - phenolic foam - reference Y50.2325
 - Non-domestic heating installations, Building Regulations - nitrile rubber - reference Y50.2326
 - Non-domestic heating installations, ECA Enhanced maximum permitted heat losses - reference Y50.2327
 - Domestic central heating and hot water systems, ECA Enhanced maximum permitted heat losses - reference Y50.2331
 - Domestic central heating and hot water systems, Building Regulations - phenolic foam - reference Y50.2336
 - Domestic central heating and hot water systems, Building regulations - nitrile rubber - reference Y50.2337
 - Cooled water supplies, Building Regulations and condensation control on cooled and cold water supplies - phenolic foam - reference Y50.2411
 - Cooled water supplies, Building Regulations and condensation control on cooled and cold water supplies - nitrile rubber - reference Y50.2412
 - Protection against freezing
 - Phenolic foam - reference Y50.2430
 - Nitrile rubber - reference Y50.2440
- Thickness of insulation
- Thickness of insulation for refrigeration pipework to BS 5422 - reference Y50.2495#

250.090 WORKMANSHIP PIPEWORK INSULATION:

- General - reference Y50.3010
- Installation of foil faced mineral wool insulation - reference Y50.3020
- Installation of foil faced phenolic foam insulation - reference Y50.3030
- Installation of closed cell nitrile rubber insulation - reference Y50.3050
- Installation of protection
 - Polyisobutylene (PIB) - reference Y50.3120
 - Self-adhesive multi-layer laminate covering - reference Y50.3125
 - Sheet metal finish
 - Reference Y50.3130A
 - Canvas - reference Y50.3150
 - Roofing felt - reference Y50.3160
 - Aluminium sheeting - reference Y50.3170
 - Aluminium-zinc coated steel - reference Y50.3180
 - Rigid PVC - reference Y50.3190

- Flanges and valves - reference Y50.3210
- Installation where insulation is carried through pipeline support
 - Reference Y50.3230A
 - Closed cell insulation - reference Y50.3230B
- Liquid vapour barriers - reference Y50.3260
- Integrity of vapour barriers - reference Y50.3270

250.110 WORKMANSHIP EQUIPMENT INSULATION:

- General - reference Y50.3010
- Installation of insulation on tanks - reference Y50.3090
- Installation of mineral wool insulation on vessels - reference Y50.3100
- Installation of phenolic foam insulation on vessels - reference Y50.3110
- Installation of protection
 - Polyisobutylene (PIB) - reference Y50.3120
 - Self-adhesive multi-layer laminate covering - reference Y50.3125
 - Sheet metal finish
 - Reference Y50.3140A
 - Canvas - reference Y50.3150
 - Roofing felt - reference Y50.3160
 - Aluminium sheeting - reference Y50.3170
 - Aluminium-zinc coated steel - reference Y50.3180
 - Rigid PVC - reference Y50.3190
- Liquid vapour barriers - reference Y50.3260
- Integrity of vapour barriers - reference Y50.3270

251.000 TESTING AND COMMISSIONING OF MECHANICAL SERVICES

251.010 GENERAL:

- Carry out testing and commissioning as specified in section

251.020 SPECIALIST:

- Use a commissioning specialist who is a member of The Commissioning Specialists Association (CSA).
- Or approved equivalent

251.030 STATIC TESTING:

- Carry out air pressure and leakage testing on air ductwork in accordance with specification section covering air ductlines and ancillaries.
- Carry out pressure / leakage testing of builders work air shafts, voids and floor plenums where they are used for supply ventilation - reference Y51.2015
- Pressure testing
 - General - reference Y51.2010
 - Hot and cold water supply systems, water circulating systems (LTHW, MTHW, HTHW, chilled and condenser water) and steam and condense lines - reference Y51.2020
 - Underground pipework
 - Test pre-insulated bonded steel pipe systems for district heating in accordance with BS EN 13941.
 - Test pre-insulated non bonded pipe systems in accordance with the system manufacturer's recommendations.
 - Test pre-insulated bonded flexible pipe systems in accordance with the system manufacturer's recommendations.

- Underground cold water supply mains - reference Y51.2040
- Fire risers - reference Y51.2050
- Refrigerant pipework
 - Strength pressure test - reference Y51.2055A
 - Leak test - reference Y51.2055B
- Deep vacuum test - reference Y51.2055C pressure (not exceeding 0.5 bars) before commencing any flushing or testing with water.
- On completion of all cleaning, flushing and air testing operations, recharge each system with clean water and subject them to sectional hydraulic tests of one and a half times the working pressure.
- There is to be no loss of pressure for a period of not less than 30 minutes for each test.

251.040 COMMISSIONING:

- Commissioning codes - reference Y51.3020
- Commissioning
 - Water distribution
 - Including BSRIA pre-commissioning check list
 - Reference Y51.3030
 - Air distribution
 - Including BSRIA pre-commissioning check list
 - Reference Y51.3040
 - Boiler plant - reference Y51.3050
 - Steam systems - reference Y51.3052
 - Gas plant and systems - reference Y51.3055
 - Refrigerating systems - reference Y51.3060
 - Automatic control systems - reference Y51.3070
- Instruments and gauges
 - Reference Y51.3090A
- Commissioning records
 - Distribution
 - For air systems
 - To BSRIA Guide BG 49/2015 - reference Y51.3100A
 - For water systems
 - To BSRIA Guide BG 2/2010 - reference Y51.3100B
- BMS commissioning
 - Control system specification details required for commissioning - reference Y51.3110
 - Pre-commissioning - reference Y51.3120
 - Plant ready for control system commissioning
 - Reference Y51.3130A
 - Control system requirements for plant commissioning - reference Y51.3140
 - Commissioning of building services as required by ADL2 (Section 5.16-5.28).
 - Commissioning of building services as required by Scottish Technical Handbook Section 6.7.
 - Commissioning - reference Y51.3150

254.000 IDENTIFICATION - MECHANICAL

254.010 GENERAL:

- Comply with work section general clauses below
 - Requirements - reference Y54.1010
 - New systems - reference Y54.1020
 - Existing systems - reference Y54.1030
 - Colours - reference Y54.1040

- Performance and durability - reference Y54.1045
- Provide identification - mechanical as specified in work section

254.020 PIPEWORK IDENTIFICATION:

- Reference Y54.2010

254.030 DUCTWORK IDENTIFICATION:

- Reference Y54.2020

254.040 PLANT AND EQUIPMENT IDENTIFICATION:

- Type
- Application
 - Lettering
 - Laminated plates, multi-coloured with outer layer removed for lettering - reference Y54.2030B

254.045 GRAPHICAL SYMBOLS FOR USE ON EQUIPMENT IN ACCORDANCE WITH BS EN 80416:

- Reference Y54.2035

254.050 VALVE AND COCK IDENTIFICATION:

- Reference Y54.2040

254.060 MEDICAL GAS TERMINAL UNITS:

- Type
- Application

254.070 LABORATORY OUTLETS:

- Type
- Application

254.080 AIR VOLUME REGULATING AND CONTROL DAMPER IDENTIFICATION:

- Reference Y54.2070

254.090 INSTRUMENT IDENTIFICATION:

- Reference Y54.2080

254.100 DANGER AND WARNING NOTICES:

- Reference Y54.2090

254.110 SYSTEM IDENTIFICATION INSTALLATION CHARTS:

- Type
- Application
- Perspex sheet glazing with frame - reference Y54.2100A

290.000 FIXING TO BUILDING FABRIC**290.010 GENERAL:**

- Comply with work section general clauses below
 - Preparation - reference Y90.1010
 - Manufacturer's drawings - reference Y90.1020
 - Fixings - reference Y90.1030
 - Loading details - reference Y90.1040
 - Building-in by others - reference Y90.1050
 - Size of fixing - reference Y90.1060
 - Greasing of fixings - reference Y90.1070
- Carry out fixing to building fabric as specified in work section

290.020 FIXINGS:

- Standards - reference Y90.2010
- Plugs - reference Y90.2020
- Screws - reference Y90.2030
- Non-penetrative support systems - reference Y90.2080
 - Manufacturer and reference
 - Or approved equivalent.

290.030 WORKMANSHIP:

- Drilling - reference Y90.3010
- Fixing to timber rails - reference Y90.3050
- Fixing to hollow stud/tile/block wall
 - Reference Y90.3060A
- Fixing to concrete, brickwork or blockwork
 - Reference Y90.3070A
- Fixing to metalwork
 - Reference Y90.3080A
- Fixing to structural steelwork and concrete structures
 - Reference Y90.3090A
- Non-penetrative support systems for roof mounted equipment - reference Y90.3100#

291.000 OFF-SITE PAINTING AND ANTI-CORROSION TREATMENT**291.010 GENERAL**

- Comply with work section general clauses below
 - General requirements - reference Y91.1010
- Damaged finishes - reference Y91.1020

291.020 PAINT MATERIALS:

- Paint materials
 - Reference Y91.2010A
- Paint quality - reference Y91.2020

291.030 WORKMANSHIP

- Weather and other conditions - reference Y91.3020
- Cleaning and preparing for painting
 - Steel surfaces - reference Y91.3030A
 - Surfaces - reference Y91.3030B
 - Reference Y91.3030#
- Application off-site - reference Y91.3040
- Application - reference Y91.3050
- Cold galvanizing - reference Y91.3060
- Protection of bright machine parts - reference Y91.3070
- Special protective finishes

BS APPENDIX

BS 476-3:2004

Fire tests on building materials and structures. Part 3 Classification and method of test for external fire exposure to roofs

BS 476-4:1970

Fire tests on building materials and structures. Part 4 Non-combustibility test for materials

BS 476-6:1989+A1:2009

Fire tests on building materials and structures. Part 6 Method of test for fire propagation for products

BS 476-7:1997

Fire tests on building materials and structures. Part 7 Method of test to determine the classification of the surface spread of flame of products

BS 476-7:1997

Fire tests on building materials and structures. Part 7 Method of test to determine the classification of the surface spread of flame of products

BS 476-10:2009

Fire tests on building materials and structures. Part 10 Guide to principles, selection, role and application of fire testing and their outputs

BS 476-11:1982

Fire tests on the building materials and structures. Part 11 Method for assessing the heat emission from building materials

BS 476-12:1991

Fire tests on building materials and structures. Part 12 Method of test for ignitability of products by direct flame impingement

BS 476-13:1987, ISO 5657:1986

Fire tests on building materials and structures. Part 13 Method of measuring the ignitability of products subjected to thermal irradiance

BS 476-20:1987

Fire tests on building materials and structures. Part 20 Method for determination of the fire resistance of elements of construction (general principles)

BS 476-21:1987

Fire tests on building materials and structures. Methods for determination of the fire resistance of loadbearing elements of construction

BS 476-22:1987

Fire tests on building materials and structures. Part 22 Method for determination of the fire resistance of non-loadbearing elements of construction

BS 476-24:1987, ISO 6944:1985

Fire tests on building materials and structures. Part 24 Method for determination of the fire resistance of ventilation ducts

BS 476-31.1:1983

Fire tests on building materials and structures. Part 31.1 Methods for measuring smoke penetration through doorsets and shutter assemblies. Method of measurement under ambient temperature conditions

BS 476-32:1989

Fire tests on building materials and structures. Part 32 Guide to full scale fire tests within buildings

BS 476-33:1993, ISO 9705:1993

Fire tests on building materials and structures. Part 33 Full-scale room test for surface products

BS 2879:1980

Specification for draining taps (screw-down pattern)

BS 5154:1991

Specification for copper alloy globe, globe stop and check, check and gate valves.

Partially replaced by BS EN 12288

BS 5163-1:2004

Valves for waterworks purposes. Part 1 Predominantly key-operated cast iron gate valves. Code of practice

BS 5163-2:2004

Valves for waterworks purposes. Part 2 Stem caps for use on isolating valves and associated water control apparatus. Specification

BS 5422:2009

Method for specifying thermal insulating materials for pipes, tanks, vessels, ductwork and equipment

operating within the temperature range -40°C to +700°C

BS 6675:1986

Specification for servicing valves (copper alloy) for water services

BS 7350:1990

Specification for double regulating globe valves and flow measurement devices for heating and chilled water systems

BS 9999:2017

Fire safety in the design, management and use of buildings. Code of practice

BS EN 331:2015

Manually operated ball valves and closed bottom taper plug valves for gas installations for buildings

BS EN 558:2017

Industrial valves. Face-to-face and centre-to-face dimensions of metal valves for use in flanged pipe systems. PN and Class designated valves

BS EN 593:2017

Industrial valves. Metallic butterfly valves for general purposes.

BS EN 736-1:2018

Valves. Terminology. Definition of types of valves

BS EN 736-2:2016

Valves. Terminology. Definition of components of valves

BS EN 1074-1:2000

Valves for water supply. Fitness for purpose requirements and appropriate verification tests. General requirements

BS EN 1074-2:2000

Valves for water supply. Fitness for purpose requirements and appropriate verification tests. Isolating valves

BS EN 1074-3:2000

Valves for water supply. Fitness for purpose requirements and appropriate verification tests. Check valves

BS EN 1074-4:2000

Valves for water supply. Fitness for purpose requirements and appropriate verification tests. Air valves

BS EN 1074-5:2001

Valves for water supply. Fitness for purpose requirements and appropriate verification tests. Control valves

BS EN 1074-6:2008

Valves for water supply. Fitness for purpose requirements and appropriate verification tests. Hydrants

BS EN 1092-1:2018

Flanges and their joints. Circular flanges for pipes, valves, fittings and accessories, PN designated. Part 1 steel flanges

BS EN 1092-2:1997

Flanges and their joints. Circular flanges for pipes, valves, fittings and accessories, PN designated. Part 2 cast iron flanges

BS EN 1092-3:2003

Flanges and their joints. Circular flanges for pipes, valves, fittings and accessories, PN designated. Part 3 copper alloy flanges

BS EN 1092-4:2002

Flanges and their joints. Circular flanges for pipes, valves, fittings and accessories, PN designated. Part 4 aluminium alloy flanges

BS EN 1171:2015

Industrial valves. Cast iron gate valves

BS EN 1213:2000

Building valves. Copper alloy stopvalves for potable water supply in buildings. Tests and requirements

BS EN 1254-2:1998

Copper and copper alloys. Plumbing fittings. Part 2 fittings with compression ends for use with copper tubes

BS EN 1254-3:1998

Copper and copper alloys. Plumbing fittings. Part 3 Fittings with compression ends for use with plastics pipes

BS EN 1363-1:2012

Fire resistance tests. General requirements

BS EN 1366-3:2009

Fire resistance tests for service installations. Penetration seals

BS EN 1366-4:2006+A1:2010

Fire resistance tests for service installations. Linear joint seals

BS EN 1984:2010
Industrial valves. Steel gate valves

BS EN 10216-1:2013
Seamless steel tubes for pressure purposes. Technical delivery conditions. Part 1 Non-alloy steel tubes with specified room temperature properties

BS EN 10216-2:2013
Seamless steel tubes for pressure purposes. Technical delivery conditions. Part 2 Non-alloy and alloy steel tubes with specified elevated temperature properties

BS EN 10216-3:2013
Seamless steel tubes for pressure purposes. Technical delivery conditions. Part 3 Alloy fine grain steel tubes

BS EN 10216-4:2013
Seamless steel tubes for pressure purposes. Technical delivery conditions. Part 4 Non-alloy and alloy steel tubes with specified low temperature properties

BS EN 10216-5:2013
Seamless steel tubes for pressure purposes. Technical delivery conditions. Part 5 Stainless steel tubes

BS EN 10216-5:2013
Seamless steel tubes for pressure purposes. Technical delivery conditions. Part 5 Stainless steel tubes

BS EN 10217-1:2002
Welded steel tubes for pressure purposes. Technical delivery conditions. Part 1 Non-alloy steel tubes with specified room temperature properties

BS EN 10217-2:2002+A1:2005
Welded steel tubes for pressure purposes. Technical delivery conditions. Part 2 Electric welded non-alloy and alloy steel tubes with specified elevated temperature properties

BS EN 10217-3:2002
Welded steel tubes for pressure purposes. Technical delivery conditions. Part 3 Alloy fine grain steel tubes

BS EN 10217-4:2002
Welded steel tubes for pressure purposes. Technical delivery conditions. Part 4 Electric welded non-alloy steel tubes with specified low temperature properties

BS EN 10217-5:2002
Welded steel tubes for pressure purposes. Technical delivery conditions. Part 5 Submerged arc welded

non-alloy and alloy steel tubes with specified elevated temperature properties

BS EN 10217-6:2002

Welded steel tubes for pressure purposes. Technical delivery conditions. Part 6 Submerged arc welded non-alloy steel tubes with specified low temperature properties

BS EN 10217-7:2014

Welded steel tubes for pressure purposes. Technical delivery conditions. Part 7 Stainless steel tubes

BS EN 10225:2009

Weldable structural steels for fixed offshore structures. Technical delivery conditions

BS EN 10226-1:2004

Pipe threads where pressure tight joints are made on the threads. Taper external threads and parallel internal threads. Part 1 dimensions, tolerances and designation

BS EN 10226-2:2005

Pipe threads where pressure tight joints are made on the threads. Taper external threads and taper internal threads. Dimensions, tolerances and designation

BS EN 10226-3:2005

Pipes threads where pressure-tight joints are made on the threads. Verification by means of limit gauges

BS EN 10253-1:1999

Butt-welding pipe fittings. Part 1 Wrought carbon steel for general use and without specific inspection requirements

BS EN 10253-2:2007

Butt-welding pipe fittings. Part 2 Non alloy and ferritic alloy steels with specific inspection requirements

BS EN 10253-3:2008

Butt-welding pipe fittings. Wrought austenitic and austenitic-ferritic (duplex) stainless steels without specific inspection requirements

BS EN 10253-4:2008

Butt-welding pipe fittings. Wrought austenitic and austenitic-ferritic (duplex) stainless steels with specific inspection requirements

BS EN 10255:2004

Non-alloy steel tubes suitable for welding and threading. Technical delivery conditions

BS EN 12266-1:2012

Industrial valves. Testing of valves. Pressure tests, test procedures and acceptance criteria. Mandatory requirements

BS EN 12266-2:2012

Industrial valves. Testing of metallic valves. Tests, test procedures and acceptance criteria.
Supplementary requirements

BS EN 13190:2001

Thermal insulation products for buildings. Factory made products of phenolic foam (PF). Specification

BS EN 13501-2:2016

Fire classification of construction products and building elements. Classification using data from fire resistance tests, excluding ventilation services

BS EN 13547:2013

Industrial valves. Copper alloy ball valves

BS EN 13709:2010

Industrial valves. Steel globe and globe stop and check valves

BS EN 13789:2010

Industrial valves. Cast iron globe valves

BS EN 13828:2003

Building valves. Manually operated copper alloy and stainless steel ball valves for potable water supply in buildings. Tests and requirements

BS EN 13941:2009+A1:2010

Design and installation of pre-insulated bonded pipe systems for district heating

BS EN 14303:2015

Thermal insulation products for building equipment and industrial installations. Factory made mineral wool products (MW). Specification.

BS EN 14451:2005

Devices to prevent pollution by backflow of potable water. In-line anti-vacuum valves DN 8 to DN 80.
Family D, type A

BS EN 16668:2016+A1:2018

Industrial valves. Requirements and testing for metallic valves as pressure accessories

BS EN 16767:2016

Industrial valves. Steel and cast iron check valves

BS EN 80416-1:2009

Basic principles for graphical symbols for use on equipment. Part 1 Creation of symbol originals

BS EN 80416-2:2001

Basic principles for graphical symbols for use on equipment. Part 2 Form and use of arrows

BS EN 80416-3:2002+A1:2011

Basic principles for graphical symbols for use on equipment. Part 3 Guidelines for the application of graphical symbols

BS EN ISO 228-1:2003

Pipe threads where pressure-tight joints are not made on the threads. Part 1 Dimensions, tolerances and designation

BS EN ISO 9001:2015

Quality management systems. Requirements

BS ISO 5208:2015

Industrial valves. Pressure testing of metallic valves

BS ISO 7005-1:2011

Pipe flanges. Part 1 Steel flanges for industrial and general service piping systems

BS ISO 7121:2016

Steel ball valves for general-purpose industrial applications

ISO 7-1:1994

Pipe threads where pressure-tight joints are made on the threads. Part 1 Dimensions, tolerances and designation

Briefing & Overview**Bone Marrow Transplant Service, Ward 4b****Queen Elizabeth University Hospital**

The Bone Marrow Transplant (BMT) service transferred from the Beatson West of Scotland Cancer Centre on 06 June 2015.

As part of routine infection control measures for BMT, it was agreed to reintroduce the routine air sample testing in line with the frequency applied at the Beatson.

On 30 June, I was contacted by the Clinical Service Manager to notify me that Microbiology and Infection Control had received the results of the air samples. The air sample measurements were in excess of the recommended standards for a BMT Unit. At a meeting on 01 July, the ICD reported that only 1 of the 24 rooms met the specification; the other rooms has reading in excess of 5000 against an acceptable normal air particle count of 1000 for a BMT area.

It was also noted that the pentamidine treatment room should have negative air pressure however this did not appear to be in place. Dr Peters, ICD, reported that she has asked for copies of the commissioning and validation data but this had not yet been provided to her. The same data has been requested for Theatres, HDU, lobbied rooms and hepa-filter areas and will be provided to Anne and Kevin for the rest of the sites.

With regard to BMT, it was agreed that a potential solution would be to increase the air flow and ventilation to ward 4b. The aim of this being to increase the pascal measurement to between 5–10, and increase the air exchanges in the room to 12 per hour. Accordingly on the evening of 01 July the ventilation system was increased to maximum capacity. A number of other measures were also agreed:

- Move to ensure that the door and room seals are adequately air tight
- Increase the cleaning schedules to twice daily
- Introduce prophylaxis posaconazole to allograft patients (anti-fungal medication)
- Re sample the ward to assess if an improvement had been achieved.

It was agreed that it would be sensible to await the outcome of the re-sampling exercise prior to making any decision about alternative accommodation for the patients.

The group reconvened on 03 July to assess progress from the above.

It was reported that the air exchange rate being achieved was around 6 per hour, still lower than the desired 12. The pascal measurement from the rooms to the corridor was around 5; the lower end of the accepted range. The ICD reported that whilst there had been an improvement in the particle count across 9 rooms, the remainder remained non compliant and out with the accepted normal standard. The ICD also reported that there had been some fungal growth from environmental swabs taken in the unit.

Following clinical debate, it was agreed that on the balance of risk, it would be safer to transfer the patients back to the Beatson West of Scotland Cancer Centre until such times as a permanent solution could be implemented to ward 4b. However, as an evaluation of the Beatson would need to undertaken, the balance of risk suggested that it would be safer to leave the patients at QEUH over the weekend until an assessment of the Beatson could be undertaken on 06 July.

Dr Craig Williams (Lead Infection Control Doctor) returned from leave on 06 and attended the review meetings on 1100 & 1500. Dr Williams concurred with his ICD colleagues and BMT Consultants that it would be clinically appropriate to transfer the patients back to the Beatson until the environmental issues could be resolved.

Dr Williams requested the validation and commissioning results for the BMT Unit and a further engineering view on the hepa-filtration and ventilation issues. Dr Williams briefly reviewed the clinical specification for the unit and stated that it seemed fine from his interpretation. Peter Moir agreed to develop a programme of work and financial plan related to rectifying the function of the unit.

It is proposed for clinical safety, pending ambulance availability and other infrastructure support, that BMT patients and acute leukaemia patients will transfer from the Queen Elizabeth University Hospital on 8th July back to the Beatson West of Scotland Cancer Centre.

This will affect 18 patients

A communication plan will be put in place with patients and their families, press and other stakeholders. It is planned to tell the patients tomorrow once the infrastructure is in place.

Gary Jenkins
Director: Regional Services
06 July 2015



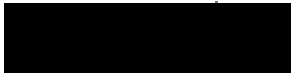
QUEEN ELIZABETH UNIVERSITY HOSPITAL



QEUH – WARD 4B

VENTILATION REPORT



Area:	Queen Elizabeth University Hospital	AHU:	31AHU63
Client:	NHS Greater Clyde & Glasgow	Client Contact:	David Bratney
Site Address:	1345 Govan Rd, Glasgow, G51 4TF	Report No:	A11356
System Condition:	Good	Date of Test:	6 th - 10 th November 2017
Test Engineer & Report Preparation:	Daniel Kane	Signature:	
H&V Approval:	Ian Stewart	Signature:	
Client Reviewed by:	David Bratney	Signature:	

KILKNOWE OFFICE
16 BARRMILL ROAD
GALSTON
AYRSHIRE
KA4 8HH



A4





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2. Executive Summary
3. Supply & extract flow rates & air change rates
4. Filter Integrity Test
5. Room Pressure Differentials
6. Schematic Layout of Adults Ward 4B
7. Calibration Certificates



Section 1 – Scope of Works

Adults Ward 4B is located on the 4th floor in Queen Elizabeth University Hospital. Adults Ward 4B is supplied by 3 Air Handling Units located on level 3 plant room, just below one level from the department.

Main traverse readings will be taken from both the supply and extract ducts and the inverter readings recorded.

To ensure compliance with SHTM03-01, the following tests will be carried out;

- 1 - Supply volume flow rates from each terminal grille and air change rates calculated.
- 2 – Record room pressures and compare with the Digital Pressure Panel
- 3 – DOP integrity test all supply HEPA filters
- 4 – Provide an electronic validation report



Section 2 – Executive Summary

Recorded the supply volumes and calculated the air change rates, all achieve or are acceptable to the required specification.

The room pressures are above the minimum required limits.

The change of HEPA filters in each individual Isolation Room was carried out and old filters boxed ready for disposal.

The DOP Filter integrity test all HEPA Filters was carried out. All filters achieved an integrity of 99.99% MPPS.



Section 3 – Air Volumes & Air Change Rates

Air Volume Methodology

Objective:

To provide documented evidence to verify the supply air volume rates through individual filter terminals are in accordance with their design volumes.

Prerequisites – Supply and Extract Air Handling Unit maintenance complete.

Test Method

- Micromanometer – calibrated and used in conjunction with Pitot tube to measure air velocity in appropriate ducting, to calculate air volume for Balometer factor.
- The HVAC System(s) is operational and stable.

Methodology:

- Hold the balometer hood over the diffuser/grille face and ensure balometer is set in the correct direction and read off the measured air volume flow rate.

Acceptance Criteria

- Calibration certificates for all test equipment are appended to the report.

Room Air Change Rate Calculation Methodology

Objective

To provide documented evidence to verify the room air change rate to each room within the Area based on measurement of the total supply air volume to the room in accordance with the design specification.

Pre-Requisites

- The tests described in the air volume methodology have been completed.

Methodology

- Insert all supply air volumes into the results table.
- Calculate the total supply air volume to each room by the addition of all supply HEPA filter flow rates within the room.
- Calculate the air change rate per hour for each room using the following equation:

Total volume of all supply terminal HEPA filter flowrates (m³/h)

Volume of the room (m³)

Acceptance Criteria

- All rooms must achieve the minimum number of air change rates specified in the design data.



Section 3 – Air Volumes & Air Change Rates

AHU Invertor Readings & Filter Pressure Drops

AHU 31-63		Primary Filter PD	55Pa
Supply Invertor	44Hz (A)	Secondary Filter PD	120Pa
Extract Invertor	30Hz (B)	Extract Filter PD	15Pa

Supply Duct Traverse

Test Point / Location	Design Volume m ³ /s	Duct Size mm	Duct Area m ²	Design Velocity m/s
TP2 / 4 th Floor Riser	0.899	700 x 350	0.245	3.67
	A	B	C	D
1	6.10	4.70	5.00	7.00
2	5.80	3.90	5.30	6.30
3	5.60	3.60	5.10	4.30
4	5.60	3.50	5.10	4.40
Total	23.10	15.70	20.50	22.00
Overall Total		81.30		
Average Velocity m/s	Test Volume m ³ /s	% Design		Static Pressure Pa
5.08	1.245	139		380

Test Point / Location	Design Volume m ³ /s	Duct Size mm	Duct Area m ²	Design Velocity m/s
TP1 / 4 th Floor Riser	1.04	500 x 500	0.25	4.16
	A	B	C	
1	5.96	5.70	5.00	
2	5.48	5.90	5.30	
3	5.31	5.20	5.10	
4	5.15	5.60	5.10	
Total	21.90	22.40	20.50	
Overall Total		64.80		
Average Velocity m/s	Test Volume m ³ /s	% Design		Static Pressure Pa
5.40	1.35	130		369



Section 3 – Air Volumes & Air Change Rates

Extract Duct Traverse

Test Point / Location	Design Volume m ³ /s	Duct Size mm	Duct Area m ²	Design Velocity m/s
Main TH	1.392	700 x 450	0.315	4.42
	A	B	C	D
1	3.80	3.20	3.30	3.90
2	3.30	3.40	3.50	3.10
3	3.60	2.50	2.50	2.80
4	3.60	2.50	2.10	2.00
Total	14.30	11.60	11.40	11.80
Overall Total			49.10	
Average Velocity m/s	Test Volume m ³ /s	% Design		Static Pressure Pa
3.069	0.967	69		120

AHU Invertor Readings & Filter Pressure Drops

AHU 31-63EF01			
Extract Invertor	70Hz (B)	Extract Filter PD	15Pa

Extract Main Test Point

Test Point / Location	Design Volume m ³ /s	Duct Size mm	Duct Area m ²	Design Velocity m/s
Main TH	0.698	500 x 350	0.175	3.99
	A	B	C	
1	6.00	5.80	5.80	
2	5.70	6.00	5.80	
3	5.80	5.70	5.90	
4	5.70	5.90	5.80	
Total	23.20	23.40	23.30	
Overall Total			69.90	
Average Velocity m/s	Test Volume m ³ /s	% Design		Static Pressure Pa
5.825	1.019	146		204

Extract Test Point

Test Point / Location	Design Volume m ³ /s	Duct Size mm	Duct Area m ²	Design Velocity m/s
TH1	0.0898	250 ϕ	0.0491	1.83
	A	B		
1	1.90	1.80		
2	2.00	1.90		
3	1.90	2.20		
4	1.90	1.70		
Total	7.70	7.60		
Overall Total			15.30	
Average Velocity m/s	Test Volume m ³ /s	% Design		Static Pressure Pa
1.9125	0.0939	105		9



Section 3 – Air Volumes & Air Change Rates

Supply Grille Volume Flow Rates

Room	Room ID	Test Volume		Design Volume l/s	% of Design
		m³/hr	l/s		
76	A4-HOW-190	324	90	80	113
77	A4-HOW-193	392	109	80	136
78	A4-HOW-195	324	90	80	113
79	A4-HOW-198	364	101	80	126
80	A4-HOW-202	385	107	80	134
81	A4-HOW-050	324	90	80	113
82	A4-HOW-053	302	84	80	105
83	A4-HOW-055	338	94	80	118
84	A4-HOW-058	328	91	80	114
85	A4-HOW-059	306	85	80	106
86	A4-HOW-062	385	107	80	134
87	A4-HOW-064	342	95	80	119
88	A4-HOW-067	335	93	80	116
89	A4-HOW-031	403	112	100	112
90	A4-HOW-029	407	113	80	141
91	A4-HOW-026	371	103	80	129
92	A4-HOW-024	382	106	80	133
93	A4-HOW-021	317	88	80	110
94	A4-HOW-020	310	86	80	108
95	A4-HOW-017	317	88	80	110
96	A4-HOW-015	396	110	80	138
97	A4-HOW-012	356	99	80	124
98	A4-HOW-011	392	109	80	136
99	A4-HOW-009	378	105	80	131



Section 3 – Air Volumes & Air Change Rates

Extract Grille Volume Flow Rates

Room	Room ID	Test Volume		Design Volume l/s	% of Design
		m³/hr	l/s		
76	A4-HOW-190	104	29	30	97
77	A4-HOW-193	104	29	30	97
78	A4-HOW-195	115	32	30	107
79	A4-HOW-198	108	30	30	100
80	A4-HOW-202	104	29	30	97
81	A4-HOW-050	94	26	30	87
82	A4-HOW-053	104	29	30	97
83	A4-HOW-055	126	35	30	116
84	A4-HOW-058	90	25	30	83
85	A4-HOW-059	95	26	30	87
86	A4-HOW-062	126	35	30	116
87	A4-HOW-064	94	26	30	87
88	A4-HOW-067	86	24	30	80
89	A4-HOW-031	94	26	30	87
90	A4-HOW-029	86	24	30	80
91	A4-HOW-026	108	30	30	100
92	A4-HOW-024	108	30	30	100
93	A4-HOW-021	108	30	30	100
94	A4-HOW-020	108	30	30	100
95	A4-HOW-017	94	26	30	87
96	A4-HOW-015	94	26	30	87
97	A4-HOW-012	112	31	30	103
98	A4-HOW-011	108	30	30	100
99	A4-HOW-009	97	27	30	90



Section 3 – Air Volumes & Air Change Rates

31-63/EF01 Extract Volume Flow Rates

Room	Grill Reference	Test Volume		Design Volume l/s	% of Design
		m³/hr	l/s		
Corridor Area	512-EG002	346	96	90	107
Corridor Area	514-EG008	274	76	75	101
Corridor Area	513-EG006	281	78	75	104
Corridor Area	513-EG008	284	79	75	105
Corridor Area	514-EG009	360	100	75	133
Corridor Area	513-EG007	310	86	77	112
Corridor Area	513-EG004	342	95	63	151
Corridor Area	513-EG003	328	91	55	165
Corridor Area	513-EG002	328	91	54	169
Corridor Area	513-EG001	389	108	60	180

125AHU05 Clean Utility Volume Flow Rates

Room	Grill Reference	Test Volume		Design Volume l/s	% of Design
		m³/hr	l/s		
Clean Utility	Supply Grille	131	36	tbc	107
Clean Utility	Extract Grille	130	36	Tbc	101

Pentamidine Treatment Room Volume Flow Rates

Room	Grill Reference	Test Volume		Design Volume l/s	% of Design
		m³/hr	l/s		
HOW-003	Supply Grille	284	79	tbc	107
HOW-003	Extract Grille	395	110	Tbc	101



Section 3 – Air Volumes & Air Change Rates Continued.....

Air Change Rates

Room Reference	Recorded Air Volume m ³ /hr	Room Volume m ³	Recorded ac/hr	Design Air Change Rates ac/hr
Room 76	324	45.9	7.1	6
Room 77	392	45.9	8.5	6
Room 78	324	45.9	7.1	6
Room 79	364	45.9	7.9	6
Room 80	385	54.0	7.1	6
Room 81	324	48.6	6.7	6
Room 82	302	45.9	6.6	6
Room 83	338	45.9	7.4	6
Room 84	328	48.6	6.7	6
Room 85	306	48.6	6.3	6
Room 86	385	45.9	8.4	6
Room 87	342	45.9	7.5	6
Room 88	335	45.9	7.3	6
Room 89	403	45.9	8.8	6
Room 90	407	45.9	8.9	6
Room 91	371	48.6	7.6	6
Room 92	382	48.6	7.3	6
Room 93	317	48.6	6.5	6
Room 94	310	48.6	6.4	6
Room 95	317	45.9	6.9	6
Room 96	396	45.9	8.6	6
Room 97	356	48.6	7.3	6
Room 98	392	48.6	8.1	6
Room 99	378	64.80	5.8	6
Clean Utility	131	36.4	3.6	6
Pentamidine	395	45.3	8.7	6

A balometer factor of 1.0 was used.

Equipment Used

Test Instruments Used	Serial No.	Calibration Due
Balometer	90526046	September 2018



Section 4 – Filter Integrity Test

Objective

To provide documented evidence to verify that each HEPA filter installation within the HVAC System(s), comprising the filter, seal and housing, does not permit the passage of particulate material in sufficient quantities to compromise the design intent of the filter. This will be achieved by smoke integrity testing.

Prerequisites

- **Aerosol generator** – calibrated to be capable of generating a poly-dispersed aerosol having the size distribution given in PD6609:2000 Annex B, Clause C.2.1.
- **Photometer** – calibrated and suitable for the measurement of mass concentration of airborne particles having the size distribution given in PD6609:2000 Annex B, Clause C.2.1 and having an accuracy of better than $\pm 5\%$ over the range of a five expandable, six decade resolution and a minimum threshold sensitivity $0.0001 \mu\text{g/l}$ and capable of measuring aerosol concentration in the range of 10 to 100mg/m^3 . The photometer shall have a sample flow rate $0.4 \pm 0.05 \text{ l/s}$
- **Sampling probe** - a suitable sampling probe is required which is designed for maximum coverage of isokinetic flow rates.
- **Calibration certificates** – are required for the above and must be appended to the test report.

Methodology

The test will be performed by introducing an aerosol challenge upstream of each HEPA filter and scanning immediately downstream of the filters and support frame.

A test report will be prepared which will include confirmation of the methodology used, results of testing for each filter, whether each test is a **pass** or **fail**, the location of any detected leaks and indication of the position and extent of any repairs and calibration certificates for all test equipment used.

Acceptance Criteria

- Aerosol concentration readings must be $\leq 0.01 \%$ of the upstream concentration within all grade of rooms.
- A test report is prepared which includes confirmation of the methodology used, results of testing for each filter, whether each test is a **pass** or **fail**. If a fail is recorded replace the filter and retest.
- Attach copy of calibration certificates for all test equipment.
-



Section 4 – Filter Integrity Test

Filter Integrity Results

Room	Room Reference ID	Filter Pressure Drop Pa	Set Upstream Concentration mg/m ³	Downstream % penetration	% Upstream Aerosol Concentration Post Scan	Pass/Fail
76	A4-HOW-190	New Filter	47	0.0001	100	Pass
77	A4-HOW-193	New Filter	52	0.0004	97	Pass
78	A4-HOW-195	New Filter	28	0.0001	98	Pass
79	A4-HOW-198	New Filter	67	0.0003	102	Pass
80	A4-HOW-202	New Filter	63	0.0009	100	Pass
81	A4-HOW-050	New Filter	34	0.0001	97	Pass
82	A4-HOW-053	New Filter	40	0.0002	100	Pass
83	A4-HOW-055	New Filter	46	0.0008	103	Pass
84	A4-HOW-058	New Filter	78	0.0005	101	Pass
85	A4-HOW-059	New Filter	65	0.0007	100	Pass
86	A4-HOW-062	New Filter	80	0.0009	100	Pass
87	A4-HOW-064	New Filter	88	0.0003	102	Pass
88	A4-HOW-067	New Filter	82	0.001	100	Pass
89	A4-HOW-031	New Filter	77	0.0002	103	Pass
90	A4-HOW-029	New Filter	74	0.0004	104	Pass
91	A4-HOW-026	New Filter	80	0.0009	100	Pass
92	A4-HOW-024	New Filter	64	0.0003	99	Pass
93	A4-HOW-021	New Filter	80	0.001	102	Pass
94	A4-HOW-020	New Filter	63	0.0008	102	Pass
95	A4-HOW-017	New Filter	21	0.0001	100	Pass
96	A4-HOW-015	New Filter	28	0.002	101	Pass
97	A4-HOW-012	New Filter	39	0.003	100	Pass
98	A4-HOW-011	New Filter	31	0.004	98	Pass
99	A4-HOW-009	New Filter	23	0.001	103	Pass
Clean Utility	HOW-039	New Filter	80	0.007	100	Pass

Test Instruments Used	Serial No.	Calibration Due
Photometer	11200	March 2018
Aerosol Generator	12198	June 2018



Section 5 - Room Pressure Differentials

Room Pressure Differential Methodology

Objective

To provide documented evidence to verify the room pressure regime throughout the Cleanroom suite is in accordance with their design values.

Pre-Requisites

All supply and extract volumes are set to client specification

- All LAF unit(s) are operational, where applicable.
- The HVAC System(s) must have been operating normally and continuously for at least 24 hours prior to commencement of the test.
- The tests are to be carried out "unmanned at rest". Ensure that area supervision have been informed to keep personnel out of the area.
- The test operator has been trained to use the test equipment and is wearing appropriate clean area clothing.
- Room pressure alarms/information;
 - High room pressure set at 15Pa
 - Low room pressure alarm set at 5Pa
 - Door open or out of specification alarm is set for a 2 minute period before alarming.
 - Room pressure alarms can be silenced from the button on the digital display set at each room door entry (on the stainless steel plate).

Methodology

- With the Micromanometer properly zeroed, attach the tubing to the positive connection on the instrument, then place the other end of the tubing underneath the room door, with the tubing going into the higher pressured room.
- Record the reading into the appropriate position on the table below.



Section 5 - Room Pressure Differentials

Room Pressure Differentials, Temperature, Humidity & Noise Levels

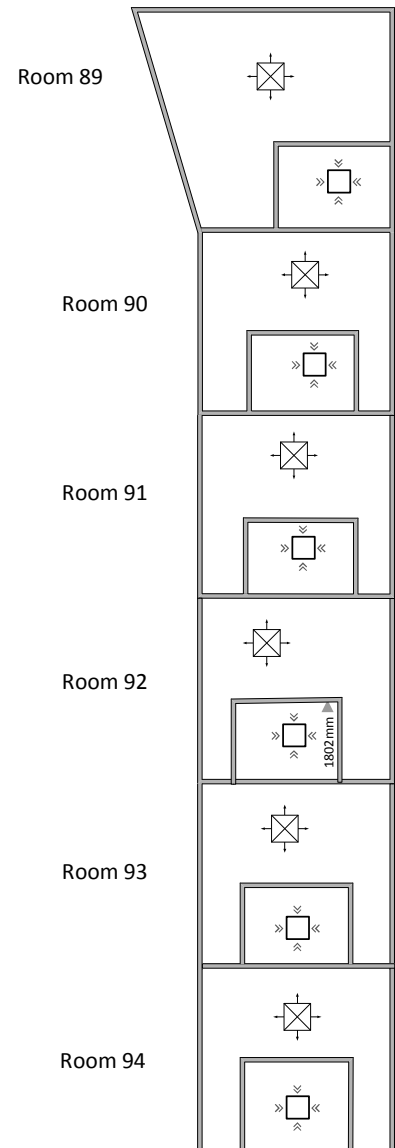
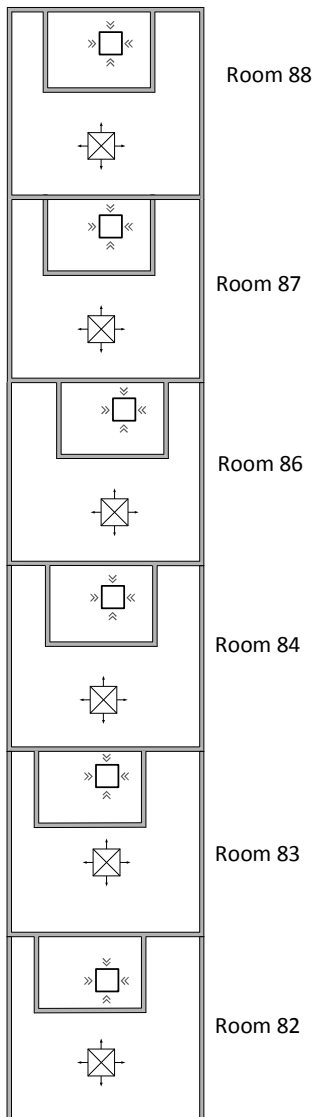
Room	Room	Recorded Pressure Pa	Target Pa	Recorded Temp Target 18-28°C	Recorded Noise Target 35dba
Room 76	Corridor	7.6	5 – 10	23.5	28.2
Room 77	Corridor	7.0	5 – 10	23.2	29.5
Room 78	Corridor	6.8	5 – 10	25.0	30.0
Room 79	Corridor	9.2	5 – 10	23.9	31.0
Room 80	Corridor	7.4	5 – 10	23.5	29.8
Room 81	Corridor	7.0	5 – 10	22.4	29.2
Room 82	Corridor	8.1	5 – 10	21.0	29.0
Room 83	Corridor	9.4	5 – 10	20.0	29.7
Room 84	Corridor	8.7	5 – 10	23.4	32.0
Room 85	Corridor	7.2	5 – 10	22.9	31.1
Room 86	Corridor	8.6	5 – 10	23.1	28.0
Room 87	Corridor	8.4	5 – 10	23.5	29.5
Room 88	Corridor	8.4	5 – 10	19.8	30.2
Room 89	Corridor	8.5	5 – 10	19.3	28.4
Room 90	Corridor	8.4	5 – 10	23.6	29.7
Room 91	Corridor	10.0	5 – 10	18.9	29.3
Room 92	Corridor	11.2	5 – 10	19.2	28.5
Room 93	Corridor	8.3	5 – 10	27.7	29.6
Room 94	Corridor	7.4	5 – 10	19.8	29.8
Room 95	Corridor	13.0	5 – 10	22.9	27.4
Room 96	Corridor	10.6	5 – 10	23.2	28.2
Room 97	Corridor	7.2	5 – 10	19.3	28.1
Room 98	Corridor	7.5	5 – 10	19.8	29.6
Room 99	Corridor	6.5	5 – 10	22.2	27.9
Clean Utility	Corridor	0.5	+	-	-
Ward 4B	Link Corridor	6	+	-	-
Ward 4B	Ward 4C	6	+	-	-
Ward 4B	Stairwell	4	+	-	-

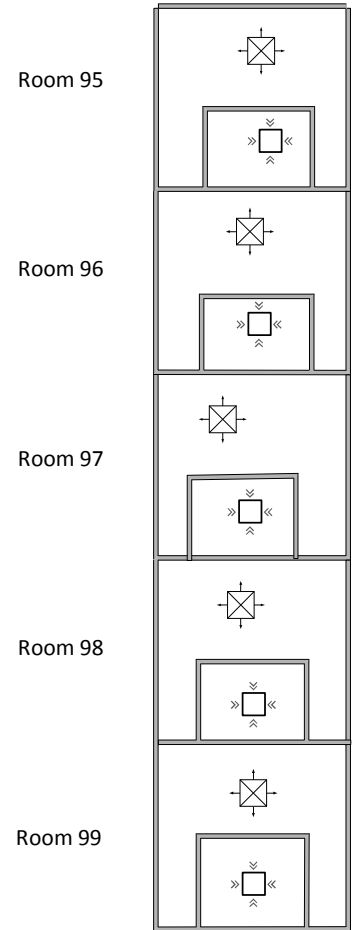
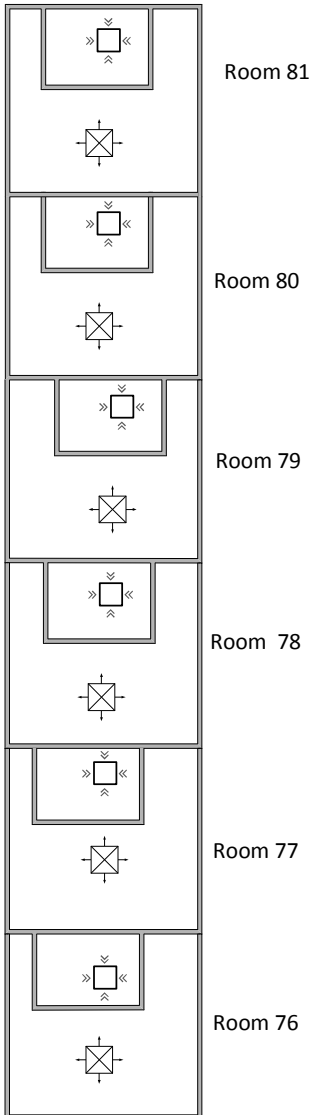
Equipment Used

Test Instrument Used	Serial Number	Calibration Due Date
Micromanometer	7827	November 2017
Environmental Meter	160506299	September 2018



Section 6 – Ward 4B Schematic







Section 7 - Calibration Certificates

CERTIFICATE OF CALIBRATION

Issued By IRC Ltd

Date of Issue 19 September 2017

Certificate Number
224854

Page 1 of 2 Pages



Instrument Repairs & Calibration
7 Howard Court Industrial Estate
East Kilbride, G74 4QZ
Tel: 01355 264120 Fax: 01355 264150
www.instrument-repairs.com

Approved Signatory

Digitally signed by Keith Low
DN: cn=Keith Low, o=IRC Ltd, ou=IRC Ltd,
ment-repairs.com, c=GB
Date: 2017.09.19 11:21:41
+01'00'

☐ N.Anderson

☐ K.Low

☐ C.Moore

☐ A.Rae

Customer : H&V Commissioning Services Ltd
Kilknowe Offices, 16 Barrmill Road
Galston KA4 8HY

Date Received : 07 September 2017

Instrument -	System ID :	IRC02204	Job Number :	R87915
	Description :	Balometer	Ref. Number :	AC-C-06
	Manufacturer :	Alnor	Site :	
	Model Number :	EBT-721	Location :	
	Serial Number :	90526046	Last Certificate Number :	
	Procedure Version :	2592	Last Calibration Date :	

Environmental Conditions

Temperature : 23°C +/- 2°C
Relative Humidity : 50% +/- 20%

Mains Voltage : 230V +/- 10V
Mains Frequency : 50Hz +/- 1Hz

Comments

A. All prime parameters found to be within specification.
Results at the time of test carry no long term stability of the instrument.
This certificate records the ON RECEIPT calibration status.
Recalibration period 52 weeks by customer request.

Traceability Information

Instrument description	Serial number	Certificate number	Cal. Date	Cal. Period
Mensor CP6000	610020	13027/8/9/30/33	09/11/2015	104

Calibrated By : K Low

Date of Calibration : 19 September 2017

This is to certify that the above instrument was fully calibrated. Work carried out was in accordance with procedures laid down in BS EN ISO/IEC 17025:2005. The accuracies of the standards used are traceable to National Standards, via UKAS approved laboratories. The copyright of this certificate is owned by IRC Ltd and may not be reproduced except with the prior written approval of the issuing laboratory. The reported expanded uncertainty is based on a standard uncertainty multiplied by a coverage factor k=2 providing a level of confidence of approximately 95%.

CERTIFICATE OF CALIBRATION

Certificate Number
224854

Page 2 of 2 Pages

Test Title	Tolerance	Applied Value	Reading	Pass/Fail
Pressure Pascals	2.8pa	249.0pa	250.0pa	Pass
	22.9pa	1 992.0pa	1 995pa	Pass
	40.4pa	3 736.0pa	3 737pa	Pass

End of Results

Uncertainties

Pressure TE69 0- 1000mBar +/- 0.01% of reading

TRACEABLE CERTIFICATION & CALIBRATION REPORT

Digital Aerosol Photometer

Customer

H & V Commissioning Services
Kilknowe Office
16 Barmill Road
Galston
Ayrshire

P.O#



ATI UK Ltd
Unit 10
Protea way
Pixmore Avenue
Letchworth
Hertfordshire
SG6 1JT
United Kingdom

Telephone:
+44 (0)1462 676446
Facsimile:
+44 (0)1462 486078

Email: saleuk@atitest.com

Web:
www.atitest.co.uk

Environmental Conditions			
Temperature	22.4	°C	
Ambient Pressure	100	kPa	

Model	ATI-2G		
Serial No.	11200		
ID#	2248		

Calibration Equipment			
	Multimeter	Electronic Balance	Flowmeter
Model	U3402A	HP220DC	Flow Meter
Serial Number	MY50060007	D455800028	F165086/01
Cal Due Date	Apr-17	May-17	Oct-18

Calibration Data					
Volumetric Flow: L/min $\pm$ 5% of reading					
Test Point	Measurement	2G Output	ABS ERROR	Allowed ERROR	Cal status
As Found	28.30	27.60	0.70	1.4	Pass
As Left	28.30	28.20	0.10	1.4	Pass

Stray Light: Volts		
As Found	As Left	
0.0027	0.0076	

P1 = ONDINA Concentration: 100 μ g/L $\pm$ 10% of Reading*					
Test Point	Generator	2G Output	ABS ERROR	ALLOWED ERROR	CAL Status
As Found	100.00	81.30	18.70	10	Fail
As Left	100.00	100.60	-0.60	10	Pass

P2 = Emery Concentration: 100 μ g/L $\pm$ 10% of Reading*					
Test Point	Generator	2G Output	ABS ERROR	ALLOWED ERROR	CAL Status
As Found	100.00	80.80	19.20	10	Fail
As Left	100.00	99.04	0.96	10	Pass

P3 = HIGH Concentration: 100 μ g/L $\pm$ 30 μ g/L					
Test Point	Generator	2G Output	ABS ERROR	ALLOWED ERROR	CAL Status
As Found	100.00	85.00	15.00	30	Pass
As Left	100.00	103.00	-3.00	30	Pass

Notes:

Cleaned internal filters, tubing & rewired optical chamber lamp due to intermittent fault.

TUR 1:1

Condition of Unit							
AS FOUND				AS LEFT			
☐	In tolerance	☐	Inoperable	☒	Calibrated as left	☐	New instrument
☒	Out of tolerance			☐	No calibration performed		

Maintenance Performed					
☐	Rework scattering chamber	☒	Test scanning probe	☒	Leak Check
☒	Clean Sampling System	☐	Test Absolute Filter	☐	Printer
☐	Replace Cell Lamp	☐	Replace Gaskets	☒	Voltage Checks
☒	Align Optics	☒	Tighten Loose Hardware	☒	Final Test

Calibration Statement	
The instrument listed on this certificate has been calibrated against standards traceable to NIST or other recognized national metrology institutes, derived from ratio type measurements, or compared to nationally recognized consensus standards. A test uncertainty ratio of 4:1 [k=2, approx. 95% confidence level] was maintained unless otherwise stated. All results contained within this certificate relate only to the item(s) calibrated. Any number of factors may cause the calibrated item to drift out of calibration before the instruments calibration interval has expired. This certificate shall not be reproduced except in full and with written consent of ATI. This unit has been calibrated to the most recent revision of PCL-030-WI.	

Calibrated by	L. HANEA	Signed	
Cal Date	02 March 2017	Cal Due	02 March 2018

Registered Office
Unit 10
Protea way
Pixmore Avenue
Letchworth
Hertfordshire
SG6 1JT

Registered in England
No. GB 3889548

VAT Number
GB 770 8627 05000



CERTIFICATE OF COMPLIANCE AEROSOL GENERATOR

No G/29466

The Standards used have been calibrated by internal and external procedures traceable to National Standards.
This Aerosol Generator has been tested with Finavestan A80 B

Date of Calibration: 15-Jun-17	Model	Serial No
Customer H & V Commisioning Services	CF Taylor	12198
Address Kilknowe Office		
16 Barrmill Road		
Galston		
KA4 8HH		
Service Report No 29466		

STANDARDS USED

INSTRUMENT DESCRIPTION	MANUFACTURER	SERIAL No	LAST RECAL	CERT NO
Photometer	Air Techniques	12076	19-Apr-17	29181
Airflow Meter	Airflow Developments	115135	19-May-17	12574
Airflow HLF Bench	Gelman Sciences	9436-89	25-Nov-16	28644
Electrical Safety Tester	Martindale MPAT+	78491386	27-Apr-17	386428
Aerosol Diluter	Air Techniques	13940	27-Jul-16	28001

AEROSOL OUTPUT CONCENTRATION RESULTS

Inlet Bottle Pressure (PSI)	Oil Flow Valve	Heater Block Temperature (°C)	HLF Bench Airflow (L/min)	Upstream Concentration (µg/L)	ELECTRICAL SAFETY TEST RESULTS	
					Test No: 0452	
					Test Mode: Class one	
					Visual: Pass	
					Earth Test: 0.09Ω	
					Insulation Test: ^19.9MΩ	
					Load Test: 0.91KVA	
					Leakage Test: 00.1mA	
FLOW RATE						
					ATI TDA-5B	N/A LPM

CALCULATED RESULTS

Generator Output (g/min) = Upstream Concentration (µg/L) x HLF Bench Airflow (L/min) / 1,000,000

Pressure	Output (g/min)	Pressure	Output (g/min)
5psi	2.20	25psi	14.67
10psi	6.67	30psi	16.00
15psi	10.34		
20psi	12.27		

Out Of Limit Errors As Found. Comments: None.

Next Calibration Due 15-Jun-18

Engineer A.Laurance

OptiCal Sciences Limited

Envirotest House

Anglia Way, Moulton Park Industrial Estate, Northampton NN3 6JA

Telephone: 0844 334 0100 Fax: 0844 334 0101 Email: info@optical-sciences.co.uk

Visit our Website at www.optical-sciences.co.uk

QSF13 30/06/2010

CERTIFICATE OF CALIBRATION

Issued By **Cuthbertson Laird Group**Date of Issue **28 November 2016**Date Received **22 November 2016**

Certificate Number

HAM13016

Page 1 of 2

**Cuthbertson Laird Group****Parkburn Court****Glasgow Road****Hamilton****ML3 0QQ***Approved Signatory*

D. Semple

Electronically Signed

Customer : H & V Commisioning
16 Barmill Road
AyrshireGalston
KA4 8HH**Instrument -**System ID : ID216
Description : AutoZeroing Micromanometer
Manufacturer : DPM
Model Number : TT470S
Serial Number : 7827
Customer Ref:
Procedure Version 2227**Environmental Conditions**

Temperature : 20°C ± 1°C

Relative Humidity : 50%RH ± 15%RH

Mains Voltage : 240V ± 10V

Mains Frequency 50Hz ± 1Hz

Comments

This Certificate Records The On Receipt Calibration Status Of The Instrument.

Traceability Information

<i>Instrument Description</i>	<i>Serial Number</i>	<i>Certificate Number</i>	<i>Cal. Date</i>	<i>Cal. Period Weeks</i>
Air Neutronics MP6KS	0141232	20637	20/07/2015	104
Druck DPI142	2562944	24756	29/10/2016	52

Calibrated By : **D Semple**Date of Calibration : **28 November 2016**

This is to certify the above instrument was fully tested and calibrated. Work carried out was in accordance with procedures laid down in BS EN ISO/IEC 17025:2005. The accuracies of the standards used are traceable to National Standards, via UKAS approved laboratories.

CERTIFICATE OF CALIBRATION

Certificate
HAM13016

Page 2 of 2

Test Title	Applied Value	Reading	Uncertainties
Pressure			
7kPa	1.000kPa	1.01kPa	10Pa
7kPa	2.000kPa	2.01kPa	10Pa
7kPa	3.000kPa	3.01kPa	10Pa
7kPa	4.000kPa	4.02kPa	10Pa
7kPa	5.000kPa	5.03kPa	10Pa
7kPa	6.000kPa	6.03kPa	10Pa
1999Pa	400Pa	399Pa	1Pa
1999Pa	800Pa	798Pa	1Pa
1999Pa	1600Pa	1595Pa	1Pa
199.9Pa	40.0Pa	39.9Pa	0.1Pa
199.9Pa	80.0Pa	79.9Pa	0.1Pa
199.9Pa	160.0Pa	159.7Pa	0.1Pa
Velocity			
100m/s	5.0m/s	5.0m/s	1Pa
100m/s	10.0m/s	10.0m/s	1Pa
100m/s	25.0m/s	25.0m/s	1Pa
100m/s	50.0m/s	50.0m/s	1Pa

End Of Results

CERTIFICATE OF CALIBRATION

Page 1210

Issued By **Cuthbertson Laird Group**

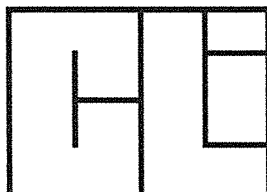
Date of Issue **04 September 2017**

Date Received **31 August 2017**

Certificate Number

HAM18771

Page 1 of 2



Cuthbertson Laird Group

Parkburn Court

Glasgow Road

Hamilton

ML3 0QQ



Approved Signatory

D. Semple

Electronically Signed

Customer : H & V Commisioning
16 Barmill Road
Ayrshire

Galston
KA4 8HH

Instrument -

System ID : ID23629
Description : Environment Meter
Manufacturer : Precision Gold
Model Number : N09AQ
Serial Number : 160506299
Customer Ref:
Procedure Version 2491

Environmental Conditions

Temperature : 20°C ± 1°C
Relative Humidity : 50%RH ± 15%RH

Mains Voltage : 240V ± 10V
Mains Frequency 50Hz ± 1Hz

Comments

This Certificate Records The On Receipt Calibration Status Of The Instrument.

Traceability Information

<i>Instrument Description</i>	<i>Serial Number</i>	<i>Certificate Number</i>	<i>Cal. Date</i>	<i>Cal. Period Weeks</i>
Pulsar P100B	035219	G002819	14/09/2016	52
Vaisala HMI41 Indicator	S1330009	A22418029-1	29/08/2017	52
Vaisala HMP41/45 Probe	J3215002	A22418029-1.	29/08/2017	52

Calibrated By : **D Semple**

Date of Calibration : **04 September 2017**

This is to certify the above instrument was fully tested and calibrated. Work carried out was in accordance with procedures laid down in BS EN ISO/IEC 17025:2005. The accuracies of the standards used are traceable to National Standards, via UKAS approved laboratories.

CERTIFICATE OF CALIBRATION

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Certificate
HAM18771

Page 2 of 2

Test Title	Applied Value	Reading	Uncertainties
Sound Level Meter			
Lo C	94dB	92.8dB	0.6dB
Hi C	94dB	93.5dB	0.6dB
Hi C	104dB	103.3dB	0.6dB
Humidity Meter			
%Rh	47.2%Rh	44.8%Rh	1.6%Rh
Temperature Meter			
°C	21.1°C	21.3°C	0.33°C
End Of Results			

QEUH – Ward 4B Works

The following documents make up the pack of information in relation to the Ward 4B upgrade works for approval by NHS GG&C Project Team.

1. Ward 4B - Description of Works
2. Ward 4B - Architectural Drawings
 - 2.1 NA-SZ-04-SK-332-001-01 (Ceiling detail)
 - 2.2 NA-ZE-04-SK-332-001-03 (Floor plan 1 of 3)
 - 2.3 NA-ZE-04-SK-332-002-03 (Floor plan 2 of 3)
 - 2.4 NA-ZE-04-SK-332-003-03 (Floor plan 3 of 3)
3. Light Fitting - Mirage MX24. Data sheet.
4. Room Pressure Gauge – Dwyer Magnahelic Gauge Series 2300-60Pa. Data sheet.
5. Access Hatch – Profilix Standard wall & ceiling panel. Data sheet.
6. Above Ceiling Maintenance Requirements.
7. Brookfield Multiplex Programme for Works
8. Proposed Access Routes
 - 8.1 For Builders materials and staff.
 - 8.2 For hospital services Core A to Ward 4C and Core C

22nd July 2015.

QEUH – Ward 4b Upgrade Works

Introduction

This documents sets out the works to be carried out to upgrade the 24 bedrooms in the Haemato-oncology Ward (4b) on Level 4 of the Queen Elizabeth University Hospital to achieve between 5 and 10 pascals differential pressure between the bedrooms and the corridors.

Works to be carried out

In order to provide a sealed room, which will assist in achieving the required 5-10 Pascals differential pressure, an MF ceiling will be installed within the 24 bedrooms. The ceiling will be taped filled and painted and sealed at all interfaces with adjoining walls and services. The ensuite rooms currently have a grid and tile type ceiling which will be retained but with the services and tiles silicon sealed .

The current recessed down lighters within the room will be fitted with a diffuser to provide an IP44 rating. On request from the NHS Estates team the diffuser will be sealed using transparent silicon.

The current ventilation system (Air handling unit 31 AHU63 located within Plantroom 31 on Level 3) serving Ward 4b is currently at its maximum performance and achieving approximately 6 air changes per hour. To ensure that there is some additional capacity within the supply unit, the motors, inverter drives (run and standby) and associated electrical supply will be upgraded. This will assist in achieving the desired room differential pressure (5-10pa) and allow for additional resistance as filters degrade. All filters within the AHU will be changed prior to re-commissioning and the AHU and supply duct work re-cleaned.

The current HEPA filters within the supply diffuser housing within the 24 bedrooms will be replaced with new filters.

The users have requested a visual indication of room pressures, to achieve this a magnahelic type analogue differential pressure gauge (as installed in isolation rooms) will be installed at each room.

During the installation process we will carry out a daily “builders” clean to maintain a level of cleanliness and follow this with a sparkle clean prior to commissioning works commencing.

Maintenance Access

At present there are mechanical and electrical services running above the ceiling of the rooms, this is generally, ventilation ductwork, Smoke dampers, heating pipework, duct mounted heating coil, heating controls, domestic water pipework, medical gas pipework, electrical containment, WIFI data point, fire alarm void detector, Nurse call input / output unit. In order to gain access to the maintainable items and items that may need access for fault finding (fire alarm void detector, smoke dampers, heating controls, electrical trunking, duct mounted heating coil, data point) access hatches will be provided in the ceiling. These hatches will be sealed after the works are complete using silicon sealant.

The HEPA filters are installed within the supply air diffuser mounting and can be accessed by removing the diffuser from the room side.

QEUH – Ward 4b Upgrade Works

Commissioning & Validation

On completion of the installation works the commissioning period will commence. The following activities will be carried out:

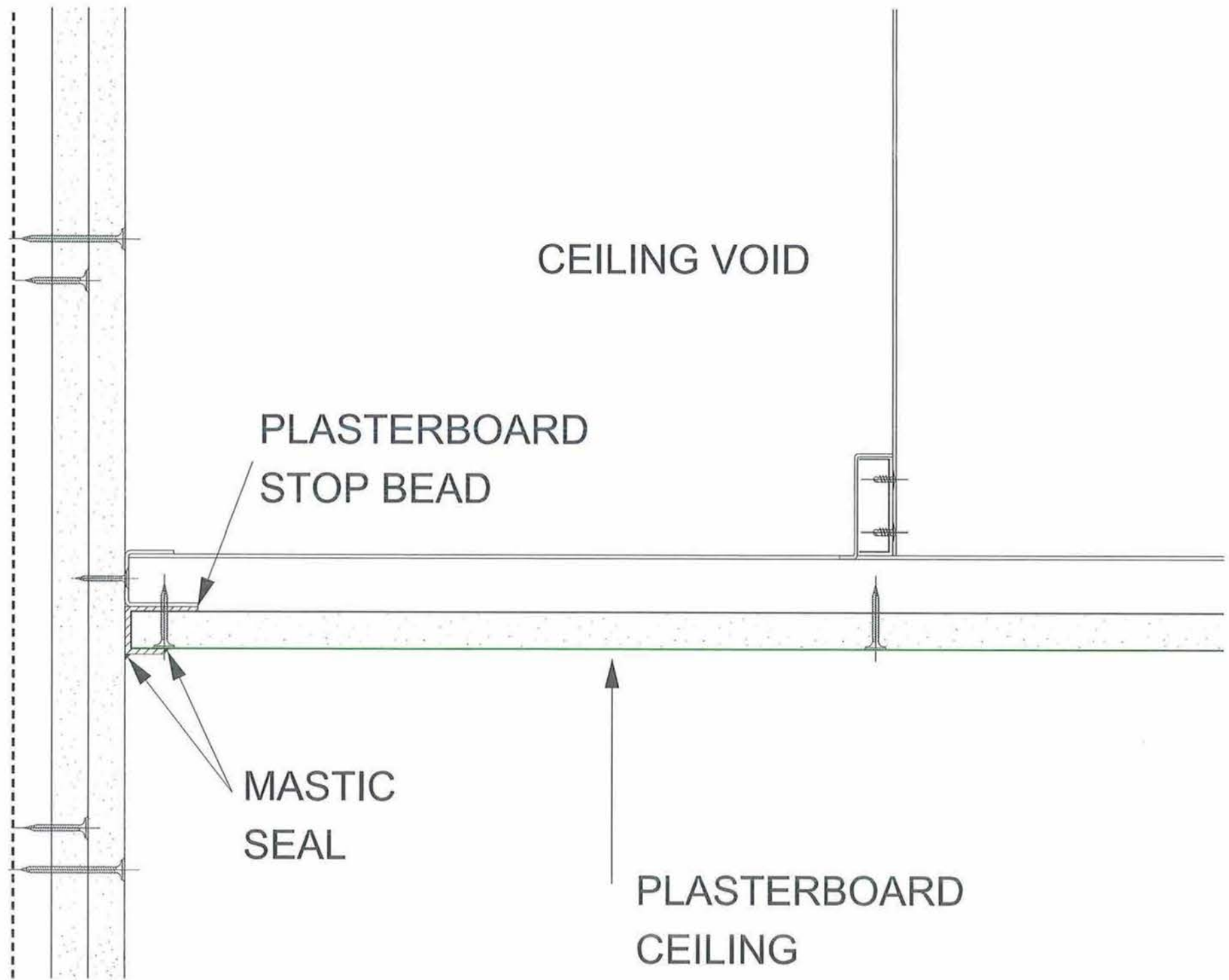
1. The Air handling Unit and Supply ductwork will be cleaned and swab samples taken for analysis.
2. The AHU filters will be changed
3. The ventilation systems (supply and extract) will be re-commissioned (initially with the existing HEPA filters remaining to avoid any possible degradation during commissioning) and room differential pressures measured to ensure 5-10 pascals are achieved
4. The existing HEPA filters will be changed and challenge tests (DOP) will be carried out on each filter.
5. Room pressures will again be measured and adjusted if required and the magnahelic gauges calibrated.
6. The ward corridor to the non-ward areas (Core C, Core G and Core A corridor) differential pressure will be measured to ensure a positive pressure is achieved.
7. Commissioning results will be collated and uploaded to Zutec

At various agreed stages throughout the process we will invite the NHS Project Team (and other interested parties) to witness the commissioning/ tests etc.

Once the above items have been completed the area will be handed back to the NHS to allow a deep clean and microbiological testing to be carried out.

Pentamidine Treatment Room

The pentamidine treatment room (HOW 004) is currently achieving an air change rate of 10 air changes per hour and is under a negative pressure (-1.5Pa). No further works are proposed for this room.



Notes:
• This drawing is copyright.
• Do not scale dimensions from this drawing.
• All discrepancies on this drawing are to be reported to the architect.
• Do not modify any element of this drawing.
• Use drawing only for purpose(s) issued.

- Designer Identification of Hazard/Risk
- Indicates a Residual Risk requiring a Compulsory Action
 - Indicates a Residual Risk for Information
 - Indicates a Residual Risk requiring a Prohibitive Action
 - Indicates a Residual Risk as a Warning

2.1

Rev	Date	Rev	Revision Notes	Chk	App
01	21/07/15	11	FIRST ISSUE	11	EW



Client

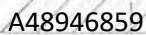
Contractor

NIGHTINGALE architects
associates
87-91 Newman Street
London
W1T 3EY
Tel: 0207 079 9500
Fax: 0207 079 9901
www.nightingaleassociates.com

Project
NEW SOUTH GLASGOW HOSPITALS
(NSGH) PROJECT

Drawing Title
PLASTERBOARD PERIMETER
DETAIL

Job No	09080	Drawn	ML	Checked	ML	Approved	EW
Status	SKETCH	Date	21/07/15	Scale	A3	1:2	
Drawing No	NA	Zone	SZ	Level	04	Type	SK
Content	332	Sequential	001	Rev	01		



2.3

▲NA-ZE-04-PL-332-514▲

▼ NA-ZE-04-PL-332-512 ▼

New South Glasgow Hospitals

Whitecroft
lighting

Mirage MX24

B

REFERENCE

R02

R02E

CATALOGUE NUMBERS

MX24Y226P/SRFA525 - Standard

MX24Y226PEP/SRFA525 - Emergency

MXA24-IP44 - Attachment

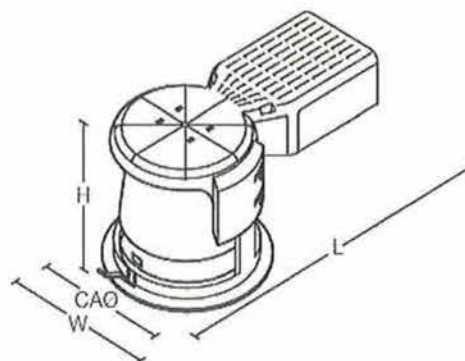
DESCRIPTION

MIRAGE MX24 - Compact fluorescent downlighter, with a 240mm diameter white bezel and vacuum metalised plain reflector. With IP44 attachment. Supplied and fitted with a 1 metre lead and Wago 5 pole flat plug suitable for Wago tee.

IMAGE



DIMENSIONS



DIMENSIONS (L x W x H)

420mm x 240mm x 171mm High, Cut Out :- 230mm

LAMPS

2 x 26W TC-D

CONTROL GEAR

DALI

FINISH

White

EMERGENCY

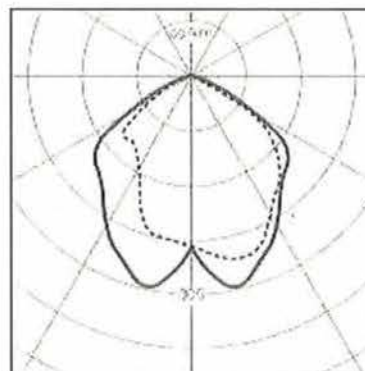
Em pro - 3hr Integral

WEIGHT

2.0kg - Standard

3.0kg - Emergency

PHOTOMETRY (Indicative only)





A48946859



Series
2000

Magnehelic® Gage Models & Ranges

Bezel provides flange for flush mounting in panel.

Clear plastic face is highly resistant to breakage. Provides undistorted viewing of pointer and scale.

Precision litho-printed scale is accurate and easy to read.

Calibrated range spring is flat spring steel. Small amplitude of motion assures consistency and long life. It reacts to pressure on diaphragm. Live length adjustable for calibration.

Red tipped pointer of heat treated aluminum tubing is easy to see. It is rigidly mounted on the helix shaft.

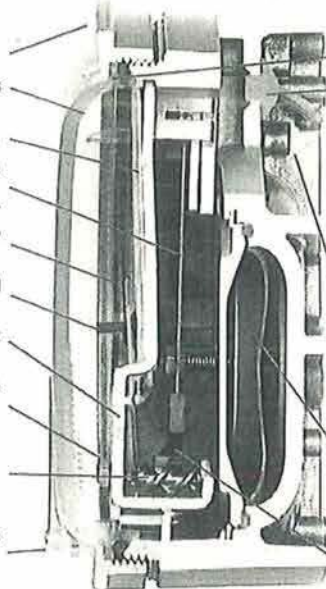
Pointer stops of molded rubber prevent pointer over-travel without damage.

"Wishbone" assembly provides mounting for helix, helix bearings and pointer shaft.

Jeweled bearings are shock-resistant mounted; provide virtually friction-free motion for helix. Motion damped with high viscosity silicone fluid.

Helix is precision made from an alloy of high magnetic permeability. Mounted in jeweled bearings, it turns freely, following the magnetic field to move the pointer across the scale.

Zero adjustment screw is conveniently located in the plastic cover, and is accessible without removing cover. O-ring seal provides pressure tightness.



O-ring seal for cover assures pressure integrity of case.

OVERPRESSURE PROTECTION

Blowout plug is comprised of a rubber plug on the rear which functions as a relief valve by unsealing and venting the gage interior when over pressure reaches approximately 25 psig (1.7 bar). To provide a free path for pressure relief, there are four spacer pads which maintain 0.023" clearance when gage is surface mounted. Do not obstruct the gap created by these pads.

The blowout plug is not used on models above 180" of water pressure, medium or high pressure models, or on gages which require an elastomer other than silicone for the diaphragm.

The blowout plug should not be used as a system overpressure control. High supply pressures may still cause the gage to fail due to over pressurization, resulting in property damage or serious injury. Good engineering practices should be utilized to prevent your system from exceeding the ratings or any component.

Die cast aluminum case is precision made and Iridite-dipped to withstand 168 hour salt spray corrosion test. Exterior finished in baked dark gray hammerfold. One case size is used for all standard pressure options, and for both surface and flush mounting.

Silicone rubber diaphragm with integrally molded O-ring is supported by front and rear plates. It is locked and sealed in position with a sealing plate and retaining ring. Diaphragm motion is restricted to prevent damage due to overpressures.

Samarium Cobalt magnet mounted at one end of range spring rotates helix without mechanical linkages.

Model	Range Inches of Water	Model	Range PSI	Model	Range MM of Water	Model	Range, kPa	Dual Scale Air Velocity Units For use with pitot tube
2000-00N†	0.05-0.2	2201	0-1	2000-6MM†	0-6	2000-0.5KPA	0-0.5	Range in W.C./ Velocity FPM 2000-00AV† 0-25/ 300-2000 2000-0AV† 0-50/ 500-2800 2001AV 0-1.0/ 500-4000 2002AV 0-2.0/ 1000-5600 2005AV 0-5.0/ 2000-8800 2010AV 0-10/ 2000-12500
2000-00†	0-25	2202	0-2	2000-10MM†	0-10	2000-1KPA	0-1	
2000-0†	0-50	2203	0-3	2000-15MM	0-15	2000-1.5KPA	0-1.5	
2001	0-1.0	2204	0-4	2000-25MM	0-25	2000-2KPA	0-2	
2002	0-2.0	2205	0-5	2000-30MM	0-30	2000-2.5KPA	0-2.5	
2003	0-3.0	2210*	0-10	2000-50MM	0-50	2000-3KPA	0-3	
2004	0-4.0	2215*	0-15	2000-80MM	0-80	2000-4KPA	0-4	
2005	0-5.0	2220*	0-20	2000-100MM	0-100	2000-5KPA	0-5	
2006	0-6.0	2230**	0-30	2000-125MM	0-125	2000-8KPA	0-8	
2008	0-8.0			2000-150MM	0-150	2000-10KPA	0-10	
2010	0-10			2000-200MM	0-200	2000-15KPA	0-15	
2012	0-12			2000-250MM	0-250	2000-20KPA	0-20	
2015	0-15			2000-300MM	0-300	2000-25KPA	0-25	
2020	0-20					2000-30KPA	0-30	
2025	0-25							
2030	0-30							
2040	0-40							
2050	0-50							
2060	0-60							
2080	0-80							
2100	0-100							
2120	0-120							
2150	0-150							
2160	0-160							
2180*	0-180							
2250*	0-250							
Zero Center Ranges								
2300-00†	0.125-0.125							
2300-0†	0.25-0.25							
2301	0.5-0.5							
2302	1-0-1							
2304	2-0-2							
2310	5-0-5							
2320	10-0-10							
2330	15-0-15							
							</	

VELOCITY AND VOLUMETRIC FLOW UNITS

Scales are available on the Magnehelic® that read in velocity units (FPM, m/s) or volumetric flow units (SCFM, m³/s, m³/h). Stocked velocity units with dual range scales in inches w.c. and feet per minute are shown above. For other ranges contact the factory. When ordering volumetric flow scales please specify the maximum flow rate and its corresponding pressure. Example: 0.5 in w.c. = 16,000 CFM.

ACCESSORIES

A-321, Safety Relief Valve
A-448, 3-piece magnet kit for mounting Magnehelic® gage directly to magnetic surface
A-135, Rubber gasket for panel mounting
A-401, Plastic Carry Case



A-310A 3-Way Vent Valves

In applications where pressure is continuous and the Magnehelic® gage is connected by metal or plastic tubing which cannot be easily removed, we suggest using Dwyer A-310A vent valves to connect gage. Pressure can then be removed to check or re-zero the gage.

5.0



DATA SHEET

Profilex Standard Wall & Ceiling Panel

Specification

Application: Wall and ceilings

Performance: Non-fire rated

Lock: Budget lock

Frame: Picture frame

Door: Flush metal door

Size (mm): 550x550

Product code: 5200115021

Weight (kg): 6

General information

A general purpose, non-fire rated, beaded frame access panel for application in both walls and ceilings, making access to hidden services quick and easy. This panel is widely specified in Gypframe and MF metal systems as well as being suitable for blockwork construction. It is covered by British Gypsum SpecSure® Lifetime Warranty system, which ensures quality and technical support throughout the building life span. Could serve as a base for any bespoke access panel that is required.

Description

The panel is designed to seamlessly fit within plasterboard as well as masonry constructions. Fitted with a budget lock, flush metal face, manufactured in zinc coated mild steel, 1.2mm gauge. It is fitted with a picture frame where the supporting construction has already been built. The panels are factory painted in polyester powder coated RAL 9910 gloss white and the frame remains visible after installation. Powder coat etch primer white available upon request as a bespoke access panel option. Foam dust seal fitted to the front of the frame

Hinge: pin hinge

Door: removable

Dimensions

Panel is manufactured in 3 standard dimensions, further sizes available on request as bespoke access panels.

Standard dimensions are as follows – hinge side stated first (mm):

300 x 300

450 x 450

550 x 550

600 x 600

The 550 x 550 panel is specially designed to fit seamlessly into British Gypsum framed systems, i.e. panel size 550mm x 550mm to fit between 600mm stud centres.

Installation

1. Insert frame into prepared aperture. Ensure the pre-cut hole is 10mm larger all around than the panel size.
2. For large size, heavy panels, take the door off.
3. Using screws, fix the frame into the framework / masonry ensuring:
 - The fixings are made using the pre-prepared holes on all 4 sides of the frame - it helps to prevent cracking.
 - When screwing through the beaded frame flange, ensure that the heads of the screws are below the edge of the frame, spaced at 150mm centres.
4. Replace the door if removed. When the door is shut, ensure the gap between the panel and the door is equal all around.
5. Apply tape directly over where the beaded frame meets the plasterboard (to assist in preventing cracking).
6. Finish with plaster or joint compound
7. Decorate as required.

Artex Ltd
Pashore Lane
Ruddington, Nottingham
NG11 6AE
www.Profilex.co.uk

Standard panels: 0800 0326345 Bespoke panels: 0115 984 9116

DATA SHEET



Fire Ratings

All Profilex Access Panels are tested in accordance with BS476: Part22: 1987 or BS EN1634-1: 2000. All tests were carried out at The Building Test Centre at British Gypsum, East Leake.

Below summaries our range and certificates

Panel range	Type of protection	EN / BS	Test number
Non-Fire rated access panels	n/a	n/a	No test required – non fire rated
FR1 Wall panels	Integrity (both directions)	EN	BTC 17168F
FR1 Wall panels	Integrity (both directions)	BS	BTC 17468F - Panel A
FR1 Wall panels	Integrity (both directions)	BS	BTC 17468F - Panel D
FR1 Ceiling (Metal faced)	Integrity	BS	BTC 17469F - Panel 3
FR1 Ceiling (Plasterboard faced)	Integrity	BS	BTC 17469F - Panel 4
FR1 Ceiling (Metal faced)	Integrity	BS	BTC 17469F - Panel 5
FR1 Ceiling (Metal faced)	Integrity	BS	BTC 17469F - Panel 6
FR1 Loft Hatch Panel (Metal Faced)	Integrity	BS	BTC 17469F - Panel 1
FR2 panel	Integrity	BS	BTC 2047F

Maintenance

Profilex Access Panels are designed to be maintenance free. An occasional wipe over to remove any marks on the paintwork finish is sufficient. The piano hinge and lock mechanism may be oiled periodically if required, with a standard metal lubricant, to ensure trouble-free door operation.

Spares

A range of spare and replacement parts are available. Please contact Artex Ltd. at the address shown on this leaflet for details of your nearest stockist.

Artex Ltd.
Pasture Lane
Ruddington, Nottingham
NG11 6AE
www.Profilex.co.uk

Standard panels: 0800 0326345 Bespoke panels: 0115 984 9116



Maintainable Equipment	Maintenance Requirement	Comment
Smoke Dampers	12 Monthly	Visual Inspection
Fire Alarm Void Detector	12 Monthly	Test
Heating Controls	12 Monthly	Check Operation
Electrical Trunking	5 Yearly	Inspection & test
Heater Battery	12 Monthly	Check & Clean fins as required

米

Revision Date: 20/07/2015

A48946859

A48946859 *NOTE: NHS DEEP CUBAN & RE-COMMISSION OF WARD FOLLOWS ON FROM 28th SEPT.

• Do not scale or copy from this drawing
 • All dimensions are in millimetres unless otherwise stated
 • Do not modify any dimensions or details
 • This drawing is for information only

Drawn: [Name] / Checked: [Name] / Date: [Date]

X TYPE YOUR NOTES HERE

Access to / from
Labs FM area

8.1

Access to level
4 via FM lift

A48946859

05.03.12.2.00	Issued for information	Rev. 1.0
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05.03.12.2.00	Issued for information	Rev. 1.0
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05.03.12.2.00	Issued for information	Rev. 1.0
05.03.12.2.00	Issued for information	Rev. 1.0

Rev. 1.0 Date: 28/09/10



Brookfield BM
MULTIPLEX

NIGHTINGALE
associates architects

27th Floor, 100
100, 100, 100
100, 100, 100
100, 100, 100

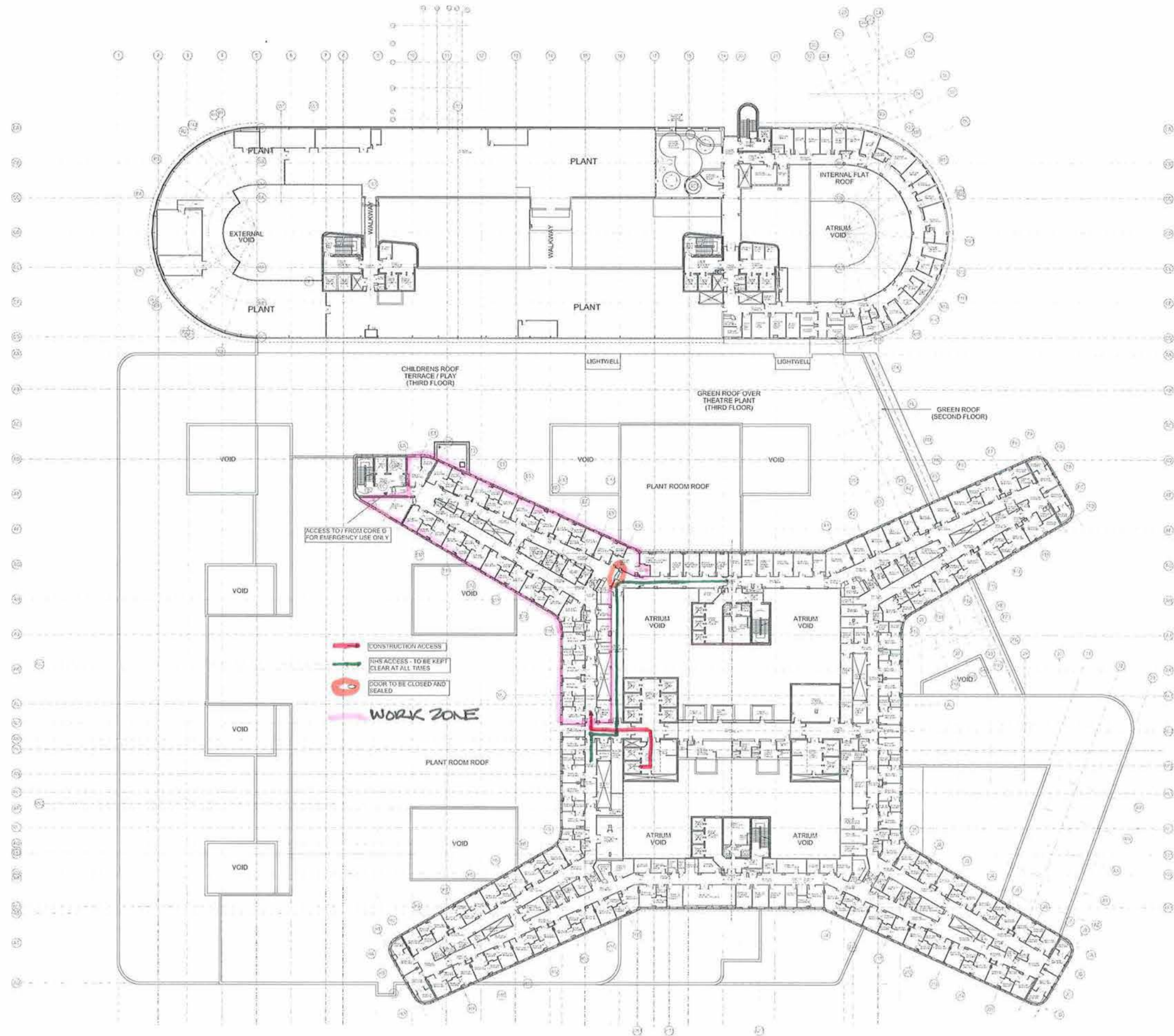
Project:
NEW SOUTH GLASGOW HOSPITALS
(NSGH) PROJECT

Drawing Title:
BASEMENT PLAN

Job No.	Drawn	Checked	Approved
00080	EW	EW	EW
Date:	28/09/10	28/09/10	28/09/10
Scale:	1:300	1:300	1:300

Sheet	Rev.	Date	By	Check
NA XX B1 PL 252 150	06			

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21	2016-11-15	NY	ISSUED FOR AS BUILT	NY	A
22	2016-11-18	CA	Issued for Information	CA	C
23	2016-11-22	CA	Issued for Information	CA	C
25	2016-11-22	CA	Issued for Information	CA	C
24	2016-11-10	CA	Issued to Building Control for Permitting Purposes	CA	C
23	2016-11-11	CA	Issued for Information	NY	D
22	2016-11-10	CA	Issued for Information, Confirmation	CA	D
21	2016-11-08	CA	Issued for Information	CA	D
Ref.	Date	Doc	Relevant Code	CA	App



Others



Contractors

Brookfield **BM**
MULTIPLY

NIGHTINGALE architects
associates

02033 Imperial Street
London
E11 1EX
Tel: 0207 078 9400
Fax: 0207 078 9501
www.nightingaleassociates.com

Project
NEW SOUTH GLASGOW HOSPITALS
(NSGH) PROJECT

FOURTH FLOOR PLAN

Job No. 00000	Drawn ---	Checked EW	Approved EW
Notes AS BUILT		1st Drawn Date 28/09/10	Scale (All) 1:300
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Cont'd	Rev	Issued	Date
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**Brookfield
MULTIPLEX**



QUEEN ELIZABETH UNIVERSITY HOSPITAL



WARD 4B UPGRADE WORKS

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- 1. Description of works carried out**
- 2. Summary of Testing & Commissioning**
- 3. Room Air Permeability Results**
- 4. Ventilation Commissioning and HEPA Filter Testing**
- 5. Ventilation Duct Work cleaning report**
- 6. Room Pressure Monitoring System Commissioning
Report**
- 7. Room Pressure Monitoring System O&M Information &
Drawings**
- 8. Client Training Register**

QEUH – Ward 4b Upgrade Works

Introduction

This documents sets out the works carried out to upgrade the 24 bedrooms in the Haemato-oncology Ward (4b) on Level 4 of the Queen Elizabeth University Hospital to achieve between 5 and 10 pascals differential pressure between the bedrooms and the corridors.

Works carried out

In order to provide a sealed room, an MF plasterboard ceiling has been installed within the 24 bedrooms. The ceiling has been taped and painted and sealed at all interfaces with adjoining walls and services. The en-suite grid and tile ceiling has been retailed but with the services and tiles silicon sealed .

To ensure that the rooms were sufficiently sealed we have carried out room air permeability testing to the parameters set out in SHPN 04-01 Supplement 1.

The recessed down lighters within the room have all been fitted with a diffuser to provide an IP44 rating.

The ventilation (Supply and extract) to the ward bedrooms is provided by Air handling unit 31 AHU63 and the corridor is provided with extract ventilation from extract fan 31-63 EF01 (both the fan and AHU are located within Plantroom 31 on Level 3). In order to provide a more robust ventilation system and to assist in achieving the desired room pressures the AHU supply fans, motors and frequency inverters (duty and standby) were uprated. The ventilation systems have been re-balanced to achieve the room differential pressures (between 5-10Pa) and the pressure from the corridor to the rest of the hospital (positive pressure). The AHU filters were replaced.

The 24 bedrooms are fitted with HEPA filtration in the supply diffusers. A new HEPA filter has been fitted and validated in each room as part of the works. DoP test ports are provided within the ductwork above the ceiling in each room to allow each room HEPA to be tested.

A digital differential pressure monitoring system has been installed within the ward. Sensors have been located above the corridor ceilings linked to air tubes in the rooms and corridor which measure the differential pressure from the room to the corridor with a read out of the pressure displayed on an panel next to the room door. The pressures of all the rooms are displayed on a central panel located at the nurses station. If the pressure in the room drops below 5Pa or above 15pa for more than 2 minutes then an alarm will sound at the room display and at the central display at the nurses station, the audible alarm can be silenced at both the room display and the central display. When the rooms return to within the parameters then the alarms will automatically reset.

Maintenance Access

There are mechanical and electrical services running above the ceiling of the rooms, this is generally, ventilation ductwork, Smoke dampers, heating pipework, duct mounted heating coil, heating controls, domestic water pipework, medical gas pipework, electrical containment, WIFI data point, fire alarm void detector, Nurse call input / output unit. In order to gain access to the maintainable items and items that may need access for fault finding (fire alarm void detector, smoke dampers, heating controls, electrical trunking, duct mounted heating coil, data point) hatches have been provided in the ceiling. These hatches have been sealed using silicon sealant and would need to be re-sealed after they have been opened for access.

QEUH – Ward 4b Upgrade Works

Commissioning & Validation

On completion of the installation works the following commissioning and validation has been carried out:

1. The Air handling Unit and Supply ductwork were cleaned and swab samples taken for analysis.
2. The AHU filters were changed
3. The ventilation systems (supply and extract) were re-commissioned
4. Air Permeability tests were carried out in the 24 rooms.
5. The room to corridor pressures were set and measured
6. The corridor to hospital pressures were measured
7. The room supply HEPA filters have been changed and challenge tests completed (DOP)
8. The new Room differential pressure monitoring system has been commissioned and validated

AHU Ref:	Room Ref	HEPA Filter Fitted	Design Air Change	Design Room Pressure	Vent Commissioned	Room Pressure Measured	HEPA Tested	Air Perm Test
31 AHU 63 Supply & Extract	HOW-031	Yes	6	5-10Pa	Yes	Yes	Yes	Yes
31 AHU 63 Supply & Extract	HOW-029	Yes	6	5-10Pa	Yes	Yes	Yes	Yes
31 AHU 63 Supply & Extract	HOW-026	Yes	6	5-10Pa	Yes	Yes	Yes	Yes
31 AHU 63 Supply & Extract	HOW-024	Yes	6	5-10Pa	Yes	Yes	Yes	Yes
31 AHU 63 Supply & Extract	HOW-021	Yes	6	5-10Pa	Yes	Yes	Yes	Yes
31 AHU 63 Supply & Extract	HOW-020	Yes	6	5-10Pa	Yes	Yes	Yes	Yes
31 AHU 63 Supply & Extract	HOW-017	Yes	6	5-10Pa	Yes	Yes	Yes	Yes
31 AHU 63 Supply & Extract	HOW-015	Yes	6	5-10Pa	Yes	Yes	Yes	Yes
31 AHU 63 Supply & Extract	HOW-012	Yes	6	5-10Pa	Yes	Yes	Yes	Yes
31 AHU 63 Supply & Extract	HOW-011	Yes	6	5-10Pa	Yes	Yes	Yes	Yes
31 AHU 63 Supply & Extract	HOW-009	Yes	6	5-10Pa	Yes	Yes	Yes	Yes
31 AHU 63 Supply & Extract	HOW-067	Yes	6	5-10Pa	Yes	Yes	Yes	Yes
31 AHU 63 Supply & Extract	HOW-064	Yes	6	5-10Pa	Yes	Yes	Yes	Yes
31 AHU 63 Supply & Extract	HOW-062	Yes	6	5-10Pa	Yes	Yes	Yes	Yes
31 AHU 63 Supply & Extract	HOW-059	Yes	6	5-10Pa	Yes	Yes	Yes	Yes
31 AHU 63 Supply & Extract	HOW-058	Yes	6	5-10Pa	Yes	Yes	Yes	Yes
31 AHU 63 Supply & Extract	HOW-055	Yes	6	5-10Pa	Yes	Yes	Yes	Yes
31 AHU 63 Supply & Extract	HOW-053	Yes	6	5-10Pa	Yes	Yes	Yes	Yes
31 AHU 63 Supply & Extract	HOW-050	Yes	6	5-10Pa	Yes	Yes	Yes	Yes
31 AHU 63 Supply & Extract	HOW-202	Yes	6	5-10Pa	Yes	Yes	Yes	Yes
31 AHU 63 Supply & Extract	HOW-198	Yes	6	5-10Pa	Yes	Yes	Yes	Yes
31 AHU 63 Supply & Extract	HOW-195	Yes	6	5-10Pa	Yes	Yes	Yes	Yes
31 AHU 63 Supply & Extract	HOW-193	Yes	6	5-10Pa	Yes	Yes	Yes	Yes
31 AHU 63 Supply & Extract	HOW-190	Yes	6	5-10Pa	Yes	Yes	Yes	Yes



Abbey Park
Humber Road
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CV3 4AQ
UK

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www.rsk.co.uk

Our ref: SBB/524395

FAO: Gillon Armstrong
Brookfield Multiplex Europe
Site Office
Institute of Neurological Science
Queen Elizabeth University Hospital
1345 Govan Road
Glasgow
G51 4TF

Email only: Gillon.Armstrong [REDACTED]

27th October 2015

Dear Mr Armstrong

**New South Glasgow Hospital –Isolation Room Testing
Adult's Hospital Ward Bed 4B**

I write to confirm the results of the air permeability testing which we have undertaken on the isolation rooms within Ward 4B.

Testing was undertaken to prove compliance with the requirement of HBN 04 Supplement 1 – Isolation Facilities in Acute Settings. This requires that the enclosure have 'an average leakage rate of no more than 1 l/s of air per m³ of envelope volume' at a positive and negative pressure differential of 20Pa. Further, the measured positive and negative leakage rates should be within 5% of each other.

Each test included the entrance lobby and main room. The ceiling mounted air supply and extract grilles were temporarily sealed with tape during the tests. No further temporary sealing was present at the time of the tests. A 'Minneapolis' door fan system was utilised to undertake each test. The fan was installed within the lobby access door to the corridor to each enclosure. A multipoint test in accordance with CIBSE TM23; 2000 was undertaken to ensure maximum accuracy.

Cont'd



RSK Environment Ltd
Registered office
34 Albyn Place • Aberdeen • Aberdeenshire • AB10 1FW • UK
Registered in Scotland No. 115530
www.rsk.co.uk

A48946859



Test Results

Bed 76 (HOW-190)	
Positive pressure test result;	0.680 l/s per m ² at 20Pa
Negative pressure test result;	0.647 l/s per m ² at 20Pa
Variation between +ve and -ve results;	4.85%
Average result;	0.664 l/s per m ² at 20Pa
Test results comply with the required criteria laid down in HBN 04 Supplement 1	
Bed 77 (HOW-193)	
Positive pressure test result;	0.856 l/s per m ² at 20Pa
Negative pressure test result;	0.844 l/s per m ² at 20Pa
Variation between +ve and -ve results;	1.40%
Average result;	0.850 l/s per m ² at 20Pa
Test results comply with the required criteria laid down in HBN 04 Supplement 1	
Bed 78 (HOW-195)	
Positive pressure test result;	0.858 l/s per m ² at 20Pa
Negative pressure test result;	0.886 l/s per m ² at 20Pa
Variation between +ve and -ve results;	3.16%
Average result;	0.872 l/s per m ² at 20Pa
Test results comply with the required criteria laid down in HBN 04 Supplement 1	
Bed 79 (HOW-198)	
Positive pressure test result;	0.953 l/s per m ² at 20Pa
Negative pressure test result;	0.986 l/s per m ² at 20Pa
Variation between +ve and -ve results;	3.35%
Average result;	0.970 l/s per m ² at 20Pa
Test results comply with the required criteria laid down in HBN 04 Supplement 1	
Bed 80 (HOW-202)	
Positive pressure test result;	0.580 l/s per m ² at 20Pa
Negative pressure test result;	0.589 l/s per m ² at 20Pa
Variation between +ve and -ve results;	1.52%
Average result;	0.584 l/s per m ² at 20Pa
Test results comply with the required criteria laid down in HBN 04 Supplement 1	

**Test Results Continued**

Bed 81 (HOW-050)	
Positive pressure test result;	0.742 l/s per m ² at 20Pa
Negative pressure test result;	0.744 l/s per m ² at 20Pa
Variation between +ve and -ve results;	0.27%
Average result;	0.743 l/s per m ² at 20Pa
Test results comply with the required criteria laid down in HBN 04 Supplement 1	
Bed 82 (HOW-053)	
Positive pressure test result;	0.897 l/s per m ² at 20Pa
Negative pressure test result;	0.917 l/s per m ² at 20Pa
Variation between +ve and -ve results;	2.18%
Average result;	0.907 l/s per m ² at 20Pa
Test results comply with the required criteria laid down in HBN 04 Supplement 1	
Bed 83 (HOW-055)	
Positive pressure test result;	0.997 l/s per m ² at 20Pa
Negative pressure test result;	0.967 l/s per m ² at 20Pa
Variation between +ve and -ve results;	3.01%
Average result;	0.957 l/s per m ² at 20Pa
Test results comply with the required criteria laid down in HBN 04 Supplement 1	
Bed 84 (HOW-058)	
Positive pressure test result;	0.808 l/s per m ² at 20Pa
Negative pressure test result;	0.842 l/s per m ² at 20Pa
Variation between +ve and -ve results;	4.04%
Average result;	0.825 l/s per m ² at 20Pa
Test results comply with the required criteria laid down in HBN 04 Supplement 1	
Bed 85 (HOW-059)	
Positive pressure test result;	0.847 l/s per m ² at 20Pa
Negative pressure test result;	0.842 l/s per m ² at 20Pa
Variation between +ve and -ve results;	0.59%
Average result;	0.844 l/s per m ² at 20Pa
Test results comply with the required criteria laid down in HBN 04 Supplement 1	

**Test Results Continued**

Bed 86 (HOW-062)	
Positive pressure test result;	0.889 l/s per m ³ at 20Pa
Negative pressure test result;	0.914 l/s per m ³ at 20Pa
Variation between +ve and -ve results;	2.74%
Average result;	0.902 l/s per m ³ at 20Pa
Test results comply with the required criteria laid down in HBN 04 Supplement 1	
Bed 87 (HOW-064)	
Positive pressure test result;	0.947 l/s per m ³ at 20Pa
Negative pressure test result;	0.919 l/s per m ³ at 20Pa
Variation between +ve and -ve results;	2.96%
Average result;	0.933 l/s per m ³ at 20Pa
Test results comply with the required criteria laid down in HBN 04 Supplement 1	
Bed 88 (HOW-067)	
Positive pressure test result;	0.725 l/s per m ³ at 20Pa
Negative pressure test result;	0.744 l/s per m ³ at 20Pa
Variation between +ve and -ve results;	2.55%
Average result;	0.716 l/s per m ³ at 20Pa
Test results comply with the required criteria laid down in HBN 04 Supplement 1	
Bed 89 (HOW-031)	
Positive pressure test result;	0.786 l/s per m ³ at 20Pa
Negative pressure test result;	0.753 l/s per m ³ at 20Pa
Variation between +ve and -ve results;	4.20%
Average result;	0.770 l/s per m ³ at 20Pa
Test results comply with the required criteria laid down in HBN 04 Supplement 1	
Bed 90 (HOW-029)	
Positive pressure test result;	0.856 l/s per m ³ at 20Pa
Negative pressure test result;	0.828 l/s per m ³ at 20Pa
Variation between +ve and -ve results;	3.27%
Average result;	0.842 l/s per m ³ at 20Pa
Test results comply with the required criteria laid down in HBN 04 Supplement 1	

**Test Results Continued*****Bed 91 (HOW-026)***

Positive pressure test result;	0.994 l/s per m ³ at 20Pa
Negative pressure test result;	0.994 l/s per m ³ at 20Pa
Variation between +ve and -ve results;	0%
Average result;	0.994 l/s per m ³ at 20Pa

Test results comply with the required criteria laid down in HBN 04 Supplement 1

Bed 92 (HOW-024)

Positive pressure test result;	0.947 l/s per m ³ at 20Pa
Negative pressure test result;	0.903 l/s per m ³ at 20Pa
Variation between +ve and -ve results;	4.64%
Average result;	0.925 l/s per m ³ at 20Pa

Test results comply with the required criteria laid down in HBN 04 Supplement 1

Bed 93 (HOW-021)

Positive pressure test result;	0.750 l/s per m ³ at 20Pa
Negative pressure test result;	0.739 l/s per m ³ at 20Pa
Variation between +ve and -ve results;	1.47%
Average result;	0.744 l/s per m ³ at 20Pa

Test results comply with the required criteria laid down in HBN 04 Supplement 1

Bed 94 (HOW-020)

Positive pressure test result;	0.750 l/s per m ³ at 20Pa
Negative pressure test result;	0.742 l/s per m ³ at 20Pa
Variation between +ve and -ve results;	1.07%
Average result;	0.746 l/s per m ³ at 20Pa

Test results comply with the required criteria laid down in HBN 04 Supplement 1

Bed 95 (HOW-017)

Positive pressure test result;	0.756 l/s per m ³ at 20Pa
Negative pressure test result;	0.783 l/s per m ³ at 20Pa
Variation between +ve and -ve results;	3.45%
Average result;	0.770 l/s per m ³ at 20Pa

Test results comply with the required criteria laid down in HBN 04 Supplement 1

**Test Results Continued*****Bed 96 (HOW-015)***

Positive pressure test result;	0.961 l/s per m ³ at 20Pa
Negative pressure test result;	0.919 l/s per m ³ at 20Pa
Variation between +ve and -ve results;	4.37%
Average result;	0.940 l/s per m ³ at 20Pa

Test results comply with the required criteria laid down in HBN 04 Supplement 1

Bed 97 (HOW-012)

Positive pressure test result;	0.939 l/s per m ³ at 20Pa
Negative pressure test result;	0.947 l/s per m ³ at 20Pa
Variation between +ve and -ve results;	0.84%
Average result;	0.943 l/s per m ³ at 20Pa

Test results comply with the required criteria laid down in HBN 04 Supplement 1

Bed 98 (HOW-011)

Positive pressure test result;	0.930 l/s per m ³ at 20Pa
Negative pressure test result;	0.956 l/s per m ³ at 20Pa
Variation between +ve and -ve results;	2.72%
Average result;	0.943 l/s per m ³ at 20Pa

Test results comply with the required criteria laid down in HBN 04 Supplement 1

Bed 99 (HOW-009)

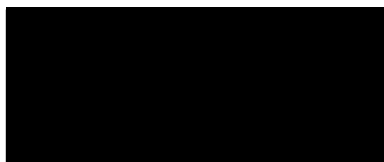
Positive pressure test result;	0.792 l/s per m ³ at 20Pa
Negative pressure test result;	0.806 l/s per m ³ at 20Pa
Variation between +ve and -ve results;	1.61%
Average result;	0.799 l/s per m ³ at 20Pa

Test results comply with the required criteria laid down in HBN 04 Supplement 1



I trust that the above results are self explanatory, but please do not hesitate to contact me if you should have any queries.

Yours sincerely



Stuart B Borland BSc BArch RIAS
Director
Building Science Division
RSK Environment Limited

H & V COMMISSIONING Est 1975
SERVICES LTD

H & V

H & V



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16 BARRMILL ROAD
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KA4 8HH
TEL – 01563 821991
FAX – 01563822220
e-mail - talk2us@handv.co.uk

ISSUED BY: IAN MCKENZIE

APPROVED BY: KAREN GAVIN

DATE: 7TH OCTOBER 2015

DATE: 19TH OCTOBER 2015

PRESENTATION BY: AD

QEUH – WARD 4B

VENTILATION REPORT

JOB No. 5902

OCTOBER 2015

**MERCURY ENGINEERING & BUILDING SERVICES LTD.
MERCURY HOUSE
PAVILION 3
FINNIESTON BUSINESS PARK
MINERVA WAY
GLASGOW
G3 8AU**



QEUH – WARD 4B

VENTILATION REPORT

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AHU 63 Supply (4th Floor Haematology)

AHU 63 Extract (4th Floor Haematology)

31-63/EF01 (4th Floor Haematology)

AHU 63 Room Pressures, Supply & Extract Volumes

AHU 63 Supply Filter Integrity Test

Calibration Certificates

QEUH – WARD 4B
VENTILATION REPORT

AHU 63 SUPPLY (4TH FLOOR HAEMATOLOGY)

H & V
H & V
H & V

Commissioning Services Ltd

EST: 1975

Killnowe Office,
 16 Barrmill Road,
 Galston,
 Ayrshire, KA48HH.
 TEL N°. 01563 821991
 FAX N°. 01563 822220
 E-Mail: talk2us@handy.co.uk

CONTRACT: NSGH, ADULT & CHILDRENS HOSPITAL – PLANTROOM 31

SYSTEM: 31 – AHU 63 SUPPLY (4TH FLOOR HAEMATOLOGY)

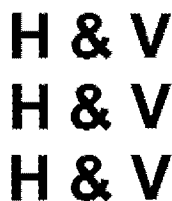
AIR SYSTEMS PRE COMMISSIONING SHEET		✓	X	N/A
1.	Check AHU for damage and that all the components are secure	✓		
2.	Check the transit straps have been removed, if applicable	✓		
3.	Check pulleys are secure, tight, aligned and belts are correctly tensioned, if applicable	✓		
4.	Check with the controls engineer that the system is available to run and that plant rotation is correct	✓		
5.	Check all ductwork/air terminals are fitted and that air regulating dampers are open	✓		
6.	Check louvres are fitted and clear from obstructions, if applicable	✓		
7.	Check fire dampers are open, if applicable	✓		
8.	Check the motor overloads are suitable and set			✓
9.	Check VAV or CAV boxes are installed correctly and ready for use.			✓
10.	Check the floor plenums are complete, if applicable			✓
11.	Complete commissioning test sheets.	✓		

COMMENTS:

ENGINEER: IAN MCKENZIE

DATE: 7/10/15

SHEET 2 OF 10



Commissioning Services Ltd

EST: 1975

Kilknowe Office,
16 Barrmill Road,
Galston,
Ayrshire, KA48HH.
TEL N°. 01563 821991
FAX N°. 01563 822220
E-Mail: talk2us@handv.co.uk

CONTRACT: NSGH, ADULT & CHILDRENS HOSPITAL – PLANTROOM 31

AHU TEST SHEET

SYSTEM: 31 – AHU 63 SUPPLY (4TH FLOOR HAEMATOLOGY)

AHU									
AHU Manufacturer		Barkell		Fan Size		355			
Fan Manufacturer		Comefri		AHU Serial No		OP1B3043173			
Fan Type		Centrifugal		AHU Model N°.		NTHZ 355 R			
		Design		Test		% Design			
Air Volume (L/S)		2800		2426		87			
External Static Pressure (Pa)		2616		Inlet	356	Outlet	663	Total	1019
Fan Rotational Speed (R.P.M)		3850		3089					
Filter Test Data	Pre Filter (Pa)	Inlet	*	Outlet	*	ΔP		55	
	Sec Filter (Pa)	Inlet	*	Outlet	*	ΔP		120	
MOTOR									
Manufacturer		TEC		Output kW		11.0			
Serial N°		1411-0923253		Motor Full Load Current		19.8		Amps	
Voltage		400		Motor Running Current		15.0		Amps	
		Design		Test					
Rotational Speed.		2930		2574					
DRIVE DETAILS									
Motor Pulley/Shaft Size (mmØ)		180 X 2		38		Motor Pulley Taper Lock Size		2012	
Fan Pulley/Shaft Size (mmØ)		150 X 4		50		Fan Pulley Taper Lock Size		2517	
Belt Type/Size		XPZ		975		N°. Of Belts		4	
Shaft Centres mm		270		Adjustment		-	30	+	20 mm
Variable Speed Drive		Yes		Set Point		44 Hz			
STANDBY PLANT									
Test Air Volume	2426	Inlet Pressure	*	Motor Rotational Speed	2574	Motor Running Current			
% Design	87	Outlet Pressure	*	Fan Rotational Speed	3089	15.0		Amps	
Variable Speed Drive		Yes		Set Point		44 Hz			
Comments. Motor 2 Serial No. 1411-0923253 Motor & Fan Pulley = SPZ Control static pressure set point = 663 Pa * Filter pressures taken from magnehelic gauges. Main Volume = TH1 - 1348 l/s + TH2 – 1078 l/s = 2426 l/s									
Instrument Used (Ref N°.) HV05/1, HV05/4 & HV05/5									
Date: 7/10/15		Engineer: Ian McKenzie & Daniel Kane						Sheet 3 of 10	

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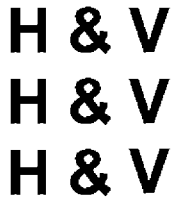
DUCT VOLUME TEST SHEET

SYSTEM: 31 – AHU 63 SUPPLY (4TH FLOOR HAEMATOLOGY)

VELOCITY PROFILE (taken facing air flow)

TEST HOLE LOCATION: LEVEL 4 RISER T3

Test Hole Ref		Duct Dia (mm)		Duct Size (mm)		Duct Area		Design Air Volume		Design Air Velocity	
				Width x Height		M2		L/S		M/S	
TH1				500	500	0.2500		1040		4.16	
5.90	5.80	5.10									
5.50	5.70	5.10									
5.30	5.50	5.20									
5.10	5.50	5.00									
Velocity Sub Totals											
21.80	22.50	20.40									
Total Velocity		Number of Readings		Average Velocity		Measured Air Volume		% Design		Static Pressure	
M/S				M/S		L/S				Pa	
64.7		12		5.39		1348		130		365	
Remarks: Test hole serves Branch A											
Instrument Used: HV05/1											
Date: 7/10/15		Engineer: Ian McKenzie & Daniel Kane								Sheet 4 of 10	

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CONTRACT: NSGH, ADULT & CHILDRENS HOSPITAL – PLANTROOM 31**DUCT VOLUME TEST SHEET****SYSTEM: 31 – AHU 63 SUPPLY (4TH FLOOR HAEMATOLOGY)**

VELOCITY PROFILE (taken facing air flow)

TEST HOLE LOCATION: LEVEL 4 RISER T3

Test Hole Ref		Duct Dia (mm)		Duct Size (mm)		Duct Area		Design Air Volume		Design Air Velocity	
				Width x Height		M2		L/S		M/S	
TH2				700	350	0.2450		900		3.67	
6.00	4.80	4.50	7.10								
6.00	3.70	3.00	5.90								
5.50	3.50	2.90	4.50								
Velocity Sub Totals											
17.50	12.00	10.20	13.10								
Total Velocity	Number of Readings		Average Velocity		Measured Air Volume		% Design		Static Pressure		
M/S			M/S		L/S				Pa		
52.8	12		4.40		1078		120		376		
Remarks: Test Hole serves Branch B											
Instrument Used: HV05/1											
Date: 7/10/15		Engineer: Ian McKenzie & Daniel Kane							Sheet 5 of 10		

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SYSTEM: 31 – AHU 63 SUPPLY (4TH FLOOR HAEMATOLOGY)

TEST HOLE LOCATION: CEILING VOID

(

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GRILLE TEST SHEET

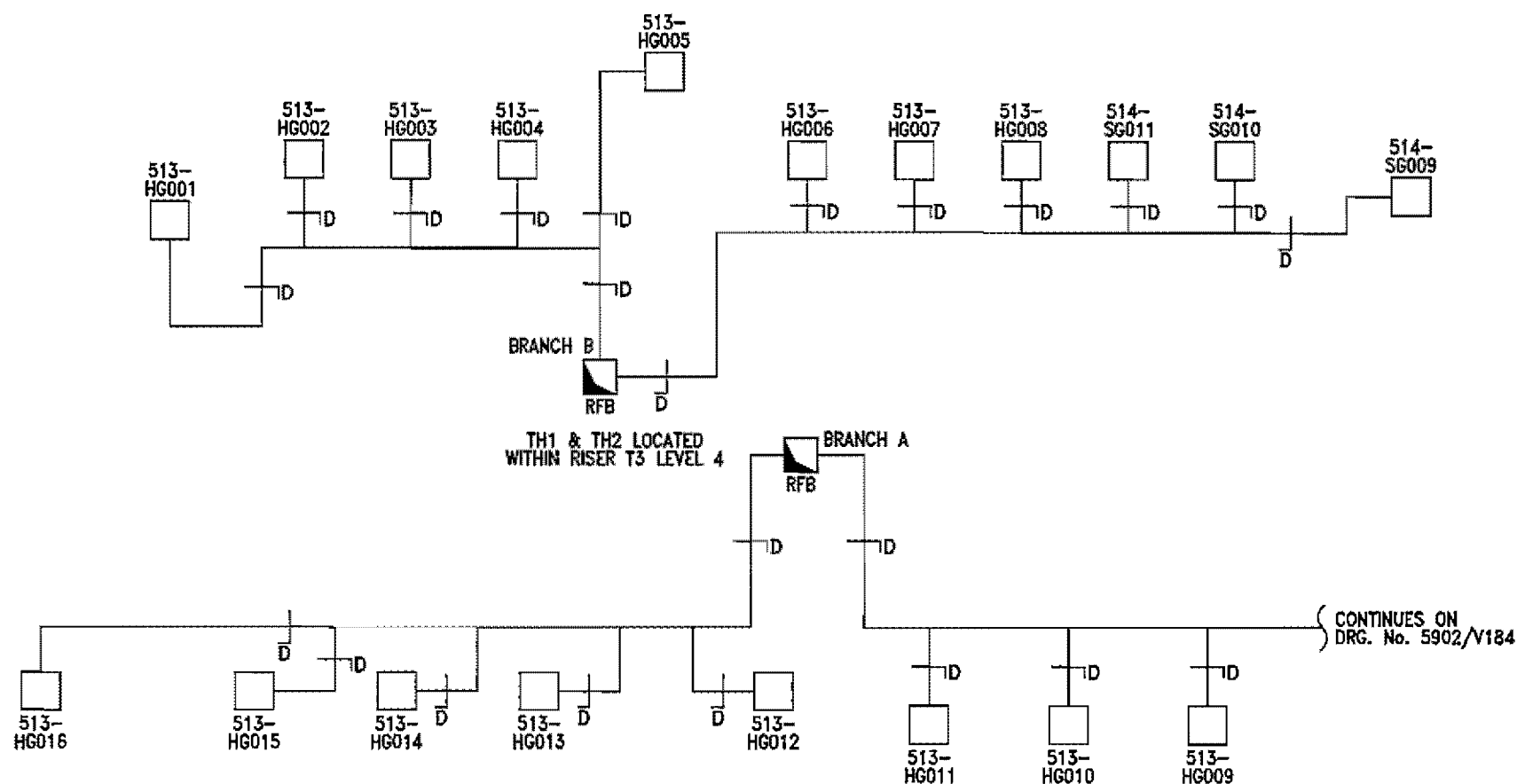
SYSTEM: 31 – AHU 63 SUPPLY (4TH FLOOR HAEMATOLGY)

Remarks: *Pressurised room, therefore direct Balometer readings recorded and used as final reading. Room volumes set to control room differential pressures.

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GRILLE TEST SHEET

SYSTEM: 31 – AHU 63 SUPPLY (4TH FLOOR HAEMATOLOGY)



FOURTH FLOOR

SHEET: 9 OF 10

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CONTINUES ON
DRG. No. 5902/V183512-
HG001512-
HG002512-
HG003512-
HG004512-
HG005

FOURTH FLOOR

31-AHU63

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PLANTROOM 31

SHEET: 10 OF 10

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31-AHU 63 SUPPLY
4TH FLOOR HAEMATOLOGY

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DATE:

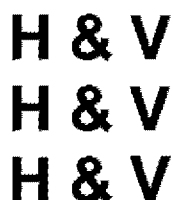
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DRG. No.:

5902/V184

QEUH – WARD 4B
VENTILATION REPORT

AHU 63 EXTRACT (4TH FLOOR HAEMATOLOGY)

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SYSTEM: 31 – AHU 63 EXTRACT (4TH FLOOR HAEMOTOLOGY)

AIR SYSTEMS PRE COMMISSIONING SHEET		✓	X	N/A
1.	Check AHU for damage and that all the components are secure	✓		
2.	Check the transit straps have been removed, if applicable	✓		
3.	Check pulleys are secure, tight, aligned and belts are correctly tensioned, if applicable	✓		
4.	Check with the controls engineer that the system is available to run and that plant rotation is correct	✓		
5.	Check all ductwork/air terminals are fitted and that air regulating dampers are open	✓		
6.	Check louvres are fitted and clear from obstructions, if applicable	✓		
7.	Check fire dampers are open, if applicable	✓		
8.	Check the motor overloads are suitable and set			✓
9.	Check VAV or CAV boxes are installed correctly and ready for use.			✓
10.	Check the floor plenums are complete, if applicable			✓
11.	Complete commissioning test sheets.	✓		

COMMENTS:

ENGINEER: IAN MCKENZIE

DATE: 7/10/15

SHEET 2 OF 9

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AHU TEST SHEET

SYSTEM: 31 – AHU 63 EXTRACT (4TH FLOOR HAEMOTOLOGY)

AHU									
AHU Manufacturer		Barkell		Fan Size		355			
Fan Manufacturer		Comefri		AHU Serial No		OP1B3043173			
Fan Type		Centrifugal		AHU Model N°.		NTHZ 355 R			
		Design		Test		% Design			
Air Volume (L/S)		1391		965		69			
External Static Pressure (Pa)		535		Inlet	170	Outlet	28	Total	198
Fan Rotational Speed (R.P.M)		1900		1907					
Filter Test Data	Pre Filter (Pa)	Inlet	*	Outlet	*	ΔP		15	
	Sec Filter (Pa)	Inlet	N/A	Outlet	N/A	ΔP		N/A	
MOTOR									
Manufacturer		TEC		Output kW		2.2			
Serial N°		1305-0984906		Motor Full Load Current		8.51		Amps	
Voltage		400		Motor Running Current		2.5		Amps	
		Design		Test					
Rotational Speed.		1445		1445					
DRIVE DETAILS									
Motor Pulley/Shaft Size (mmØ)		132 x 1		28		Motor Pulley Taper Lock Size		1610	
Fan Pulley/Shaft Size (mmØ)		100 x 2		40		Fan Pulley Taper Lock Size		1610	
Belt Type/Size		XPA		932		N°. Of Belts		2	
Shaft Centres mm		280		Adjustment		-	40	+	20 mm
Variable Speed Drive		Yes		Set Point		30 Hz			
STANDBY PLANT									
Test Air Volume	965	Inlet Pressure	*	Motor Rotational Speed	1445	Motor Running Current			
% Design	69	Outlet Pressure	*	Fan Rotational Speed	1907	2.5		Amps	
Variable Speed Drive		Yes		Set Point		30 Hz			
Comments. Motor 2 Serial No. 1305-098491 Motor & Fan Pulley = SPA * Filter pressures taken from magnehelic gauges.									
Instrument Used (Ref N°.) HV05/1, HV05/4 & HV05/5									
Date: 7/10/15		Engineer: Ian McKenzie & Daniel Kane						Sheet 3 of 9	

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DUCT VOLUME TEST SHEET

SYSTEM: 31 – AHU 63 EXTRACT (4TH FLOOR HAEMOTOLOGY)

VELOCITY PROFILE (taken facing air flow)

TEST HOLE LOCATION: LEVEL 4 RISER T4

Test Hole Ref		Duct Dia (mm)		Duct Size (mm)		Duct Area		Design Air Volume		Design Air Velocity	
				Width x Height		M2		L/S		M/S	
Main TH				700	450	0.3150		1391		4.42	
3.70	3.40	3.60	3.80								
3.40	3.20	3.20	3.30								
3.50	2.70	2.40	2.80								
3.40	2.40	2.10	2.10								
Velocity Sub Totals											
14.00	11.70	11.30	12.00								
Total Velocity		Number of Readings		Average Velocity		Measured Air Volume		% Design		Static Pressure	
M/S				M/S		L/S				Pa	
49		16		3.06		965		69		114	
Remarks:											
Instrument Used: HV05/1											
Date: 7/10/15		Engineer: Ian McKenzie & Daniel Kane								Sheet 4 of 9	

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DUCT VOLUME TEST SHEET

SYSTEM: 31 – AHU 63 EXTRACT (4TH FLOOR HAEMATOLOGY)

TEST HOLE LOCATION: CEILING VOID

[illegible]

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GRILLE TEST SHEET

SYSTEM: 31 – AHU 63 EXTRACT (4TH FLOOR HAEMOTOLOGY)

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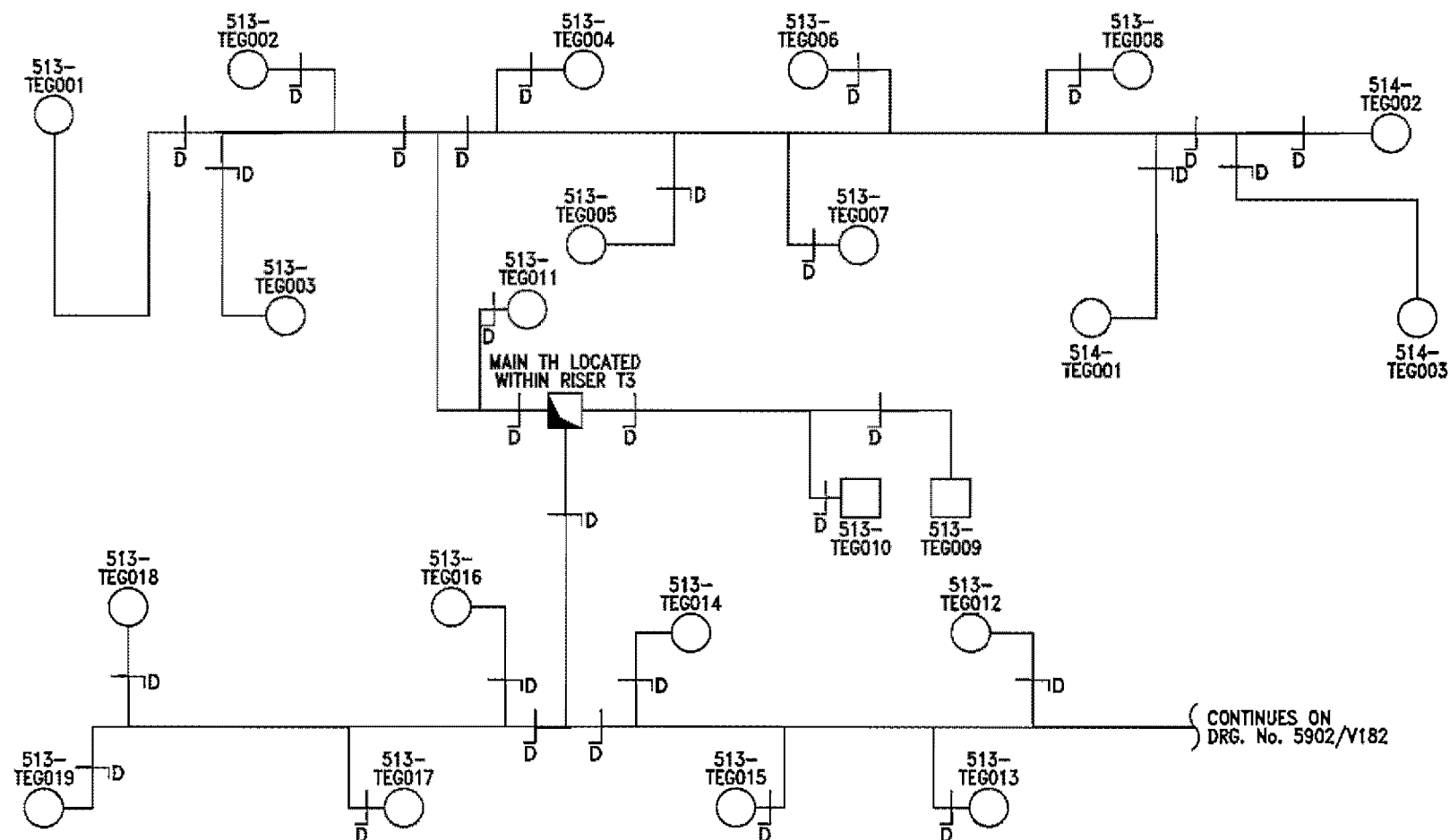
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GRILLE TEST SHEET

SYSTEM: 31 – AHU 63 EXTRACT (4TH FLOOR HAEMATOLOGY)

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FOURTH FLOOR

SHEET: 8 OF 9

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4TH FLOOR HAEMATOLOGY

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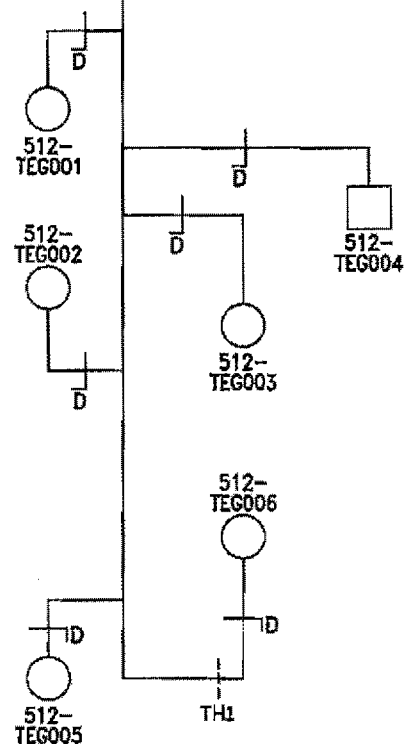
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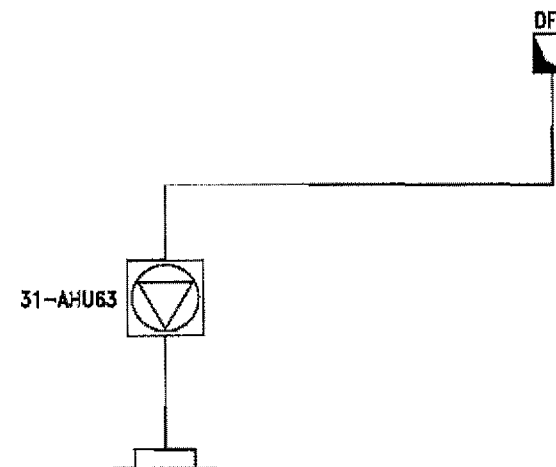
01/07/15

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5902/V181

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DRG. No. 5902/V181

FOURTH FLOOR



PLANTROOM 31

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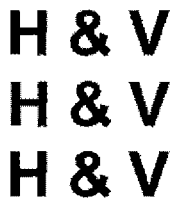
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QEUH – WARD 4B
VENTILATION REPORT

31-63/EF01 (4TH FLOOR HAEMATOLOGY)

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SYSTEM: 31 – 63/EF01 (4TH FLOOR HAEMATOLOGY)

AIR SYSTEMS PRE COMMISSIONING SHEET		✓	X	N/A
1.	Check Fan for damage and that all the components are secure	✓		
2.	Check the transit straps have been removed, if applicable	✓		
3.	Check pulleys are secure, tight, aligned and belts are correctly tensioned, if applicable			✓
4.	Check with the controls engineer that the system is available to run and that plant rotation is correct	✓		
5.	Check all ductwork/air terminals are fitted and that air regulating dampers are open	✓		
6.	Check louvres are fitted and clear from obstructions, if applicable	✓		
7.	Check fire dampers are open, if applicable	✓		
8.	Check the motor overloads are suitable and set			✓
9.	Check VAV or CAV boxes are installed correctly and ready for use.			✓
10.	Check the floor plenums are complete, if applicable			✓
11.	Complete commissioning test sheets.	✓		

COMMENTS

ENGINEER: IAN MCKENZIE

DATE: 7/10/15

SHEET 2 OF 7

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DIRECT DRIVE FAN TEST SHEET SYSTEM: 31 – 63/EF01 (4TH FLOOR HAEMATOLOGY)

FAN									
AHU Manufacturer		Not Applicable		Fan Size		Not Stated			
Fan Manufacturer		Sandometal		Fan Serial No		1304370-313			
Fan Type		Plug		Fan Model N°.		ESDM1/1			
		Design		Test				% Design	
Air Volume (L/S)		699		1011				145	
External Static Pressure (Pa)		325		Inlet	241	Outlet	68	Total	309
Filter Test Data	Pre Filter (Pa)	Inlet	N/A	Outlet	N/A			ΔP	N/A
	Sec Filter (Pa)	Inlet	N/A	Outlet	N/A			ΔP	N/A
MOTOR									
Manufacturer		Ziehl-Abegg		Output kW		1.1			
Serial N°		13010169		Motor Full Load Current		2.53		Amps	
Voltage		230		Motor Running Current		1.66		Amps	
		Design		Test					
Rotational Speed R.P.M		1430		1158					
DRIVE DETAILS									
Variable Speed Drive				Yes		Set Point		70 Hz (Max 86 Hz)	
Comments: N/A – Not Applicable System volume set to control corridor pressure from pressurised rooms.									
Instrument Used (Ref N°.) HV05/1, HV05/4 & HV05/5									
Date: 7/10/15		Engineer: Ian McKenzie & Daniel Kane						Sheet 3 of 7	

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DUCT VOLUME TEST SHEET

SYSTEM: 31 – 63/EF01 (4TH FLOOR HAEMATOLOGY)

VELOCITY PROFILE (taken facing air flow)

Test Hole Ref		Duct Dia (mm)		Duct Size (mm)		Duct Area		Design Air Volume		Design Air Velocity	
				Width x Height		M2		L/S		M/S	
Main TH				500 350		0.1750		699		3.99	
5.90	6.00	5.60									
5.80	5.70	5.80									
5.70	5.70	5.70									
5.80	5.80	5.80									

Velocity Sub Totals

23.20	23.20	22.90									
-------	-------	-------	--	--	--	--	--	--	--	--	--

Total Velocity	Number of Readings	Average Velocity	Measured Air Volume	% Design	Static Pressure
M/S		M/S	L/S		Pa
69.3	12	5.78	1011	145	196

Remarks:

Instrument Used: HV12/1

Date: 7/10/15

Engineer: Ian McKenzie & Daniel Kane

Sheet 4 of 7

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DUCT VOLUME TEST SHEET

SYSTEM: 31 – 63/EF01 (4TH FLOOR HAEMATOLOGY)

VELOCITY PROFILE (taken facing air flow)

Test Hole Ref		Duct Dia (mm)		Duct Size (mm)		Duct Area		Design Air Volume		Design Air Velocity	
				Width x Height		M2		L/S		M/S	
TH1		250				0.0491		90		1.83	
1.70	1.70										
1.90	1.90										
1.90	2.00										
1.90	1.90										

Velocity Sub Totals

7.40	7.50										
------	------	--	--	--	--	--	--	--	--	--	--

Total Velocity	Number of Readings	Average Velocity	Measured Air Volume	% Design	Static Pressure
M/S		M/S	L/S		Pa
14.9	8	1.86	91	102	11

Remarks: Test Volume 91l/s + Balometer Volume 79l/s = 1.15 Factor.

Instrument Used: HV05/1

Date: 7/10/15

Engineer: Ian McKenzie & Daniel Kane

Sheet 5 of 7

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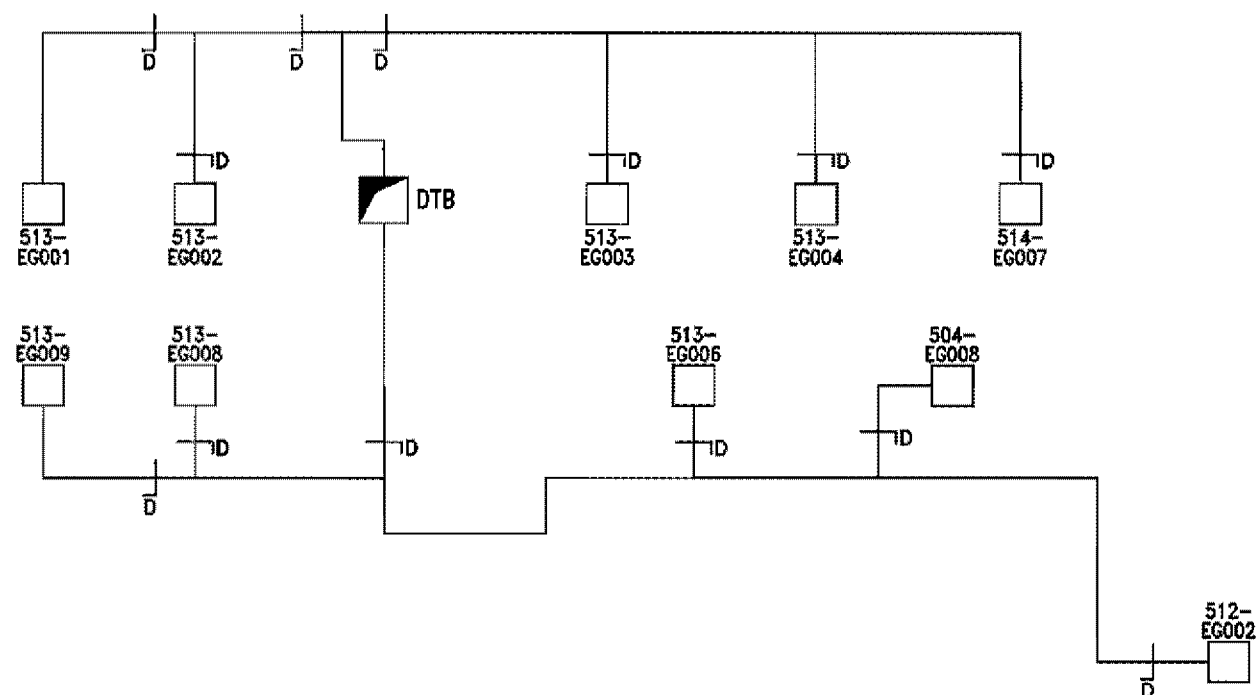
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GRILLE TEST SHEET

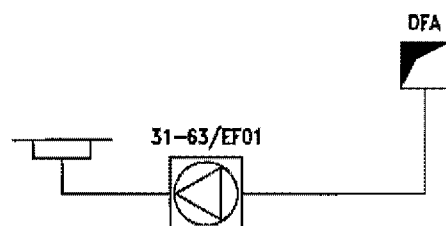
SYSTEM: 31 – 63/EF01 (4TH FLOOR HAEMATOLOGY)

REV: 19/10/15

A48946859



4TH FLOOR



3RD FLOOR PLANTROOM 31

SHEET: 7 OF 7

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 31-63/EF01 4TH FLOOR
 HAEMATOLOGY

DRAWN:
 KL/SM

DATE:
 18/12/14

DRG. No.:
 5902/V 3

QEUH – WARD 4B
VENTILATION REPORT

AHU 63 ROOM PRESSURES, SUPPLY & EXTRACT VOLUMES



New South Glasgow Hospital

31AHU63 - Level 4 - 4B Wards – Room Pressures, Supply & Extract Air Volumes

Room Bed Ref.:	Room Door Ref.:	Room to Corridor Pressure Set Pa		Minimum Supply Design Volume l/s	Supply Grille Volume l/s	Extract Grille Volumes l/s
		Micro-manometer Reading Pa	Room Digital Display Pa			
76	HOW190	7.0	7.0	80	91	30
77	HOW193	7.0	7.0	80	97	30
78	HOW195	7.1	7.0	80	92	31
79	HOW198	7.7	7.1	80	95	30
80 XL	HOW202	6.9	7.1	100	105	30
81	HOW050	6.9	7.0	80	84	29
82	HOW053	6.8	6.8	80	83	30
83	HOW055	7.1	6.6	80	87	32
84	HOW058	7.8	7.7	80	83	28
85	HOW059	7.7	7.1	80	84	30
86	HOW062	7.1	7.2	80	106	31
87	HOW064	7.4	7.6	80	100	30
88	HOW067	7.9	7.8	80	91	30
89 XL	HOW031	7.0	7.1	100	103	33
90	HOW029	7.6	7.8	80	96	30
91	HOW026	7.5	7.6	80	98	33
92	HOW024	7.8	7.9	80	99	30
93	HOW021	7.1	7.2	80	83	30
94	HOW020	7.7	7.6	80	82	31
95	HOW017	7.5	7.8	80	82	30
96	HOW015	7.1	7.2	80	99	31
97	HOW012	6.2	6.7	80	90	30
98	HOW011	6.9	7.2	80	98	30
99 XL	HOW099	6.3	6.4	100	100	31

Room Pressures to be set between 5Pa and 10Pa target pressure 7Pa $\pm$ 1Pa



Comments:

Above readings were finalised and witnessed by BM's Julie Miller 6th October 2015.

NB: Door seals have been trimmed to achieve room to corridor differential pressures and the required minimum air change rate (standard size rooms air volume design minimum 80l/s and the 3 larger rooms at a minimum air volume 100l/s).

31AHU63 Supply set at 44Hz

31AHU63 Extract set at 30Hz

31-63EF01 Corridor extract set at 70Hz (Set to control room corridor pressure)

Ward 4B corridor pressure is set to external corridors at approximately +10Pa.

Room pressure alarms/information;

- 1) High room pressure set at 15Pa
- 2) Low room pressure alarm set at 5Pa
- 3) Door open or out of specification alarm is set for a 2 minute period before alarming.
- 4) Room pressure alarms can be silenced from the button on the digital display set at each room door entry (on the stainless steel plate).

Report compiled and finalised by Ian McKenzie (H&V)
8th October 2015

QEUH – WARD 4B
VENTILATION REPORT

AHU 63 SUPPLY FILTER INTEGRITY TEST



31AHU63 Supply - Level 4 - 4B Wards - HEPA Filter Integrity Test Report

Room Bed Ref.:	Room Door Ref.:	HEPA Filter S/N:	Upstream Aerosol Concentration Pre Scan	Maximum Ratio % Penetration	Recorded Downstream Concentration Ratio %	% Upstream Aerosol Concentration Post Scan	Pass/Fail
76	HOW190	007000-35157	62mg/m ³	≤0.01%	0.0011%	109%	Pass
77	HOW193	006997-35157	59mg/m ³	≤0.01%	0.0004%	111%	Pass
78	HOW195	006991-35157	71mg/m ³	≤0.01%	0.0014%	97%	Pass
79	HOW198	007002-35157	76mg/m ³	≤0.01%	0.0006%	102%	Pass
80	HOW202	007012-35157	63mg/m ³	≤0.01%	0.0034%	92%	Pass
81	HOW050	007009-35157	62mg/m ³	≤0.01%	0.0054%	98%	Pass
82	HOW053	007014-35157	51mg/m ³	≤0.01%	0.0014%	108%	Pass
83	HOW055	006996-35157	35mg/m ³	≤0.01%	0.0042%	105%	Pass
84	HOW058	007001-35157	53mg/m ³	≤0.01%	0.0006%	101%	Pass
85	HOW059	007007-35157	66mg/m ³	≤0.01%	0.0014%	103%	Pass
86	HOW062	006995-35157	67mg/m ³	≤0.01%	0.0002%	104%	Pass
87	HOW064	006998-35157	55mg/m ³	≤0.01%	0.0006%	104%	Pass
88	HOW067	006993-35157	60mg/m ³	≤0.01%	0.0010%	100%	Pass
89	HOW031	007003-35157	75mg/m ³	≤0.01%	0.0011%	102%	Pass
90	HOW029	006999-35157	70mg/m ³	≤0.01%	0.0009%	101%	Pass
91	HOW026	007006-35157	72mg/m ³	≤0.01%	0.0007%	98%	Pass
92	HOW024	007013-35157	57mg/m ³	≤0.01%	0.0002%	111%	Pass
93	HOW021	006992-35157	17mg/m ³	≤0.01%	0.0012%	96%	Pass
94	HOW020	007011-35157	52mg/m ³	≤0.01%	0.0008%	110%	Pass
95	HOW017	007008-35157	75mg/m ³	≤0.01%	0.0005%	106%	Pass
96	HOW015	007010-35157	47mg/m ³	≤0.01%	0.0009%	96%	Pass
97	HOW012	007004-35157	42mg/m ³	≤0.01%	0.0021%	104%	Pass
98	HOW011	007005-35157	44mg/m ³	≤0.01%	0.0023%	98%	Pass
99	HOW099	006944-35157	43mg/m ³	≤0.01%	0.0007%	109%	Pass



New South Glasgow Hospital

31AHU63 Supply - Level 4 - 4B Wards - HEPA Filter Integrity Test Report

Test Instruments Used	Serial No.	Calibration Due
Photometer	TDA-2G	March 2016
Aerosol Generator	ATI Aerosol Generator	March 2016

RESULTS (Enter Pass / Fail) Results and test conditions are compliant with BS EN ISO 14644-3	PASS
--	------

	COMPLETED BY:	WITNESSED BY
PRINT:	Ian McKenzie	
SIGNATURE:		
DATE:	8 th October 2015	

QEUH – WARD 4B
VENTILATION REPORT

CALIBRATION CERTIFICATES



CERTIFICATE OF COMPLIANCE AEROSOL GENERATOR

No G/26262

The Standards used have been calibrated by internal and external procedures traceable to National Standards.
This Aerosol Generator has been tested with Shell Ondina EL Oil.

Date of Calibration: 16-Mar-15	Model	Serial No
Customer H & V Commissioning Services	Vicount 1300	1025732
Address Kilknowe Office		
16 Barrmill Road		
Galston, Ayrshire		
KA4 8HH		
Service Report No 26262		

STANDARDS USED

INSTRUMENT DESCRIPTION	MANUFACTURER	SERIAL No	LAST RECAL	CERT NO
Photometer	Air Techniques	12076	23-Jan-15	26127
Airflow Meter	Kanomax Climomaster	440952	4-Jul-14	640820
Airflow HLF Bench	Gelman Sciences	9436-89	18-Sep-14	25629
Electrical Safety Tester	MicroPAT+	78491386	20-Mar-14	337772
Aerosol Diluter	Air Techniques	11645	3-Dec-14	25929

AEROSOL OUTPUT CONCENTRATION RESULTS

ELECTRICAL SAFETY TEST RESULTS

Inlet Bottle Pressure (PSI)	Oil Flow Valve	Heater Block Temperature (°C)	HLF Bench Airflow (L/min)	Upstream Concentration (µg/L)	Test No: 213
10	-	316	14,375.9	45	Test Mode: Class one
20	-	316	14,375.9	130	Visual: Pass
30	-	316	14,375.9	200	Earth Test: 0.06 Ω
40	-	316	14,375.9	280	Insulation Test: ^19.9 MΩ
50	-	316	14,375.9	350	Load Test: 0.00 KVA
					Leakage Test: 00.1 mA
					FLOW RATE
					ATI TDA-5B
					N/A LPM

CALCULATED RESULTS

Generator Output (g/min) = Upstream Concentration (µg/L) x HLF Bench Airflow (L/min) / 1,000,000

Pressure	Output (g/min)	Pressure	Output (g/min)
10 psi	0.65	50 psi	5.03
20 psi	1.87		
30 psi	2.88		
40 psi	4.03		

Out Of Limit Errors As Found. Comments: None

Next Calibration Due 16-Mar-16

Engineer A.KERR

OptiCal Sciences Limited

Envirotest House

Anglia Way, Moulton Park Industrial Estate, Northampton NN3 6JA

Telephone: 0844 334 0100 Fax: 0844 334 0101 Email: info@optical-sciences.co.uk

Visit our Website at www.optical-sciences.co.uk

QSF13 30/06/2010



SERVICE REPORT

DATE: 16-Mar-15

CUSTOMER H & V Commissioning Services
 ADDRESS Kilknowe Office
 16 Barrmill Road
 Galston, Ayrshire
 KA4 8HH
 CONTACT Angela Daly
 PURCHASE ORDER NO 4778/IS/AC
 OSL ORDER REF 23048

ENGINEER Adam Kerr	WORK REQUIRED Repair / Service / output
HOURS as per quote	CALIBRATION CERT. ISSUED 26262
TRAVELLING TIME	MODEL LV1300
OTHER EXPENSES	SERIAL NO 1025732

☐ CONTRACT ☐ WARRANTY ☒ CUSTOMER A/C OTHER

On inspection of instrument blowing fuses and failing portable appliance test

Fault traced to heater elements failing

Replaced 2 x heater elements - OK

Portable appliances test carried out, See electrical safety results

Using LAF Bench, 1000:1 diluter and Ref Photometer, recorded output concentration

Calculate output g/min

Checked normal working functions of instrument - OK

PART NO.	QTY.	DESCRIPTION	ELECTRICAL SAFETY TEST RESULTS
	2	Heater elements	Visual: pass
			E. Continuity: 0.06Ω
			Fuse Rating: -
			Insulation: >19.9 MΩ
			Run Test: 0.00 KVA
			Flash: N/A
FOR OFFICE USE ONLY: T = L =			Test No: 213

ENGINEER SIGNATURE

SERVICE REPORT No 26262



ISO 9001

OptiCal Sciences Limited
 Envirotest House
 Anglia Way, Moulton Park Industrial Estate, Northampton NN3 6JA
 Telephone: 0844 334 0100 Fax: 0844 334 0101 Email: info@optical-sciences.co.uk
 Visit our Website at www.optical-sciences.co.uk



QSF19
 03/05/2010

A48946859

CERTIFICATE OF CALIBRATION

Issued By IRC Ltd

Date of Issue 27 August 2015

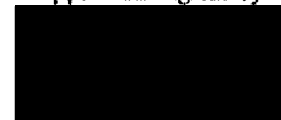
Certificate Number
205772

Page 1 of 2 Pages



Instrument Repairs & Calibration
7 Howard Court Industrial Estate
East Kilbride, G74 4QZ
Tel: 01355 264120 Fax: 01355 264150
www.instrument-repairs.com

Approved Signatory



☐ F. Silo ☐ N. Anderson ☐ K. Low ☒ C. Moore ☐ A. Rae

Customer : H&V Commissioning Services Ltd
Kilknowe Offices, 16 Barrmill Road
Galston KA4 8HY

Date Received : 20 August 2015

Instrument -	System ID :	IRC02093	Job Number :	R70380-1
	Description :	Micromanometer	Ref. Number :	HV5-01
	Manufacturer :	DPM	Site :	
	Model Number :	TT470S	Location :	
	Serial Number :	7471		
	Procedure Version :	774		

Environmental Conditions

Temperature :	23°C +/- 2°C	Mains Voltage :	230V +/- 10V
Relative Humidity :	50% +/- 20%	Mains Frequency :	50Hz +/- 1Hz

Comments

The instrument stabilised in the laboratory for 4 hours prior to calibration.
Results at the time of test carry no long term stability of the instrument.
This certificate records the ON RECEIPT calibration status.
Recalibration period 52 weeks by customer request.

Traceability Information

Instrument description	Serial number	Certificate number	Cal. Date	Cal. Period
Mensor CP6000	610020	N18686&7 N18673	19/04/2013	156

Calibrated By : C. Moore

Date of Calibration : 27 August 2015

This is to certify that the above instrument was fully calibrated. Work carried out was in accordance with procedures laid down in BS EN ISO/IEC 17025:2005. The accuracies of the standards used are traceable to National Standards, via UKAS approved laboratories. The copyright of this certificate is owned by IRC Ltd and may not be reproduced except with the prior written approval of the issuing laboratory. The reported expanded uncertainty is based on a standard uncertainty multiplied by a coverage factor k=2 providing a level of confidence of approximately 95%.

CERTIFICATE OF CALIBRATION

Certificate Number
205772

Page 2 of 2 Pages

Test Title	Tolerance	Applied Value	Reading	Pass/Fail
Pascal				
	100fa	0.00pa	0.0pa	Pass
	200fa	20.00pa	20.1pa	Pass
	400fa	40.00pa	40.1pa	Pass
	600fa	60.00pa	60.9pa	Pass
Kilopascals				
0.500kpa	5pa	0.5kpa	0.50kpa	Pass
1.00kpa	20pa	1.000kpa	1.00kpa	Pass
2.00kpa	30pa	2.000kpa	2.00kpa	Pass
3.00kpa	40pa	3.000kpa	3.00kpa	Pass
4.00kpa	50pa	4.000kpa	4.00kpa	Pass
5.00kpa	60pa	5.000kpa	5.00kpa	Pass
6.00kpa	70pa	6.000kpa	6.00kpa	Pass

End of results

Uncertainties

Pressure TE69 15 - 1000mBar +/- 0.04% of reading

CERTIFICATE OF CALIBRATION

Issued By IRC Ltd

Date of Issue 22 September 2015

Certificate Number
206411

Page 1 of 2 Pages



Instrument Repairs & Calibration
7 Howard Court Industrial Estate
East Kilbride, G74 4QZ
Tel: 01355 264120 Fax: 01355 264150
www.instrument-repairs.com

Approved Signatory



☐ N. Anderson

☐ K. Low

☒ C. Moore

☐ A. Rae

Customer : H&V Commissioning Services Ltd
 Kilknowe Offices, 16 Barrmill Road
 Galston KA4 8HY

Date Received : 15 September 2015

Instrument -	System ID :	IRC02515	Job Number :	R70680-2
	Description :	Clamp Meter	Ref. Number :	HV5-4
	Manufacturer :	Ideal	Site :	
	Model Number :	61-768	Location :	
	Serial Number :	051102797	Last Certificate Number :	192495
	Procedure Version :	1.01	Last Calibration Date :	09/05/2014

Environmental Conditions

Temperature : 23°C +/- 2°C
Relative Humidity : 50% +/- 20%

Mains Voltage : 230V +/- 10V
Mains Frequency : 50Hz +/- 1Hz

Comments

The instrument stabilised in the laboratory for 4 hours prior to calibration.
 Results at the time of test carry no long term stability of the instrument.
 This certificate records the ON RECEIPT calibration status.
 Recalibration period 52 weeks by customer request.

Traceability Information

<i>Instrument description</i>	<i>Serial number</i>	<i>Certificate number</i>	<i>Cal. Date</i>	<i>Cal. Period</i>
5500 Multifunction Calibrator	6305020	048278	05/11/2014	52

Calibrated By : C. Moore

Date of Calibration : 22 September 2015

This is to certify that the above instrument was fully calibrated. Work carried out was in accordance with procedures laid down in BS EN ISO/IEC 17025:2005. The accuracies of the standards used are traceable to National Standards, via UKAS approved laboratories. The copyright of this certificate is owned by IRC Ltd and may not be reproduced except with the prior written approval of the issuing laboratory. The reported expanded uncertainty is based on a standard uncertainty multiplied by a coverage factor k=2 providing a level of confidence of approximately 95%.

CERTIFICATE OF CALIBRATION

Certificate Number
206411

Page 2 of 2 Pages

Test Title	Tolerance	Applied Value	Reading	Pass/Fail
DC Voltage				
4V D.C. Range	21.5mV	3.900 0V	3.900V	Pass
40V D.C. Range	215mV	39.000V	38.98V	Pass
400V D.C. Range	2.2V	390.00V	389.8V	Pass
1000V D.C. Range	7V	1 000.00V	1 000V	Pass
AC Voltage				
4V A.C. @ 50Hz	54.8mV	3.900 0V	3.905V	Pass
40V A.C. @ 50Hz	548mV	39.000V	39.02V	Pass
400V A.C. @ 50Hz	5.5V	390.00V	390.2V	Pass
750V A.C. @ 50Hz	19.3V	750.00V	750V	Pass
DC Current				
100.0A D.C. Range	1.5A	100.00A	99.6A	Pass
200.0A D.C. Range	3.5A	200.00A	199.7A	Pass
400.0A D.C. Range	5A	300.00A	298.7A	Pass
400.0A D.C. Range	6.4A	390.00A	388.8A	Pass
600A D.C. Range	7.3A	450.00A	448A	Pass
600A D.C. Range	13.3A	550.00A	547A	Pass
AC Current				
400.0A A.C. @ 50Hz	2.7A	100.00A	99.6A	Pass
400.0A A.C. @ 50Hz	4.4A	200.00A	200.0A	Pass
400.0A A.C. @ 50Hz	6.1A	300.00A	300.2A	Pass
400.0A A.C. @ 50Hz	7.6A	390.00A	390.2A	Pass
600A A.C. @ 50Hz	23.5A	450.00A	448A	Pass
600A A.C. @ 50Hz	26.5A	550.00A	548A	Pass
Resistance				
400Ω Range	1.4Ω	100.00Ω	100.0Ω	Pass
4kΩ Range	14Ω	1.000 0kΩ	1.000kΩ	Pass
40kΩ Range	140Ω	10.000kΩ	9.98kΩ	Pass
400kΩ Range	1.4kΩ	100.00kΩ	99.8kΩ	Pass
4MΩ Range	94kΩ	1.000 0MΩ	0.998MΩ	Pass

End of results.

Uncertainties

DC Voltage	+/- 12ppm +1 LSD
AC Voltage	0 to 1000V 0.01% +/- 1 digit
DC Current	0 to 10A 0.008% +/- 1 digit
AC Current	0 to 1000A 0.2% +/- 2 Digits
Resistance	0 to 10M 0.005% +/- 1 Digit

CERTIFICATE OF CALIBRATION

Issued By IRC Ltd

Date of Issue 22 September 2015

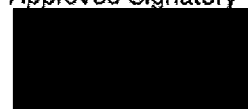
Certificate Number
206403

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Instrument Repairs & Calibration
7 Howard Court Industrial Estate
East Kilbride, G74 4QZ
Tel: 01355 264120 Fax: 01355 264150
www.instrument-repairs.com

Approved Signatory



☐ N. Anderson

☐ K. Low

☒ C. Moore

☐ A. Rae

Customer : H&V Commissioning Services Ltd
Kilknowe Offices, 16 Barrmill Road
Glasgow KA4 8HY

Date Received : 15 September 2015

Instrument -	System ID :	IRC02517	Job Number :	R70680-3
	Description :	Digital Tachometer	Ref. Number :	HV5-5
	Manufacturer :	Standard	Site :	
	Model Number :	ST-6236B	Location :	
	Serial Number :	06111857	Last Certificate Number :	192491
	Procedure Version :	688	Last Calibration Date :	09/05/2014

Environmental Conditions

Temperature : 23°C +/- 2°C
Relative Humidity : 50% +/- 20%

Mains Voltage : 230V +/- 10V
Mains Frequency : 50Hz +/- 1Hz

Comments

The instrument stabilised in the laboratory for 4 hours prior to calibration.
Results at the time of test carry no long term stability of the instrument.
This certificate records the ON RECEIPT calibration status.
Recalibration period 52 weeks by customer request.

Traceability Information

Instrument description	Serial number	Certificate number	Cal. Date	Cal. Period
5500 Multifunction Calibrator	6305020	048278	05/11/2014	52

Calibrated By : C. Moore

Date of Calibration : 22 September 2015

This is to certify that the above instrument was fully calibrated. Work carried out was in accordance with procedures laid down in BS EN ISO/IEC 17025:2005. The accuracies of the standards used are traceable to National Standards, via UKAS approved laboratories. The copyright of this certificate is owned by IRC Ltd and may not be reproduced except with the prior written approval of the issuing laboratory. The reported expanded uncertainty is based on a standard uncertainty multiplied by a coverage factor k=2 providing a level of confidence of approximately 95%.

CERTIFICATE OF CALIBRATION

Certificate Number
206403

Page 2 of 2 Pages

Test Title	Tolerance	Applied Value	Reading	Pass/Fail
RPM Measured	1.5RPM	1 000.0RPM	1 000RPM	Pass
	2RPM	2 000.0RPM	2 000RPM	Pass
	2.5RPM	3 000.0RPM	3 000RPM	Pass
	3RPM	4 000.0RPM	3 999RPM	Pass
	3.5RPM	5 000.0RPM	4 999RPM	Pass
	6RPM	10 000.0RPM	10 000RPM	Pass

End of results

Uncertainties

AC Voltage 0 to 1000V 0.01% +/- 1digit
Frequency 0.1ppm ± 1digit

**CERTIFICATE OF CALIBRATION****CALIBRATION SUMMARY**

UK01-26273

The instrument under test was calibrated against standards which are either traceable to National Standards or are derived by approved ratio techniques. Any number of factors may cause the instrument to drift out of calibration before the calibration interval has expired.

Prepared For: H & V Commissioning Services Limited
Kilknowe Office
16 Barrmill Road
Galston
Ayrshire, KA4 8HH

Service Report No.: UK01- 26273

Make: ATI

Model: TDA-2G

Serial No.: 14086

Date of Calibration: 17-Mar-15

Calibration Due Date: 17-Mar-16

Calibration Procedure: OSL-10015

The instrument complies with the specification at the measured points.

Comments:

None

Calibration Performed By: S. Wakefield

Date: 17-Mar-15

Signature:



CERTIFICATE OF CALIBRATION



UK01-26273

STANDARDS TRACEABILITY

Statement of Traceability

The Instrument Standards used have been calibrated by an external laboratory, and are traceable to National Standards. The calibration below has been performed to meet the requirements of ISO-10012:2003. The photometer has been calibrated for use with ISO 14644-3

Instrument Standards

Description	Manufacturer	Serial No.	Last Recal.	Cert. No.
Digital Voltmeter	Robin	910000537	13-Feb-15	351759
Airflow Meter	TSI	40450819003	20-May-14	N/A
Pico-Ampere Source	Keithley	80964	14-Oct-14	TERISO_633508
Reference Photometer	ATI	13487	19-Nov-14	25908
Aerosol Dilutor 1000:1	ATI	13940	4-Mar-15	26275

CALIBRATION TEST DATA

System Voltages

Location	As Found	As Left	Tolerance
J9-1	5.09 V	5.09 V	+5.0 ± 0.1 V
J9-5	15.0 V	15.0 V	+15.0 ± 0.45V
J9-6	-15.03 V	-15.03 V	-15.0 ± 0.45V

Flow Rate Verification/Calibration

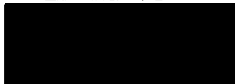
Expected	As Found	As Left	Tolerance
28.3 LPM	29.1 LPM	28.3 LPM	28.3 ± 2.8 LPM

Calibration Results

Test	Expected	As Found	As Left	Tolerance
Straylight	<0.007	0.0019	0.0013	N/A
100% Setting	100 µg/L	90 µg/L	100 µg/L	±10%
Internal Reference Settings	DOP = (Total Finevestan A80B)			

Calibration Performed By: S. Wakefield

Date: 17-Mar-15

Signature: 

OptiCal Sciences Limited
 Envirotech House, Anglia Way, Moulton Park Industrial Estate, Northampton NN3 6JA
 Telephone: 0844 334 0100 Fax: 0844 334 0101 Email: info@optical-sciences.co.uk
 Visit our website at www.optical-sciences.co.uk

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 28/11/2012

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A48946859



CERTIFICATE OF CALIBRATION



UK01-26273

Amplifier Linearity			
Photometer Reading	As Found	As Left	Tolerance
0.001%	0.80	0.80	$0.80 \pm 0.04 \times 10^{-10}$
0.01%	0.80	0.80	$0.80 \pm 0.04 \times 10^{-9}$
0.10%	0.80	0.80	$0.80 \pm 0.04 \times 10^{-8}$
1.0%	0.80	0.80	$0.80 \pm 0.04 \times 10^{-7}$
10%	0.76	0.76	$0.80 \pm 0.04 \times 10^{-6}$
100%	0.80	0.80	$0.80 \pm 0.04 \times 10^{-5}$

Comparison Results	
Reference Reading ($\mu\text{g/L}$)	U.U.T. Reading ($\mu\text{g/L}$)
100	100
10	10
1	1
0.1	0.1
0.01	0.01
0.001	0.001

Temperature & Humidity During Calibration	
Temperature	Humidity
24 °C	32 %RH

Condition of Calibration, As Found:	Condition, As Left:
☒ In Tolerance ☐ Out of Tolerance ☐ Inoperable	☒ In Tolerance

Maintenance Performed			
☒ Rework Scattering Chamber	☒ Align Optics	☐ Replace Absolute Filter	☒ Leak Test
☐ Replace Smoke Chamber	☒ Test Scanning Probe	☐ Replace Exhaust Filter	☐ Hours Hours Run
☐ Replace/Clean Tubing	☒ Test Electrical Connections	☐ Replace Gaskets	☐ X.XX Firmware Version
☐ Clean Valve	☒ Perform Voltage Measurements	☒ Tighten Loose Hardware	☒ Final Test

Calibration Performed By: S. Wakefield

Date: 17-Mar-15

Signature: 

OptiCal Sciences Limited
 Envirotech House, Anglia Way, Moulton Park Industrial Estate, Northampton NN3 6JA
 Telephone: 0844 334 0100 Fax: 0844 334 0101 Email: info@optical-sciences.co.uk
 Visit our website at www.optical-sciences.co.uk

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 28/11/2012

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A48946859



OptiCal Sciences

SERVICE REPORT

DATE: 17-Mar-15

CUSTOMER H & V Commissioning Services Limited
ADDRESS Kilknowe Office
 16 Barrmill Road
 Galston
 Ayrshire, KA4 8HH
CONTACT Angela Daly
PURCHASE ORDER NO 4787/IS/AC
OSL ORDER REF 23042

ENGINEER S.Wakefield

HOURS As Quote

TRAVELLING TIME N/A

OTHER EXPENSES N/A

WORK REQUIRED Repair and Recalibration

CALIBRATION CERT. ISSUED 26273

MODEL ATI TDA-2G

SERIAL NO 14086

☐ CONTRACT ☐ WARRANTY ☒ CUSTOMER A/C OTHER

Replaced Selector valve knob. Checked Power supplies and reset flow to 1.0 CFM

Stripped, cleaned and realigned optics.

Calibrated using Lab Standard Photometer, Picoamp Source and 1000:1 Diluter.

Reset internal reference to 100%. Checked response at various concentrations.

Checked Straylight, Op Amp null point, leak test, operation, and clean down.

PART NO.	QTY.	DESCRIPTION	ELECTRICAL SAFETY TEST RESULTS
10409	1	Selector valve knob	Visual:
			E. Continuity:
			Fuse Rating:
			Insulation:
			Run Test:
			Flash: N/A
FOR OFFICE USE ONLY: T = , L =			Test No:

ENGINEER SIGNATURE

SERVICE REPORT No 26273



ISO 9001

OptiCal Sciences Limited
 Envirotech House
 Anglia Way, Moulton Park Industrial Estate, Northampton NN3 6JA
 Telephone: 0844 334 0100 Fax: 0844 334 0101 Email: info@optical-sciences.co.uk
 Visit our Website at www.optical-sciences.co.uk


 QSF19
 03/05/2010

A48946859

SYSTEM HYGIENICS

SOUTHERN GENERAL HOSPITAL GLASGOW

POST CLEAN REPORT

7th September 2015

SYSTEM HYGIENICS

Chaucer Industrial Estate, Dittons Road, Polegate East Sussex, BN26 6JF
Tel: 01323 481170 Fax: 01323 483061

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Before and After Photographs	4
Certificate of Analysis	14
Certificate of Cleanliness	15

INTRODUCTION

The ventilation ductwork systems have been thoroughly internally cleaned as detailed in this report.

All cleaning has been carried out to B&ES Guide to Good Practice TR19 (2nd Edition) cleanliness verification standards whereby no more than 0.3g dust / m² duct surface may be found using the 15 litre/min Preferred Vacuum Test Method.

We have taken photographs from various locations before and after our works have taken place to demonstrate the hygiene condition of ventilation ductwork systems.

Signed

Date



15th September 2015

Mr. Jeff Gardner

SALES ENGINEER

Email Address:



Mobile:



PHOTO LOG		
Locations: Location	Before Clean	After Clean
Level 4 – Supply duct	1	2
Level 4 – Supply duct	3	4
Level 4 – Supply duct	5	6
Level 4 – Supply duct	7	8
Level 4 – Supply duct	9	10
Level 4 – Supply duct	11	12
Level 4 – Supply duct	13	14
AHU 63 – Fresh air intake	15	16
AHU 64 – Filter chamber	17	18
AHU 63 – Fan chamber	19	20



1. Level 4 – Supply duct – Before clean.

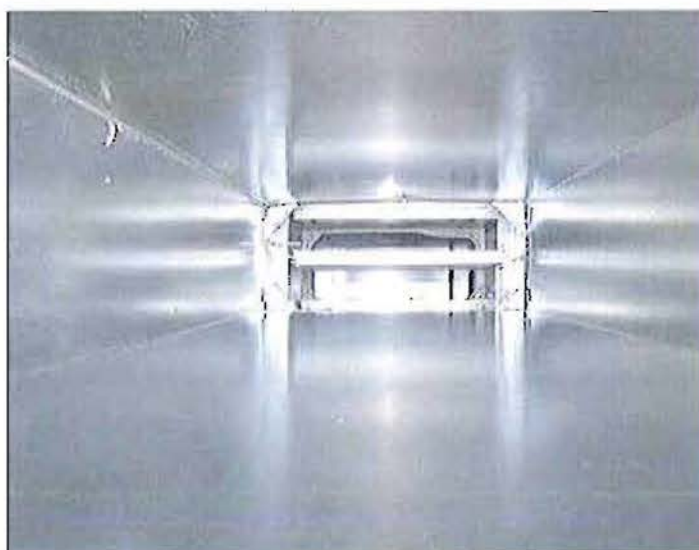


2. Level 4 – Supply duct – After clean.

SYSTEM HYGIENICS



3. Level 4 – Supply duct – Before clean.



4. Level 4 – Supply duct – After clean.



5. Level 4 – Supply duct – Before clean.



6. Level 4 – Supply duct – After clean.

SYSTEM HYGIENICS

7

Southern General Hospital - Glasgow
Post Clean Report

7th September 2015



7. Level 4 – Supply duct – Before clean.



8. Level 4 – Supply duct – After clean.

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9. Level 4 – Supply duct – Before Clean.



10. Level 4 – Supply duct – After Clean.



11. Level 4 – Supply duct – Before Clean.



12. Level 4 – Supply duct – After Clean.

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13. Level 4 – Supply duct – Before Clean.



14. Level 4 – Supply duct – After Clean.

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15. AHU 63 – Fresh air intake – Before Clean.



16. AHU 63 – Fresh air intake – After Clean.

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17. AHU 63 – Filter chamber – Before Clean.



18. AHU 63 – Filter chamber – After Clean.



19. AHU 63 – Fan chamber – Before Clean.



20. AHU 63 – Fan chamber – After Clean.

SYSTEM HYGIENICS



SYS/15/133
Issue no.1

University of
Hertfordshire
Hatfield Hens
AL10 9AB

Biodet

Laboratory 01707 284522
Email Biodet@herts.ac.uk

System Hygienics Ltd
Chaucer Industrial Estate
Dittons Road, Polegate
East Sussex BN26 6JF

Ref: SYS/15/133
Date: 21st September 2015
Log No. 1761

CERTIFICATE OF ANALYSIS

Job No.:

Operator: M. Hickenbottom

Date Sampled: 09-Sep-2015

Date Received: 16-Sep-2015

Filters were weighed to determine the amount of particulate contamination.

Results:

Sample Nº	Location	Filter Difference (mg)
1	4 th floor Supply Duct	0.0
2	4 th floor Supply Duct	0.0
3	4 th floor Supply Duct	0.0
4	4 th floor Supply Duct	0.1
5	4 th floor Supply Duct	0.2
6	4 th floor Supply Duct	0.0



I.MOSS
TECHNICAL MANAGER

21st September 2015

CERTIFICATE OF CLEANLINESS

*We hereby certify that the Extract & Supply Systems
(referred to in the photo log) serving:-*

**Southern General Hospital
75 Hardgate Road
Glasgow**

have been cleaned and completed on 07 September 2015

*In accordance with B&ES Guide to Good Practice TR/19
(2nd Edition) standard, whereby no more than 0.3g dust per 1m²
internal surfaces did remain. Please refer to legislation set out
overleaf and attached laboratory analysis results reference*

SYS/15/133 dated 21 September 2015

System examined by our representative Mr Mark Hickenbottom.

presented by

SYSTEM HYGIENICS LIMITED

**Chaucer Industrial Estate
Dittons Road, Polegate
East Sussex BN26 6JF**

Signed



24 September 2015

Date

STD78

EXCERPTS FROM WORKPLACE (HEALTH, SAFETY AND WELFARE) REGULATIONS 1992

MAINTENANCE OF WORKPLACE, AND OF EQUIPMENT, DEVICES AND SYSTEMS
Regulation 5

(1) The workplace and the equipment, devices and systems to which this regulation applies shall be maintained (including cleaned as appropriate) in an efficient state, in efficient working order and in good repair.

(2) Where appropriate, the equipment, devices and systems to which this regulation applies shall be subject to a suitable system of maintenance.

(3) The equipment, devices and systems to which this regulation applies are:-

(a) Equipment and devices a fault in which is liable to result in a failure to comply with any of these Regulations; and

(b) Mechanical ventilation systems provided pursuant to regulation 6 (whether or not they include equipment or devices within sub-paragraph (a) of this paragraph).

Approved Code of Practice (Regulation 5)

20. The workplace, and the equipment and devices mentioned in these Regulations, should be maintained in an efficient state, in efficient working order and in good repair. 'Efficient' in this context means efficient from the view of health, safety and welfare (not productivity or economy). If a potentially dangerous defect is discovered, the defect should be rectified immediately or steps should be taken to protect anyone who might be put at risk, for example by preventing access until the work can be carried out or the equipment replaced. Where the defect does not pose a danger but makes the equipment unsuitable for use, for example a sanitary convenience with a defective flushing mechanism, it may be taken out of service until it is repaired or replaced, but if this would result in the number of facilities being less than that required by the Regulations, the defect should be rectified without delay.

21. Steps should be taken to ensure that repair and maintenance work is carried out properly.

22. Regulation 5(2) requires a system of maintenance where appropriate, for certain equipment and devices and for ventilation systems. A suitable system of maintenance involves ensuring that:

(a) regular maintenance (including, as necessary, inspections, testing, adjustment, lubrication and cleaning) is carried out at suitable intervals;

(b) any potentially dangerous defects are remedied, and that access to defective equipment is prevented in the meantime;

(c) regular maintenance and remedial work is carried out properly; and

(d) a suitable record is kept to ensure that the system is properly implemented and to assist in validating maintenance programmes.

VENTILATION

Regulation 6

(1) Effective and suitable provision shall be made to ensure that every enclosed workplace is ventilated by a sufficient quantity of fresh or purified air.

(2) Any plant used for the purpose of complying with paragraph (1) shall include an effective device to give visible or audible warning of any failure of the plant where necessary for reasons of health or safety.

(3) This Regulation shall not apply to any enclosed workplace or part of a workplace which is subject to the provision of:-

(a) section 30 of the Factories Act 1961;

(b) regulations 49 to 52 of the Shipbuilding and Ship-Repairing Regulations 1960;

System Hygienics Ltd recommends that the systems mentioned in our Certificate of Cleanliness be cleaned on at least an annual basis in accordance with the above Loss Prevention Council recommendations.

A specific Risk Assessment, taking account of the likely rate of grease accumulation and other factors, should be carried out to establish the required inspection and cleaning frequency.

SYSTEM HYGIENICS

System Hygienics Ltd, Chancery Red Estate, Polegate, E Sussex, BN26 6JF

(c) regulation 21 of the Construction (General Provisions) Regulations 1961;

(d) regulation 18 of the Docks Regulations 1958.

Approved Code of Practice (Regulation 6)

32. In the case of mechanical ventilation systems which recirculate air, including air-conditioning systems, recirculated air should be adequately filtered to remove impurities. To avoid air becoming unhealthy, purified air should have some fresh air added to it before being recirculated. Systems should therefore be designed with fresh air inlets which should be kept open.

33. Mechanical ventilation systems (including air-conditioning systems) should be regularly and properly cleaned, tested and maintained to ensure that they are kept clean and free from anything which may contaminate the air.

34. The requirement of regulation 6(2) for a device to give warning of breakdown applies only 'where necessary for reasons of health or safety'. It will not apply in most workplaces. It will, however, apply to 'dilution ventilation' systems used to reduce concentration of dust or fumes in the atmosphere, and to any other situation where a breakdown in the ventilation system would be likely to result in harm to workers.

35. Regulation 6 covers general workplace ventilation, not local exhaust ventilation for controlling employees' exposure to asbestos, lead, ionising radiations or other substances hazardous to health. There are other health and safety regulations and approved codes of practice on the control of such substances.

EXCERPTS FROM HVCA GUIDE TO GOOD PRACTICE TR19
'Cleanliness of Ventilation Systems'

Section 9 - Verification of Cleanliness

9.1 The primary method of assessment is visual. For cleaned system verification the surface should be visibly clean and capable of meeting the level of cleanliness specified.

9.2 Verification where specified on general ventilation systems, should be by means of a vacuum test (VT), as described in Appendix D, based on the recommendations of the US National Air Duct Cleaners Association (NADCA) ACR 2005. A system will be considered acceptably cleaned if, following a VT, a result of not more than 0.75g/m² is achieved. This is equivalent to 0.75mg/100cm² as per ACR 2005.

9.3 It should be noted that verification should take place immediately after cleaning to avoid any possibility of post-clean interference. The client should be given the opportunity to witness testing of ductwork surfaces.

Section 5.2

A testing procedure is defined in this guide which may be used to establish whether or not it would be appropriate to clean a mechanical ventilation system. This provides one reasonable practicable way of satisfying the Regulation and ACRs relevant to the cleanliness of ventilation systems.

Section 5.5

The owner or operator should select the type(s) of test(s) and frequency to be included within their testing regime to suit the particular requirements of the building served by the ventilation system. The regime should be reviewed regularly (eg. annually), to take into account any changes in the building use, legislation and/or health and safety guidance.

Section A8

The specification should include a definition of the method of verifying the effectiveness of the treatment including the number and type of microbiological samples to be taken and their analysis eg. in-house or third-party laboratory.



Commissioning Site Report

Project Title:	New South Glasgow Hospital
Project No:	111.00566
Client:	NEL
Location:	Ward 4B
Panel Ref:	N/A
Snag List Ref:	1
System Name:	StruxureWare
Engineer:	Gary Palmeri
Date:	06/10/2015

WORK CARRIED OUT

The 24 rooms, numbered 76 to 99, each have a CMR V-Sensors installed in the ceiling outside the room with a wall mounted pressure display in the corridor. There is also a HMI (Touchscreen) display at the Nurse Station.

Each of the 24 no. sensors and displays had their wiring checked. They were then powered up and then the pressure readings checked to the corridor displays and the HMI at the Nurse Station. All units were confirmed as operating and reading correctly.

The operation of the Pressure Alarms, on each room, were checked and the Alarms confirmed at the corridor displays and the HMI at the Nurse Station. Each Alarm was acknowledged/silenced from the corridor display or the HMI.

The pressure readings displayed were confirmed by the H&V Engineers on site during the commissioning.

Signature: [REDACTED]



Functional Design Specification

New South Glasgow Hospital – Adult & Childrens

Ward 4B Nurse Station Pressure Monitoring

(See Appendix for Associated Systems)

Control Panel Type:	Ward 4B Nurse Station Pressure Monitoring Panel
Document No:	ME-XX-04-DC-S660-134
Document Revision:	R01
Revision Date:	13/10/2015

Associated Plant Ref:	Associated Plant Description:
31AHU63	AHU Type 41 Functional Design Specification

For Commissioning Use Only:	
Plantroom Zones	
Commissioning Date:	
Engineers Name:	
Engineers Signature:	

Revision History				
Revision	Date	Author	Checked by	Comments
R01	13/10/2015	CR		Record

CMR AIR MANAGEMENT

ISSUE No: R01

DATE: 13th October 2015

PROJECT: Ward 4b Hospital Ward Pressure Monitoring

Prepared for: Schneider Electric

AIRFLOW AND PRESSURE CONTROLS

INDEX

- | | | |
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| 1. | System Description | Page 2 |
| 2. | System Schematics | Page 3 |

Prepared by: Justin Congrave

Mobile: [REDACTED]

E-mail: [REDACTED]

CMR CONTROLS Ltd.
AIR MANAGEMENT SYSTEMS

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Since 1978

System Description

The area consists of 24No. Rooms which require pressure monitoring.

A V-Sensor Air Pressure Monitor will be mounted in the ceiling local to each room. A Blue PVC Tube will be connected to an Air Probe Plate on the ceiling/wall of the reference area, and a Red PVC Tube will be connected to an Air Probe Plate on the ceiling/wall of the room. A local DIS-125 Alarm Display Plate will be mounted on the wall to provide a pressure readout and audible / visual alarm, and be connected to the V-Sensor using Lapp DeviceNET Thin Cable. The V-Sensor will be wired to a Modbus Tap (Power / Communication Junction Box) using the same Lapp DeviceNET Thin Cable. The 24No. Modbus Taps will be connected together using DeviceNET Thick Cable, which will be taken back to the Nurse Station Panel.

The Nurse Station Panel will be a Stainless Steel surface mount box housing a 230Vac - 24Vdc power supply, which will feed the V-Sensors and a 7" Colour HMI. The Modbus RTU from the V-Sensors shall be read in and provide a display of the measured Room Pressures. Each differential pressure value will be displayed in Pa (Pascals) and sit within a Box which shall be Green when Healthy, changing to Flashing Red if in Alarm. When in Alarm the HMI will have a common Audible Alarm Sounder which may be silenced by pressing the Mute Button on the touch screen. When muted the Red Box will cease flashing and become static, before returning to static Green when the fault is rectified. This functionality essentially replicates that of the V-Sensor / DIS-125 Alarm Display Plate, so that any alarm can be acknowledged locally or at the Nurse Station.

The V-Sensor has integral adjustments to allow the setting of both high and low pressure alarms, along with delay timers to prevent nuisance alarms when the areas are being accessed during normal activities.

The proposed system is an instantaneous display only, and does not offer any data retention.

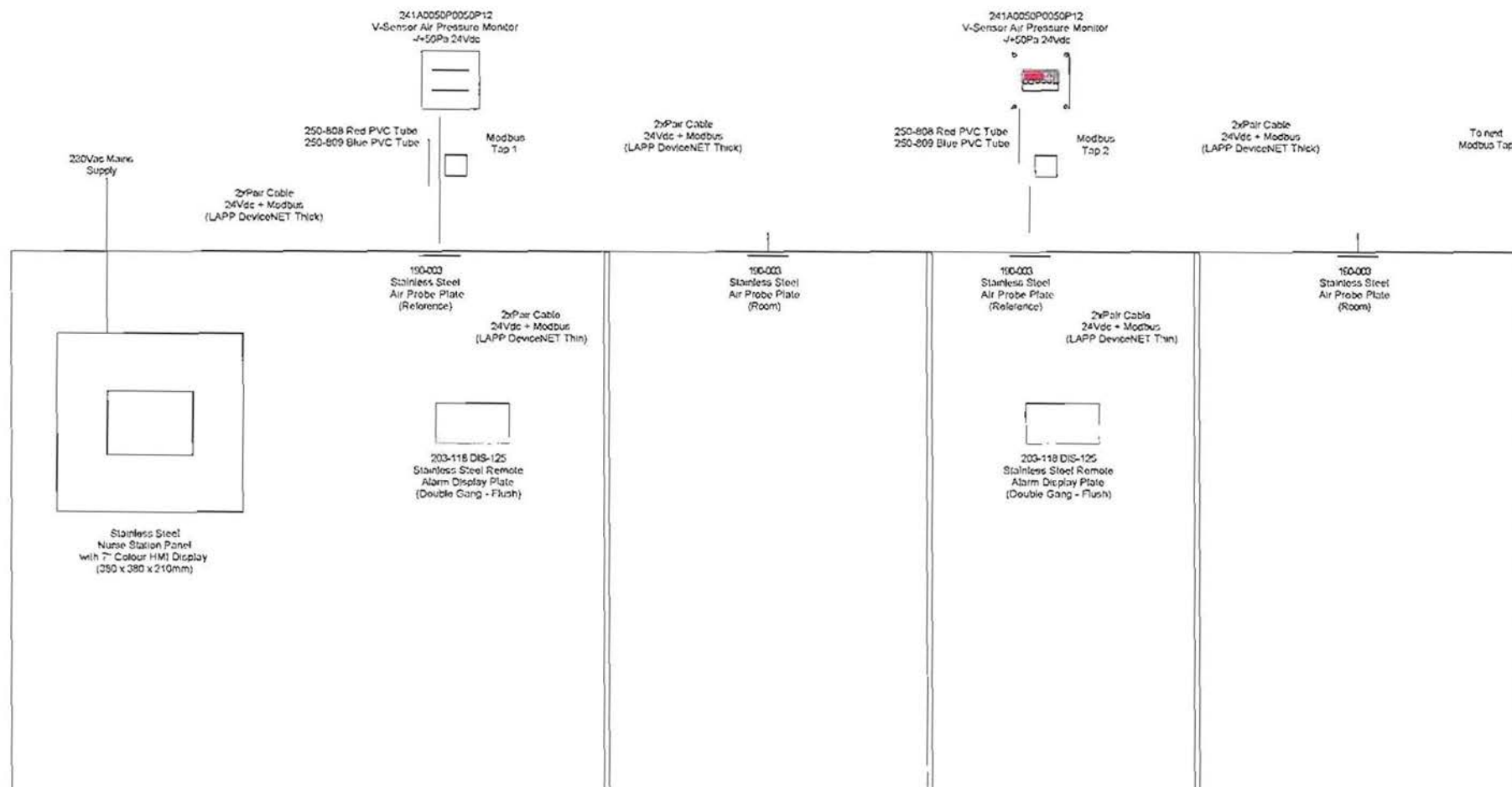
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HOSPITAL PRESSURE MONITORING SCHEMATIC



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Since 1978



Functional Design Specification

New South Glasgow Hospital – Adult & Childrens

Ward 4B Nurse Station Pressure Monitoring Instructions

(See Appendix for Associated Systems)

Control Panel Type:	Ward 4B Nurse Station Pressure Monitoring
Document No:	ME-XX-04-DC-S660-135
Document Revision:	R01
Revision Date:	14/10/2015

Associated Plant Ref:	Associated Plant Description:
31AHU63	AHU Type 41 Functional Design Specification

For Commissioning Use Only:	
Plantroom Zones	
Commissioning Date:	
Engineers Name:	
Engineers Signature:	

Revision History				
Revision	Date	Author	Checked by	Comments
R01	14/10/2015	CR		Record

QEUEH Ward 4b Room Pressure Monitoring Panel Operating Instructions

NORMAL OPERATION

The main screen on the HMI shows 24 boxes which display the pressures for each room. If the condition of the room is healthy, the border of the box will be green.

If a room goes into alarm, the border for the pressure display for that room will flash red and the HMI alarm will sound. The alarm can be muted by pressing the box which is flashing. The border will then stop flashing and will show steady red until the room comes out of alarm. Pressing the button in the lower left corner of the screen will mute all alarms. The alarm sounder in the display plate outside the room will be muted when the alarm is muted from the panel.

The main screen is the only screen used for normal operation. It is possible to swipe the display left or right to show other screens but these will be locked unless a higher level user is logged in. If a user swipes to a different screen then they will need to swipe back to the normal screen.

ADVANCED OPERATION

Normally there is no user logged in and muting of alarms is the only function available. To access higher level functions, an Engineer or Administrator will need to be logged in. In practice it is unlikely that access to higher level functions will ever be needed.

Users

Engineers can mute alarms, change alarm settings and exit or restart the application. An Engineer "cmreng" with a password 287099 was configured at the factory.

Administrators can, in addition, create other users. An Administrator "cmradmin" with a password 287222 was configured at the factory.

To login, press the Login button and then enter the password. The username is not entered and is determined from the password. If the login was successful, the name of the user will be displayed briefly. Automatic logout will occur after a few minutes.

Alarm Settings

The alarm thresholds and timer may be changed by an Engineer or Administrator. These settings are stored in the sensors but can be modified using the HMI. On the main screen, touching a pressure box to the left or right of its central point will open a window showing the alarm thresholds in Pa and the alarm time in seconds. The settings can be changed on this screen. It is recommended to close the alarm settings screen then open it again to make sure the sensor has been updated with the changes.

Restarting the HMI

The HMI can be restarted by pressing the CMR logo. Open and close Control Panel and then press the Launch Application button.

User Administration

Administrators can create, modify and delete users by pressing the Admin button. This opens the Administration screen. Operation is self explanatory. **It is important not to delete the only administrator.** If there are no administrators left then it will be impossible to do any further user administration.

Rev No	Revision Note	Date	Signature	Checked
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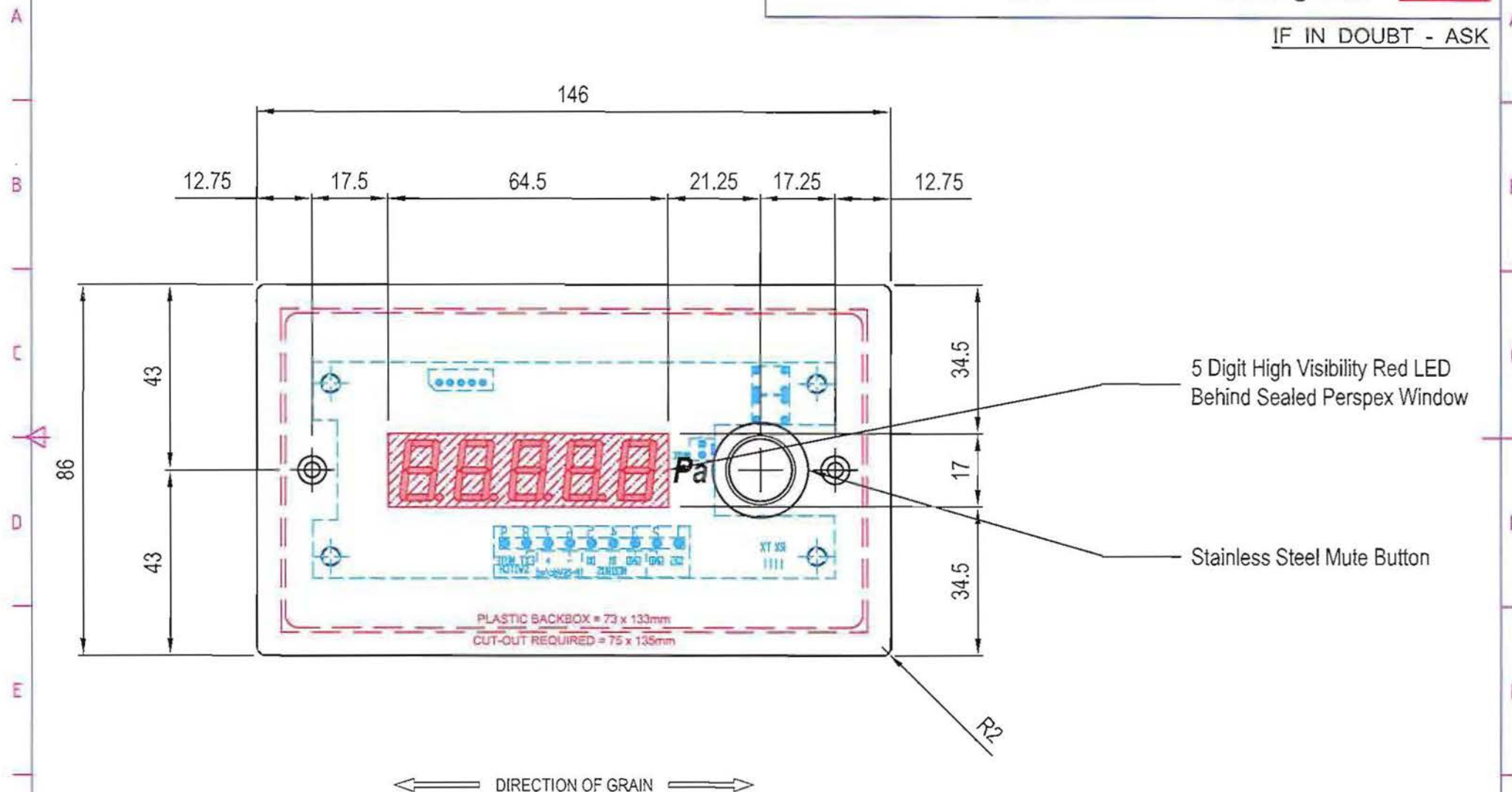
CMR CONTROLS

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IF IN DOUBT - ASK



ORG TITLE: Remote Digital LED Alarm Indicator		PROJECT: DIGITAL SENSORS		MATERIAL: 2.0mm THK 316L STAINLESS STEEL		FINISH: STAIN BRUSHED - 320G OPTISHEEN		DIMENSIONS: mm	
ORG No: M-359_1	REV: A	PART No: 203-045	ORIGINAL REF: 203-040 / 203-116	SCALE: NTS	SHEET: 1 of 1	SIZE: A4	Designed by: J.C.	Checked by: -	Drawn by: J.C.
							Date: 20/12/06		

A48946859

V-SENSOR AIR PRESSURE AIR VOLUME

- Ultra low pressure and volume measurement
- Traceable Calibration Certificate is Included
- High accuracy and repeatability
- Linear pressure or air volume output
- Both measurement and PID control output
- Two modbus for monitoring and remote display
- One alarm relay, buzzer and LED indicators
- Auto Zero and overload protection is standard
- Operator keyboard display for all functions
- Two Modbus rtu, 0..10V and 4..20mA outputs
- IP65 enclosure with easy mount wall bracket
- 24 month warranty
- 30 Years field application experience



V-SENSOR Wall Mount with Keyboard and LED display

GENERAL

The V-Sensor is a wall mount ultra low pressure transmitter which provides 0..10V and 4..20mA as well as Modbus communication over the selected range. The display can be adjusted via the keyboard to show the measured value in Pa, hPa, kPa, m/s, l/s, m³/s, m³/h and ACR (air change rate).

A PID control output can be selected, but still having one output for monitoring the pressure or volume.

The pressure ranges can be adjusted via the keyboard, but the base range is factory calibrated and certified i.e. 10, 25, 50, 100, 250 and going up to 7500 Pa. All ranges can be adjusted to +/- i.e. +/-25Pa.

Power supply 24Vdc/ac non-isolated or 24, 110 and 230Vac Isolated are available as standard.

CMR TRANSDUCER

The transducer is manufactured by CMR with high precision engineered components. The principle is the measurement of the displacement of the diaphragm by means of a push and pull variable reluctance circuit which is not effected by humidity and hence it can be used in any industrial or commercial environment. There are no mechanical connections to any of the sensing coils and the diaphragm.



CMR Transducer

Extremely low pressures can be measured with excellent repeatability and minimal hysteresis. The diaphragm displacement is so small that no air volume is required to measure the air pressure which means measurement tubing can be connected in excess of 200m throughout the building without losing accuracy or measurement speed.

The zero drift is minimized by the measuring copper coils which are matched to provide excellent self compensation. One coil measures positive and the other negative drift and therefore balances any excessive drift between two tolerance limits in its life cycle. The CMR Transducer has a proven field track record of over 30 years. All CMR Sensors are temperature compensated in a computerised climate chamber.



CMR Climate Chamber

KEYBOARD DISPLAY

A combined keyboard and LED Display is fitted into the lid and is connected to the V-Sensor board with a plug-in ribbon cable. All parameters can be accessed via the key pad. The display can also be programmed to switch off after a time and by touching a key to light up again. Normally it is always on.

PARAMETER CONFIGURATION

The duct width and height can be entered as well as the density and (mf) magnification (K) factors to scale Fan Inlet Rings, Flowgrids, Veloprobes, Oval Flowprobes, Venturis or any other velocity pressure producing probes. The volume can be linearized over 8 points to provide extremely high accuracy in measurement.

The range can be changed from -10 Pa to 30 Pa or -20 to 120 Pa. The output signals can be changed to i.e. 2..10V, 1..5V or 5..19mA. The V-Sensor has a configurable Volt Free alarm output relay.

The auto zero function is built in, which is of great advantage at very low velocity pressure measurement i.e. 0.3 Pa to have an accurate base point at all times. The auto zero can be turned off where it is not required.

The overload protection can be switched on and is ideal to protect the low pressure diaphragm. It is active whenever the sensor is powered up.

One of the outputs can be configured to be a PID control to drive fan inverters or modulating dampers and the other can be used for the actual pressure or air volume measurement for the BMS or PLC system. The set point can be sent from the BMS via modbus.

The signals can be individually smoothed. The control output can be fast but the measurement output can be dampened.

A calibration mode can be selected so that all of the parameters remain the same as commissioned and only the base sensor shall be calibrated and displayed in Pa.

MODBUS RTU COMMUNICATION

The modbus communication can be used to read and write all parameters by the remote Host which can be the BMS, PLC or PC.

REMOTE ALARM DISPLAY

A remote display DIS110 without alarm or DIS125 with alarm and mute button can be connected via Modbus if the modbus is not used for the BMS. The alarm button has green and red Led light rings to show healthy or alarm status. A buzzer is also fitted. A separate power supply can be wired to the display.



Remote Display Plate

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Precision Air Pressure and Volume Sensors

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V-SENSOR PRESSURE APPLICATIONS

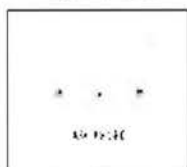
ROOM PRESSURE MEASUREMENT WITH CMR V-SENSORS



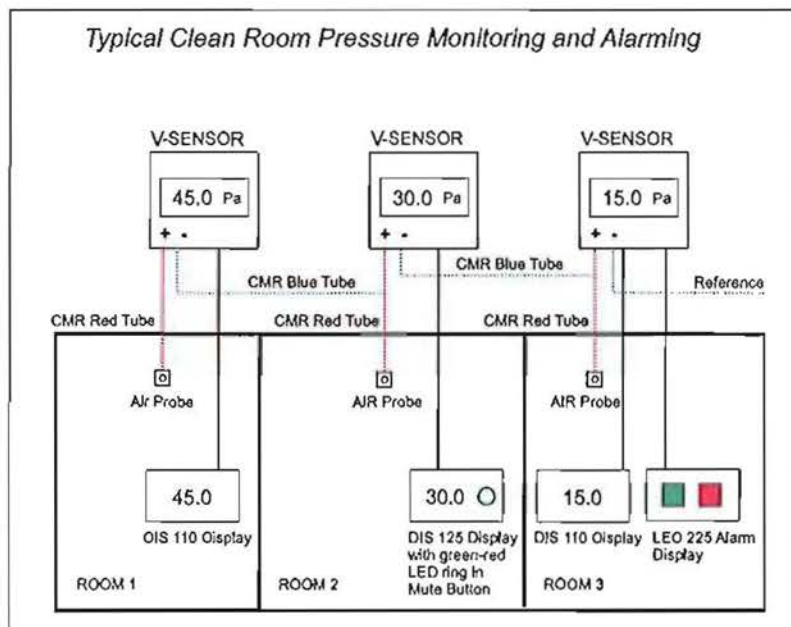
Tubes + Fittings



Ceiling Air Probe



Air Probe Plate



DIS 110 Display



DIS 125 Display



LED 225 Display

The above schematic shows a typical clean room. The room pressures are measured in cascades starting in Room 3 from a reference such as a plant room or any other stable location, then measuring across to room 2 and finally across to Room 1.

Each room has an air probe plate fitted to the ceiling. The air probes are connected to the V-Sensors with red and blue CMR PVC Tubing.

The CMR PVC tubing can be run up to 200m from the room to the P-Sensor without losing accuracy of the measurement.

Remote LED display plates are fitted for the operators to see the actual room pressure in Room 1 and 2. Room 2 has also a local illuminated alarm green and red led built as ring into the mute button and a buzzer. Room 3 has only a modbus alarm led indicator plate.

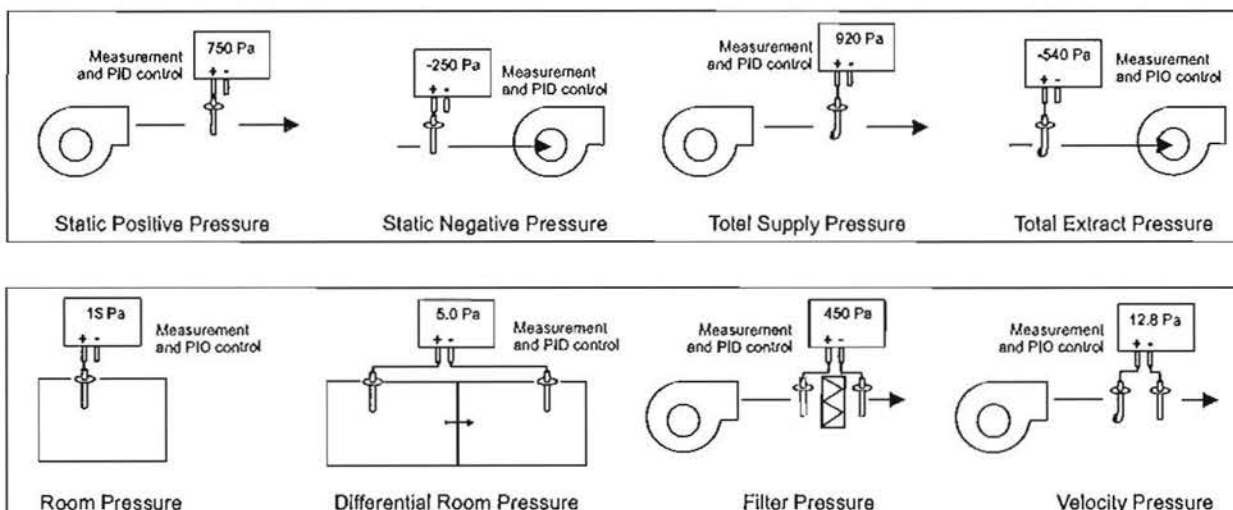
The V-Sensor is a true Low Differential Air Pressure Transmitter and can be used for static pressure, vacuum pressure and differential pressure measurements in positive or negative areas.

The operator keyboard with LED display is fitted into the lid as standard and shall display the actual pressure. All parameters can be adjusted without opening the lid.

The Pressure measurement can be transmitted via modbus rtu or analogue signals 0..10V or 4..20mA to the SCADA, BMS or Industrial PLC systems for long term monitoring.

All future calibration can be done using the calibration mode. Calibration Certificates traceable to National and International Standards (UKAS) are supplied as standard with all V-Sensors.

TYPICAL PRESSURE APPLICATIONS



CMR CONTROLS Ltd
Precision Air Pressure and Volume Sensors

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Issue V-GB-04-2

V-SENSOR AIR VOLUME APPLICATIONS

VELOCITY PRESSURE AND AIR VOLUME MEASUREMENT WITH CMR V-SENSORS



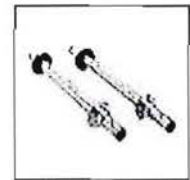
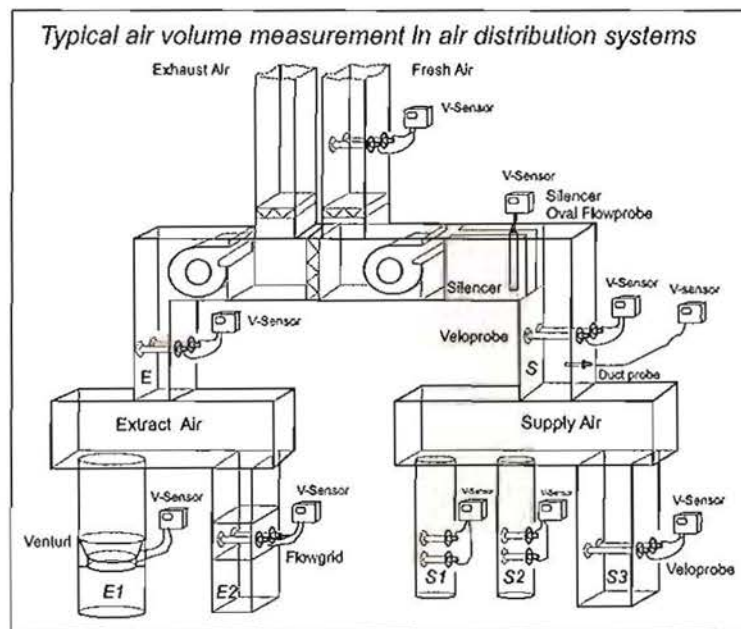
FGG Flowgrid



VVM Venturi



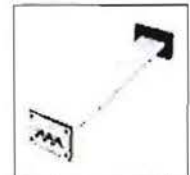
PVC Tube Fittings



CMR Veloprobes



Duct Probes



Oval Flowprobe

The CMR V-Sensor is an ultra low high precision Velocity Pressure Transmitter which has been designed to accurately measure air volumes in Ventilation Ducts. The built in Square Root Extraction and Magnification Factor Scaling makes the V-Sensor an extremely versatile measurement instrument.

It can display the actual volume in m³/s. Other Units such as m³/h, litres/s or ACR (Air change rate) can be selected via the keyboard. Any Imperial measurement units i.e. CFM are available on request.

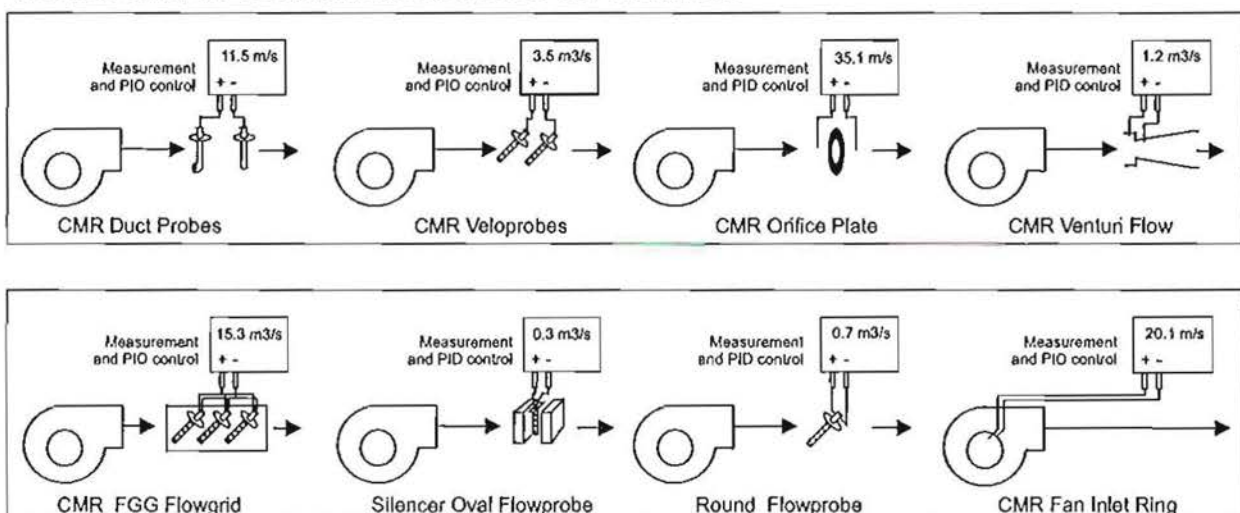
The CMR PVC tubing can be run up to 200m from the sensing station to the V-Sensor without losing the accuracy of the measurement.

The V-Sensor is used for monitoring and also controlling Volume Flow in Commercial or Process Applications and is designed to be connected to any CMR Veloprobes, Duct Probes, Flowgrids, Venturis and Fan Inlet Rings. It can also be used with any existing or custom made duct Flow Measurement Device.

The measured values can be transmitted to remote display plates, SCADA, BMS control systems or Industrial PLCs through the output signals of 0...10V, 4...20mA, modbus 1 and 2.

Calibration Certificates traceable to National and International Standards (UKAS) are supplied with all V-Sensors.

TYPICAL CMR AIR VOLUME MEASUREMENT APPLICATIONS



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Precision Air Pressure and Volume Sensors

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mail sales@cmr-controls.com

The Information is subject to change without notice



Issue V-GB-04-2

V-SENSOR VELOPROBE MEASUREMENT

GENERAL

The drawing shows a typical application for CMR Veloprobes and V-Sensors.

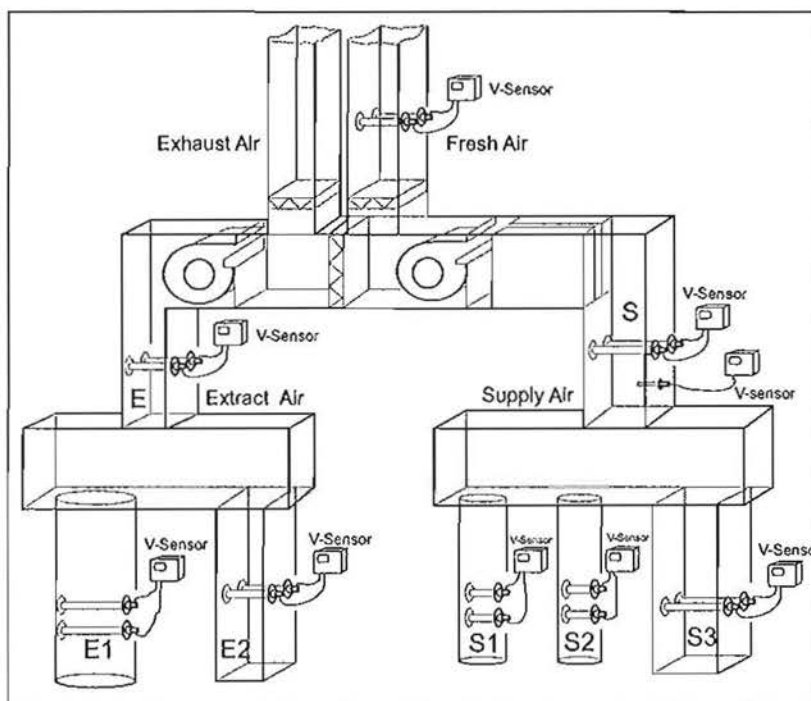
The supply air duct can either be fitted with one central Veloprobe or individual Veloprobes on each of its branches.

In many cases, the positions of the Veloprobes are very much dictated by the design of the building. The CMR Veloprobe can be fitted in almost any position in order to provide accurate measurements.

In a single supply and extract duct application, the V-Sensor measures the building's actual total supply and return volumes. As both V-Sensors are calibrated to provide a linear air volume signal, tracking of supply and extract air is now made easy.

The duct height, width or diameter, density and magnification ('K' factors) can be entered in the V-Sensor via the keyboard very easily and only the measurement range for 0..10V or 4..20mA must be given to the BMS at final commissioning.

For multiple duct applications, the total supply and extract air volume is derived by adding all air volumes from the individual ducts.



Example of Volume adding: $S = E \pm \text{an offset for positive or negative building pressure}$
 $S1 + S2 + S3 = E1 + E2 \pm \text{offset}$ or $S = E1 + E2 \pm \text{offset} - \text{etc}$

V-Sensor - scaling in m/s only.

Adjust the Impact Veloprobe (red) to face the Airflow and and adjust the Static Veloprobe (blue) to approx. 180° away from the airflow.

Scaling of the duct height and width is done in the BMS

Use the keyboard and adjust the display to m/s. Adjust the height and width to 1 and adjust the (mf) to 2.000. Press the very left hand key briefly and the sensor range is displayed for a short time, which is the range at 10V in m/s. If the range of the sensor is 100Pa then it should display 9.128 m/s.

Take a Pitot Tube reading in the duct and if the velocity is not equal to the display then adjust the magnification factor until it is equal then press the range key again to get the new range in m/s.

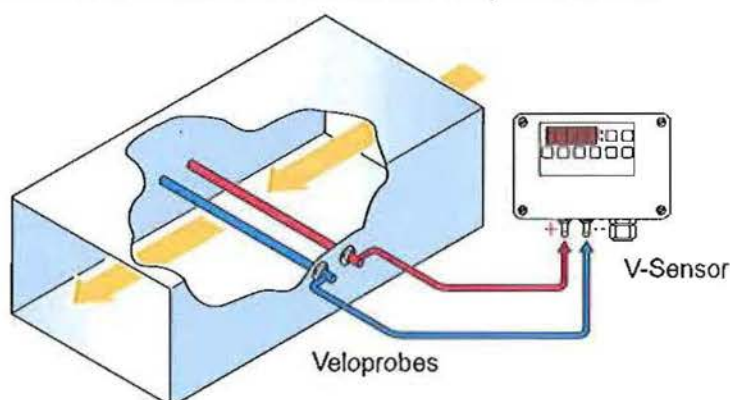
V-Sensor - scaling in m3/s - m3/h - l/s - ACR air change rate

Adjust the Impact Veloprobe (red) to face the Airflow and and adjust the Static Veloprobe (blue) to approx. 180° away from the airflow.

Scaling the range for the BMS

Use the keyboard and enter the duct height and width or simply enter the width of a round duct and keep the height at 0. Adjust the magnification factor (mf) to 2.000. Use the display key and select m3/s, m3/h, l/s or ACR (Air Change Rate) and adjust the decimal places. When pressing the left hand key the sensor range shall be displayed in the selected units at 10V. Take a Pitot Tube reading in the duct and if the volume is not equal to the display then adjust the magnification factor until it is equal then press the range key again to get the new range.

V-Sensor air volume measurement with Veloprobes in Duct



V-SENSOR

KEYBOARD FUNCTIONS

FUNCTIONS (Use Operator Manual for full Instructions)

The V-Sensor LED-Keyboard has been designed to simplify installation and commissioning. The only time the lid must be opened is for wiring during installation. Thereafter every control function can be accessed via the keyboard, even the calibration can be carried out utilising this functionality.

ZERO KEY

When pressing the zero key for 1 seconds, the V-Sensor shall perform a zero which means the pressure is taken off the sensor internally and the diaphragm is relaxed to zero.

PASSWORD

The keyboard can be password protected so that only the display can be operated, but no adjustments can be made.

RANGE KEY

Pressing the range key very quickly once will display the sensor range i.e. If it shows 100, this means the range of the sensor has been configured to 0-100Pa for 10V/20mA output. By pressing the range key for 1 seconds it enters the configuration menu:

S	Software Version	1.5
Ad	Network Address	1-254 (0 Denotes Modbus Display)
AZ	Auto Zero	on-off
P	Positive Range	i.e. + 25
n	Negative Range	i.e. - 25
Opp	Over Pressure	1(on) 0(off)
F	Zero Offset	
t	Set Point	
Sn	Modbus smoothing	doro
Adj	Internal/External	I or E
Azt	Auto Zero time Interval	1-99h
FF	Modbus float format	0-3

OUTPUT KEY

Pressing the output key very quickly once will display the sensor output configuration i.e. lin or root, which means the sensor measures pressure or airflow. By pressing the output key for 1 seconds the configuration menu can be reached:

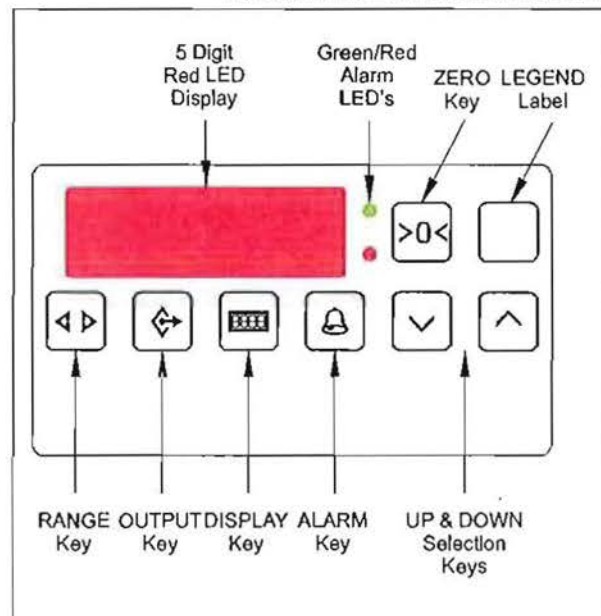
So	Output Smoothing	0-99
Lin	Output mode	linear pressure
root	Output mode	square root
e	Output scaling	F, L or Fac
F	Mag Factor	0-99.99
	Duct width	0-9999mm
I	Duct height	0-9999mm
d	Air Density Factor	0-9.99kg/m3
r	Room Size	0-9999m3
s	Small Value Shut off	0-99.99%
o	Output Re-Scaling	
bFl	Bi-Directional Flow	0 or 1

DISPLAY KEY

Pressing the display key very quickly once will display the measurement units. i.e. Pa, hPa, kPa etc, and is the units the sensor has been configured to i.e. Pa. By pressing the display key for 1 seconds it enters the configuration menu:

Sd	Display Smoothing	0-99
Pa	Pascals	
hpa	hecto Pascals	
kpa	kPa	
nnps	metres per second	
lps	litres per second	
nn3s	cubic metres per second	
nn3h	cubic metres per hour	
acr	Air Change Rate per hour	
dp	Decimal Place	0-4
pos	Display polarity (+)	
neg	Display polarity (-)	
Led	Display Activation	1 or 0
L2b	Leading Zero Blanking	1-4

V-SENSOR STANDARD LED KEYBOARD



ALARM KEY

Pressing the alarm key quickly shall mute the alarm as the V-Sensor has an alarm buzzer built in.

By pressing the alarm key for 1 seconds it enters the configuration menu:

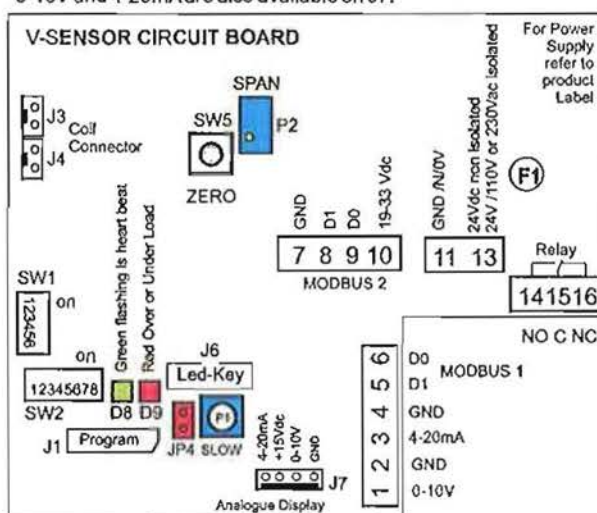
L	Low Alarm	
H	High Alarm	
t	Alarm timer 1	0-999
t	Alarm timer 2	0-999
u	Units	dU (Display Units) or Per (%)
af	Alarm Function	0-2
Sr	Self Reset	0-1
rb	Remote Buzzer	-, 0, 1 or P
rA	Remote Alarm Indication	-, 0, F or LH
rt	Re-alarm timer	0-999 minutes
tU	Alarm timer units	s or h

UP-DOWN KEY

The up and down keys are used to select the various parameters

OUTPUT SIGNAL

0-10V and 4-20mA are also available on J7.



V-SENSOR

ORDER DESCRIPTION

GENERAL

CMR manufactures the V-Sensors to suit many low pressure and volume measurement applications. Because of the variety of pressure ranges, output signals and power supplies it has been necessary to design an easy to use selection table for anybody to make up a V-Sensor specification to satisfy a requirement. On the V-Sensor Selection Table you will find all specifications available with the associated ordering code.

V-SENSOR BASE PART NUMBER

The V-Sensor Part Number starts with a base part number of the type of sensor. Code '24' which is a V-Sensor in a standard ABS enclosure.

The Part Number therefore starts with '24'.

V-SENSOR ISSUE No

The V-Sensor will have a version number to identify the model. The Code is '1' for version '1'.

The Part Number extends to '241'.

TUBE CONNECTORS

6 mm barbed nipples to fit CMR PVC Tube are fitted as standard into the ABS box. They have the Code 'A'.

4 mm barbed nipples to suit the CMR Silicone Tube are also available as Code 'B'.

The example has 6 mm barbed nipples which is standard.

The Part Number therefore extends to '241A'.

NEGATIVE PRESSURE RANGE

The Negative Range is specified as (-). If the application requires to measure a negative pressure against a reference, i.e. a room has to be at negative pressure compared with the corridor then the room has to be connected to the Red or (+) nipple. The blue (-) nipple shall be connected to the reference in this case the corridor.

The negative room pressure shall suck on the red (+) nipple and the V-Sensor produces an output signal equivalent of the negative pressure measured.

In the Example we have chosen -25 which has the Code '0025'.

The Part Number extends to '241A0025'.

If the V-Sensor must only measure in the positive Range i.e. 0-25 then the Negative Range will always be selected as 0 and the Code is always '0000'.

PRESSURE UNITS

The negative pressure and the positive pressure range must be expressed in units i.e. Pa or kPa. The CMR transducers are in Pascals (Pa) as standard.

In the example Pa was selected with Code 'P'.

The Part Number extends to '241A0025P'.

POSITIVE PRESSURE RANGE

To measure Positive Pressure against a reference it is necessary to select a positive range i.e. +25. The Code is '0025'. This means the V-Sensor selected above can measure from -25 Pa to 0 and from 0 to +25 Pa. The output Voltage would therefore be 5V or 12mA at 0 Pa.

The Part Number extends to '241A0025P0025'.

LABEL UNITS

As the V-Sensor has a fixed label next to the LED display, i.e. Pa, kPa, hPa, mB etc. It is necessary to specify the label when selecting the part number as this is all part of the validation of the instrument.

In the example Code 'P' for Pa was selected.

The Part Number extends to '241A0025P0025P'.

OUTPUT SIGNAL

The Industry Standards for Output Signals are 0-10V or 4-20mA, but other signals can be adjusted via the keyboard by the operator.

If 0-10V is the Output Signal for -25 Pa to +25 Pa then 5 V is 0 Pa. From 5V to 0V the V-Sensor measures from 0 Pa to -25 Pa i.e. (-)12.5 Pa would be 2.5V.

From 5V to 10V the V-Sensor would measure positive Pressure from 0 Pa to +25 Pa i.e. +12.5 Pa would be 7.5V.

It is standard to use equal ranges -25 Pa to +25 Pa rather than -25 Pa to +50 Pa but the V-Sensor can be adjusted via the keyboard to provide this off-set.

In the Example, we have selected Dual (0-10V & 4-20mA) which has the Code '1'.

The Part Number extends to '241A0025P0025P1'.

POWER SUPPLY

CMR can supply 24Vdc/24Vac Non-Isolated which does not have an isolation transformer, and is also suitable for 3-Wire connection. Most common is the 24Vac Isolated, 110Vac and 230Vac are less used, but also selectable. In the example we have selected 24Vac Isolated which has the Code '3'.

The Part Number extends to '241A0025P0025P13'.

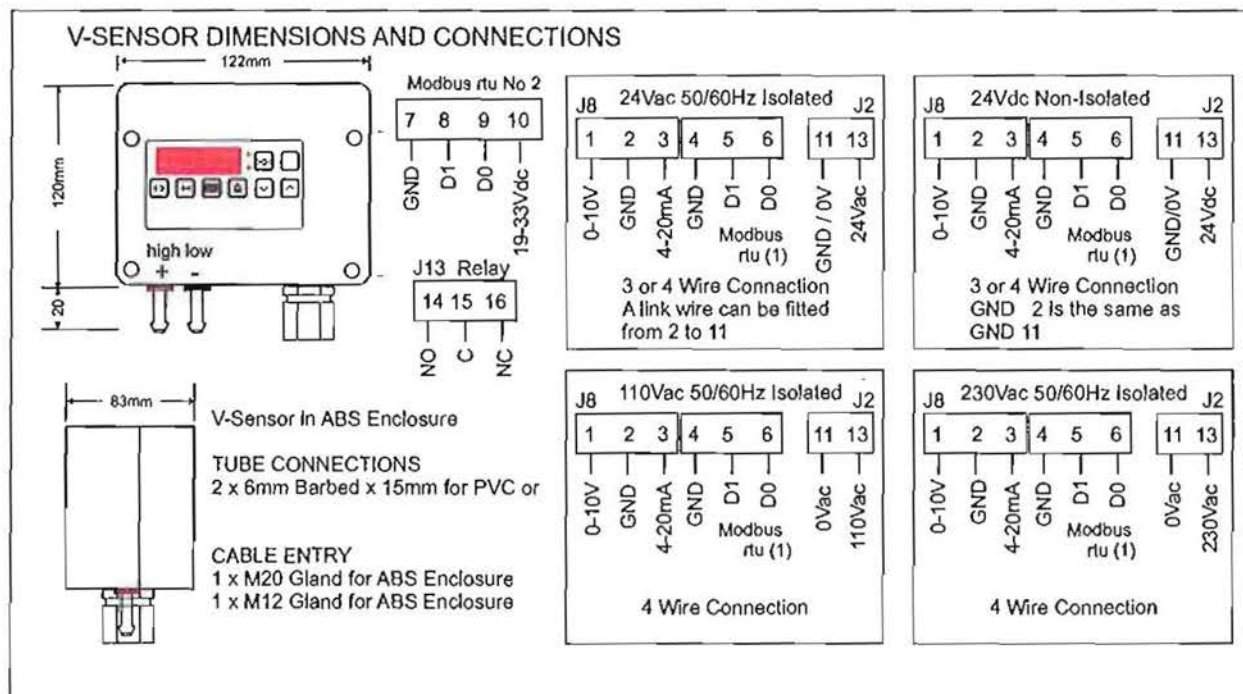
FINAL PART NUMBER

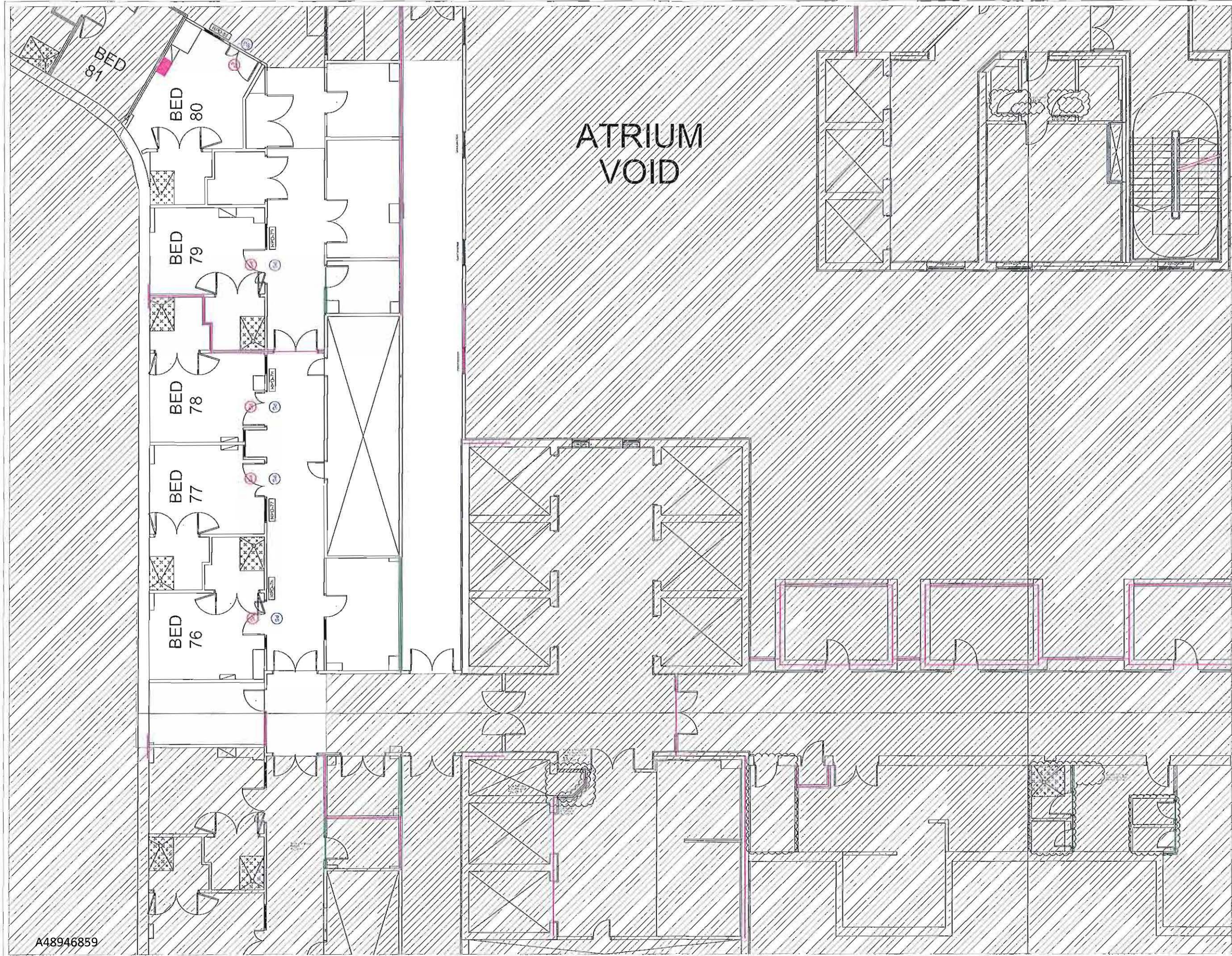
The Part Number to order is '241A0025P0025P13'.

Now try and select your own V-Sensor using the V-Sensor Order Selection Table.

V-SENSOR TECHNICAL SPECIFICATION

Measurement Range	Any Range from 0-25Pa or -/+25Pa up to 0-7500Pa or -/+7500Pa
Overload Capacity	Ranges 25Pa - 150Pa up to max 1200Pa if over pressure protection is off.
	Ranges from 200Pa - 7500Pa up to max 10 times of range if over pressure protection is off.
Media	Non corrosive gases such as Air, N ₂ , O ₂ , CO ₂ , N ₂ O and inert gases
Diaphragm Unit	Beryllium Copper suitable for high concentration of Formaldehyde - Stainless Steel on request.
AC Power Supplies	24 Vac 50/60Hz 198mA. Internal Fuse 300mA Auto-Reset.
Transformer Isolated	110Vac 50/60Hz 40mA. Fuse 315mA Wickmann.
	230Vac 50/60Hz 20mA. Fuse 315mA Wickmann.
DC Power Supplies	24 Vdc (19 to 31Vdc) smoothed 118mA Internal Fuse 300mA Auto-Reset.
Voltage Output Signal	0-10V (0 to 100% of Range) RL = 5kOhm min.
	Other output signals (e.g. 2-10V) or PID loop control is programmable via the keyboard.
Current Output Signal	4-20mA (0 to 100% of Range) RL = 500 Ohm max. (0-20mA) or PID control is programmable via keyboard
Relay Output 1A 24Vdc	One Alarm changer over volt free contact is user programmable
2 x Modbus rtu Connection	2 x Output Signal, Alarm Status, Alarm Thresholds and Alarm Timers are all readable as Modbus rtu Commands. Modbus register assignments to read and write are available in user manual.
Hysteresis/Repeatability	0.1% Typical of Full Scale.
Linearity (Accuracy)	+/- 0.25% of Full scale = > 100 Pa and 0.25Pa < 100Pa.
Zero Drift	0.05%K (+10°C to +50°C) - Automatically corrected to 0.0 if Auto-Zero function is enabled.
Operating Temperature	-10°C to +70°C.
Mounting Position	Vertical.
Weight	0.6 kg In ABS Housing.
Electrical Connections	ABS Housing: 1 x M20 Gland and 1 x M12 Gland and internal removable Screw Terminals.
Air Tube Connections	ABS Housing: Positive and Negative Pressure Barbed Nipple 6mm OD x 15mm long for CMR PVC Tube
	Alternatively Barbed Nipple 4mm OD x 15mm long for silicone tube on special request.
Enclosure	Plastic (ABS) Light Grey (RAL7035) - Protection IP65.
	EN61326-1 EMC - EN61010-1 SAFETY.
Calibration Certificate	Supplied with Certificate traceable to national and International Standards (UKAS).





NOTES

1. THE DRAWING IS TO BE USED IN CONJUNCTION WITH ALL CONTRACT DOCUMENTATION.

LEGEND

- Room Pressure Panel
- PS Pressure Sensor
- RPD-XX Room Pressure Display

AS BUILT DRAWING

Rev	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54	55	56	57	58	59	60	61	62	63	64	65	66	67	68	69	70	71	72	73	74	75	76	77	78	79	80	81	82	83	84	85	86	87	88	89	90	91	92	93	94	95	96	97	98	99	100
Rev	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54	55	56	57	58	59	60	61	62	63	64	65	66	67	68	69	70	71	72	73	74	75	76	77	78	79	80	81	82	83	84	85	86	87	88	89	90	91	92	93	94	95	96	97	98	99	100

NEW SOUTH GLASGOW HOSPITALS (NSGH) PROJECT

FOURTH FLOOR PLAN (NSGH RENAL TREATMENTS & DAY UNIT) LIGHTING LAYOUT ZONE E

Rev	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54	55	56	57	58	59	60	61	62	63	64	65	66	67	68	69	70	71	72	73	74	75	76	77	78	79	80	81	82	83	84	85	86	87	88	89	90	91	92	93	94	95	96	97	98	99	100
Rev	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54	55	56	57	58	59	60	61	62	63	64	65	66	67	68	69	70	71	72	73	74	75	76	77	78	79	80	81	82	83	84	85	86	87	88	89	90	91	92	93	94	95	96	97	98	99	100

AS BUILT

Rev 04 **PL** 600 **512** **Z1**

A48946859



NOTES

1. THIS DRAWING IS TO BE USED IN CONJUNCTION WITH THE FOLLOWING DOCUMENTS:

- Room Pressure Panel
- Pressure Sensor
- Room Pressure Display

AS BUILT DRAWING

Rev	Description	Date
01	Issue for construction	10/10/15

Legend:

- PS - Pressure Sensor
- RPD - Room Pressure Display

Logos:

- NHS
- Brookfield Multiplex
- BM

Project Information:

NEW SOUTH GLASGOW HOSPITALS
NSGH PROJECT

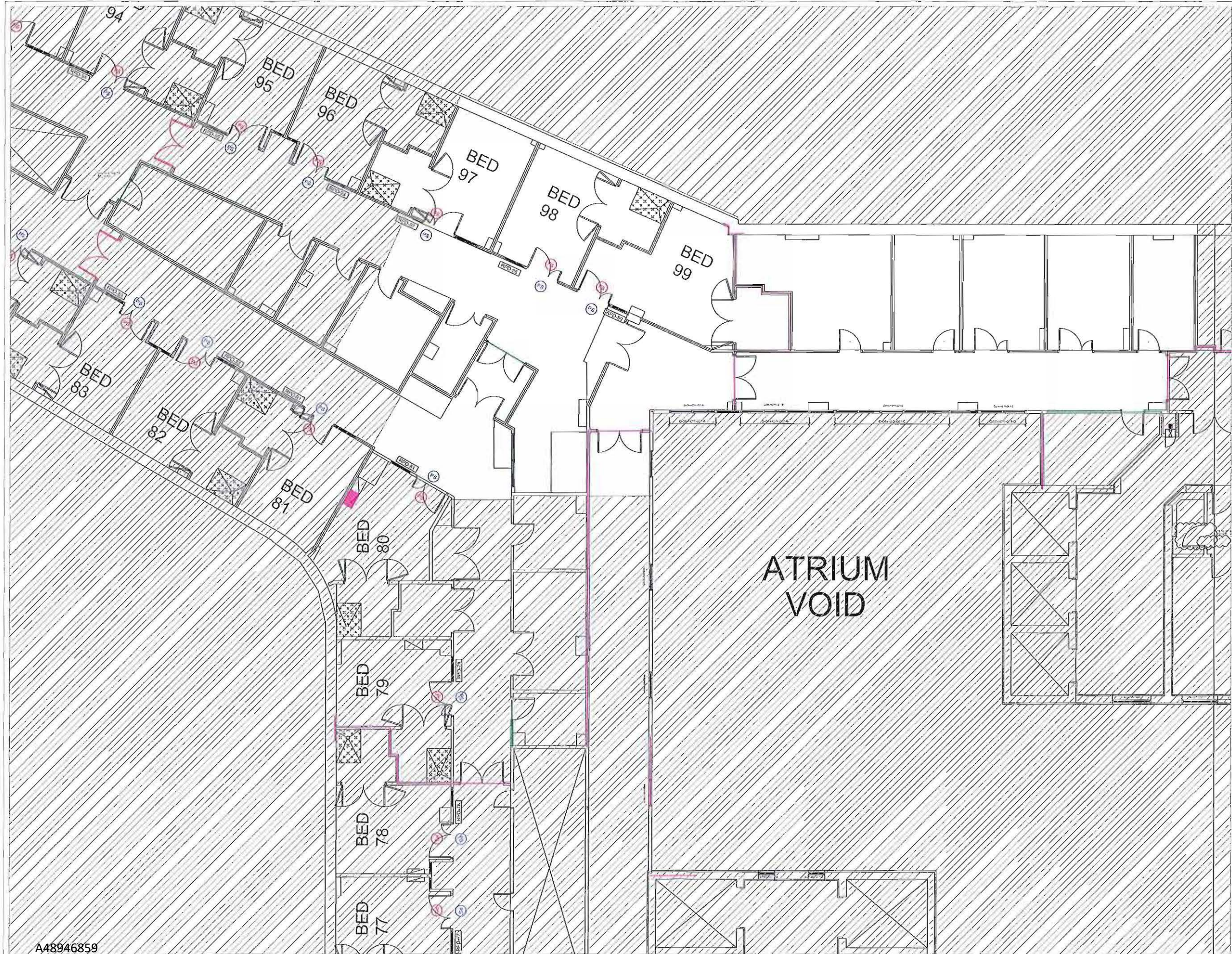
Fourth Floor Plan
NSGH HAEMATOLOGY
LAYOUT OF PRESSURE INDICATORS
ZONE E

Area	Drawn	Checked	Approved
AS BUILT	AM	JP	BN
DATE	22.10.15		

Revision Table:

Rev	Zone	Level	Drawn	Checked	Approved
01	ZE	04	PL	660	513

Scale: 1:100



NOTES

- 1. Pressurized rooms are indicated by pink shading.
- 2. Pressurized rooms are indicated by pink shading.
- 3. Pressurized rooms are indicated by pink shading.

LEGEND

- Room Pressure Panel
- Pressure Sensor
- Room Pressure Display

AS BUILT DRAWING

21	21	21	21
21	21	21	21

NHS

Brookfield MULTIPLEX

MECHANICAL ENGINEERING

NEW SOUTH GLASGOW HOSPITALS

PHYSIOLOGY PROJECT

FOURTH FLOOR PLAN

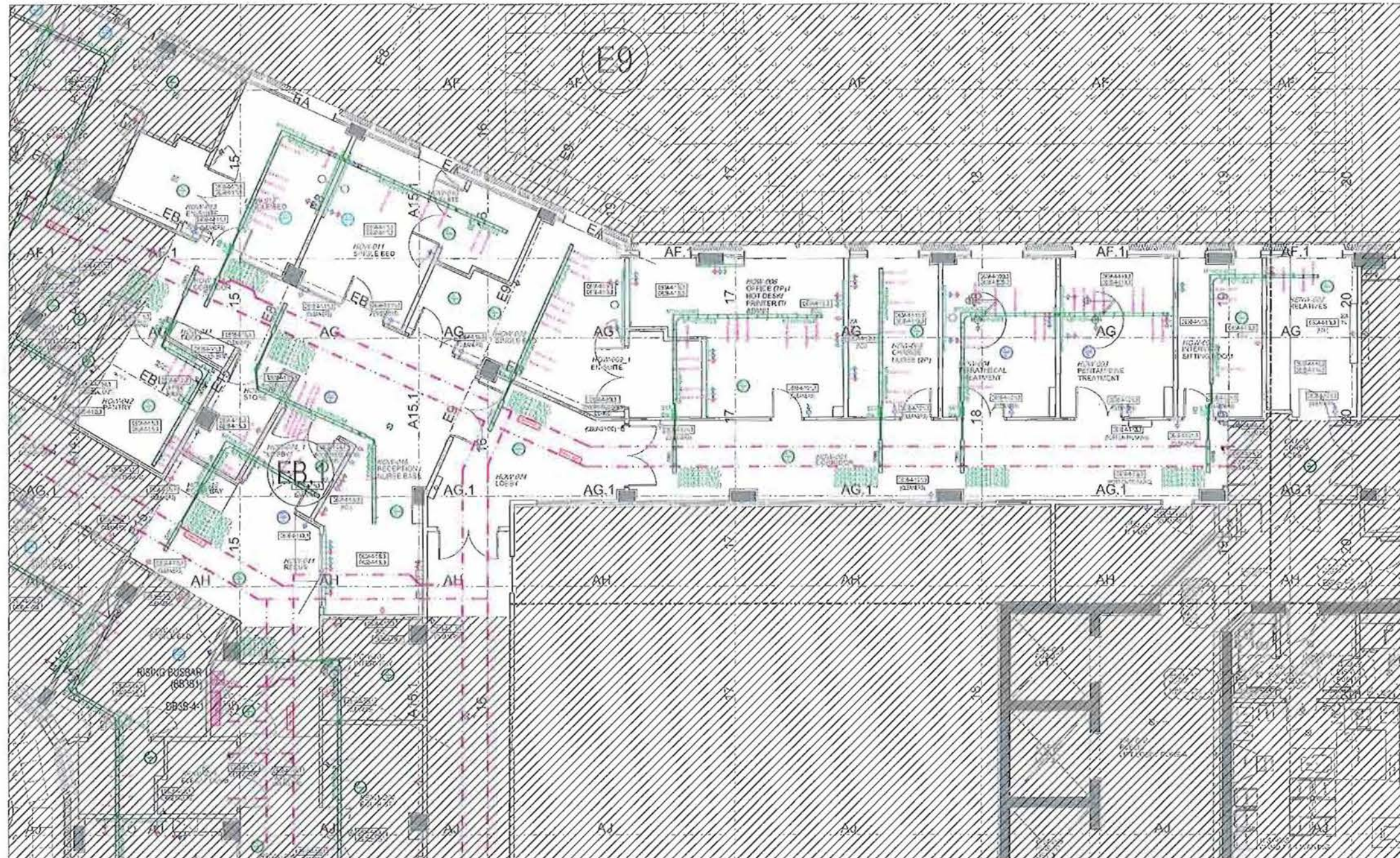
PHYSIOLOGY PROJECT

LAYOUT OF ROOM PRESSURE INDICATORS

ZONE E

DATE	BY	CHKD	APPROVED
01/03/2015	AM	JP	BR
AS BUILT		22.10.15	150

WE ZE 04 PL 660 514 Z1



AS BUILT DRAWING				
21 22 23 24 25 26			01 02 03 04	05 06 07 08
File: Exa: Rev: 001-001-001			09 10 11 12	
Date:				
Company:				
Approved By: For: Position: Name: Company: E-mail:				
Project:				
Drawing Title: NEW SOUTH GLASGOW HOSPITALS (NSGH) PROJECT				
Drawing ID: FOURTH FLOOR PLANT 150N HENRI COX COLLEGE AS BUILT MODULAR SMALL POWER LAYOUT ZONE E				
Project: GB1 0000	Area: GB1	Floor: BN	Room: GN	
Date: AS BUILT		Date: 22-10-15		
Drawing: 01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60 61 62 63 64 65 66 67 68 69 70 71 72 73 74 75 76 77 78 79 80 81 82 83 84 85 86 87 88 89 90 91 92 93 94 95 96 97 98 99 100 101 102 103 104 105 106 107 108 109 110 111 112 113 114 115 116 117 118 119 120 121 122 123 124 125 126 127 128 129 130 131 132 133 134 135 136 137 138 139 140 141 142 143 144 145 146 147 148 149 150 151 152 153 154 155 156 157 158 159 160 161 162 163 164 165 166 167 168 169 170 171 172 173 174 175 176 177 178 179 180 181 182 183 184 185 186 187 188 189 190 191 192 193 194 195 196 197 198 199 200 201 202 203 204 205 206 207 208 209 210 211 212 213 214 215 216 217 218 219 220 221 222 223 224 225 226 227 228 229 230 231 232 233 234 235 236 237 238 239 240 241 242 243 244 245 246 247 248 249 250 251 252 253 254 255 256 257 258 259 260 261 262 263 264 265 266 267 268 269 270 271 272 273 274 275 276 277 278 279 280 281 282 283 284 285 286 287 288 289 290 291 292 293 294 295 296 297 298 299 300 301 302 303 304 305 306 307 308 309 310 311 312 313 314 315 316 317 318 319 320 321 322 323 324 325 326 327 328 329 330 331 332 333 334 335 336 337 338 339 340 341 342 343 344 345 346 347 348 349 350 351 352 353 354 355 356 357 358 359 360 361 362 363 364 365 366 367 368 369 370 371 372 373 374 375 376 377 378 379 380 381 382 383 384 385 386 387 388 389 390 391 392 393 394 395 396 397 398 399 400 401 402 403 404 405 406 407 408 409 410 411 412 413 414 415 416 417 418 419 420 421 422 423 424 425 426 427 428 429 430 431 432 433 434 435 436 437 438 439 440 441 442 443 444 445 446 447 448 449 450 451 452 453 454 455 456 457 458 459 460 461 462 463 464 465 466 467 468 469 470 471 472 473 474 475 476 477 478 479 480 481 482 483 484 485 486 487 488 489 490 491 492 493 494 495 496 497 498 499 500 501 502 503 504 505 506 507 508 509 510 511 512 513 514 515 516 517 518 519 520 521 522 523 524 525 526 527 528 529 530 531 532 533 534 535 536 537 538 539 540 541 542 543 544 545 546 547 548 549 550 551 552 553 554 555 556 557 558 559 560 561 562 563 564 565 566 567 568 569 570 571 572 573 574 575 576 577 578 579 580 581 582 583 584 585 586 587 588 589 590 591 592 593 594 595 596 597 598 599 600 601 602 603 604 605 606 607 608 609 610 611 612 613 614 615 616 617 618 619 620 621 622 623 624 625 626 627 628 629 630 631 632 633 634 635 636 637 638 639 640 641 642 643 644 645 646 647 648 649 650 651 652 653 654 655 656 657 658 659 660 661 662 663 664 665 666 667 668 669 670 671 672 673 674 675 676 677 678 679 680 681 682 683 684 685 686 687 688 689 690 691 692 693 694 695 696 697 698 699 700 701 702 703 704 705 706 707 708 709 710 711 712 713 714 715 716 717 718 719 720 721 722 723 724 725 726 727 728 729 730 731 732 733 734 735 736 737 738 739 740 741 742 743 744 745 746 747 748 749 750 751 752 753 754 755 756 757 758 759 760 761 762 763 764 765 766 767 768 769 770 771 772 773 774 775 776 777 778 779 780 781 782 783 784 785 786 787 788 789 790 791 792 793 794 795 796 797 798 799 800 801 802 803 804 805 806 807 808 809 810 811 812 813 814 815 816 817 818 819 820 821 822 823 824 825 826 827 828 829 830 831 832 833 834 835 836 837 838 839 840 841 842 843 844 845 846 847 848 849 850 851 852 853 854 855 856 857 858 859 860 861 862 863 864 865 866 867 868 869 870 871 872 873 874 875 876 877 878 879 880 881 882 883 884 885 886 887 888 889 890 891 892 893 894 895 896 897 898 899 900 901 902 903 904 905 906 907 908 909 910 911 912 913 914 915 916 917 918 919 920 921 922 923 924 925 926 927 928 929 930 931 932 933 934 935 936 937 938 939 940 941 942 943 944 945 946 947 948 949 950 951 952 953 954 955 956 957 958 959 960 961 962 963 964 965 966 967 968 969 970 971 972 973 974 975 976 977 978 979 980 981 982 983 984 985 986 987 988 989 990 991 992 993 994 995 996 997 998 999 1000 1001 1002 1003 1004 1005 1006 1007 1008 1009 1010 1011 1012 1013 1014 1015 1016 1017 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Client Training & Familiarisation Register

System Description	Ward 4b Room Differential Pressure Monitoring System
Nature of Training	Detailed training – Estates Team
Date	20 th October 2015 @ 3pm

I hereby confirm that I have received training on the aforementioned systems

NAME:	SIGNATURE:	Site
WILLIAM BLACK		
BILL MURRAY		
THOMAS FEENEY		
STEPHEN CORRIE		OVER
M WARD		-
G. HARVEY		-
D BRATLEY		"
R GORDON		"
J. GURRILL		"
C. McKECHNIE		"
S. THOMAS		"
R. FREEL		"

Topics: Room Differential Pressure Monitoring System

Handout: Functional Description Documents – System Description & Operational Instructions



Client Training & Familiarisation Register

System Description	Ward 4b Room Differential Pressure Monitoring System
Nature of Training	Detailed training – Users
Date	20 th October 2015 @ 4pm

I hereby confirm that I have received training on the aforementioned systems

NAME:	SIGNATURE:	Site
Alyson Middle		
HELEN HUNTER		
Tom Bond		
FRANCES ADIE		OSCC DS/B9
MARY McAnney		OSCC HEM.
Marie McLAUGHAN		
Grant McQuade		
Wendy Campbell		
PETER MOIR		

Topics: Room Differential Pressure Monitoring System
 Handout: Functional Description Documents – System Description & Operational Instructions

NEW SOUTH GLASGOW HOSPITAL AND LABORATORY PROJECT

HAEMATO-ONCOLOGY WARD BRIEFING PAPER

January 2012

The purpose of this paper is to give a brief overview of the facilities, design principles and further work required for the Haemato-oncology Ward.

1.0 LOCATION AND CO-LOCATIONS

The Haemato-oncology Ward is located at the bottom of the ward stack, which is the fourth floor of the hospital. The Haemato-oncology Ward shares the floor with Renal Wards. (Please see Appendix 1)

There is rapid access to Theatres (second floor) Critical Care (first floor), Imaging (first floor) and Emergency Department (ground floor) through the central patient beds lifts.

2.0 SERVICES

The Haemato-oncology Ward will provide an inpatient service to patients with a range of malignant and non-malignant haematology conditions. A high proportion of patients are immunocompromised making them vulnerable to infection.

3.0 AGREED PHYSICAL LAYOUT

The bedrooms are sealed with hepafiltration positive to the rest of the hospital and all highly filtered air to H13, i.e. 99.95% as requested by infection control.

The ward has:

Clinical rooms

- 10 single beds, all ensuite with shower and toilet.
- Two treatment rooms located near the main ward entrance as follows:
 - Pentamidine Treatment Room (negatively pressured for the administration of pentamidine inhalations)
 - Intrathecal Treatment Room

Support rooms

- Reception/staff base
- Relatives Room
- Socialisation Space

- Clean Utility
- Dirty Utility
- Pantry
- Equipment Store
- Hot Desks/Charge Nurse Office

Please see Appendix 2 for the 1:200 departmental drawing.

(N.B. the Haemato-oncology Ward was originally planned as a 14 bedded ward with 4 day beds, but was then revised in February 2010 to 10 inpatient beds. The area of the ward is highlighted in orange and finishes at the Large Equipment Store, room HOW32. (The ward area is shown in orange in Appendix 2.)

Design Principles

- As with the generic wards the bedrooms all face outwards with individual views and large picture windows to maximise the light into the rooms.
- Large vision panels from the ward corridors into the bedrooms to maximise patient observation and enable patients to see the staff.
- Minimal travel distances for staff, the immediately required Support Services being located down the middle of the Ward.
- The Ward has a central Staff Base and two Nurse Touch Downs to allow a 'devolved' nursing model whereby, rather than working from one central staff base, nursing teams will be assigned to clusters of bedrooms supported by the touchdown spaces.
- Support Services, which will be shared by the 4 wards on each floor, are located in a central core between the wards, these include 6 Hot Desks, a Medicines Management Workspace, Staff Change and a Facilities Management Kitchen. On the fourth floor there is also a large Seminar Room which will be available to all GG&C staff, bookings will be undertaken centrally through Facilities Management.
- Hoists – there will be overhead hoists in two rooms these being: HOW 017 & HOW 024.
- In order to avoid visitors to renal walking through the haemato-oncology bedroom area an additional access route has been created.

Security

There will be audio visual security access to the ward - Staff will access the ward with a security access swipe card.

The Clean Utility will have a keypad entry so the door will remain closed to ensure only staff enter this area.

IT

The hospital is wireless enabled.

There are 2 x double data points and 6 x double electrical sockets at each bed. Where appropriate, IT points have been incorporated to allow barcode tracking of stock.

Pharmacy

Patient specific medication will be stored in the Patients Own Drugs (POD) storage unit within the bedroom area.

Pharmacists will work in teams from the Medicines Management Rooms attached to ward areas to support the 'My Medicines' model of care.

4.0 AREAS OF FURTHER WORK

An operational policy is required for the ward.

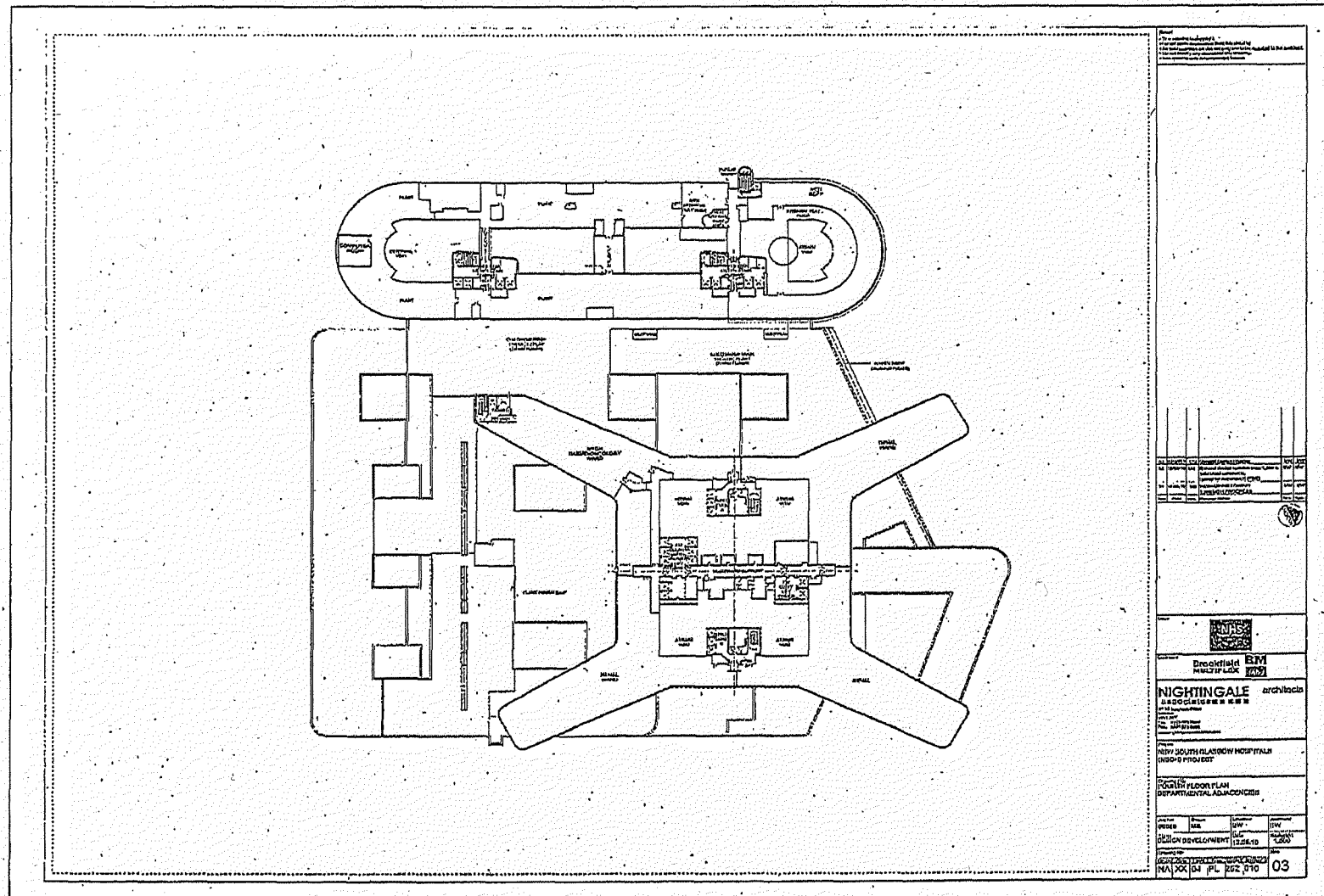
5.0 DRAWINGS

Appendix 1: 1:500 Drawing, 4th floor - Location and Co-locations

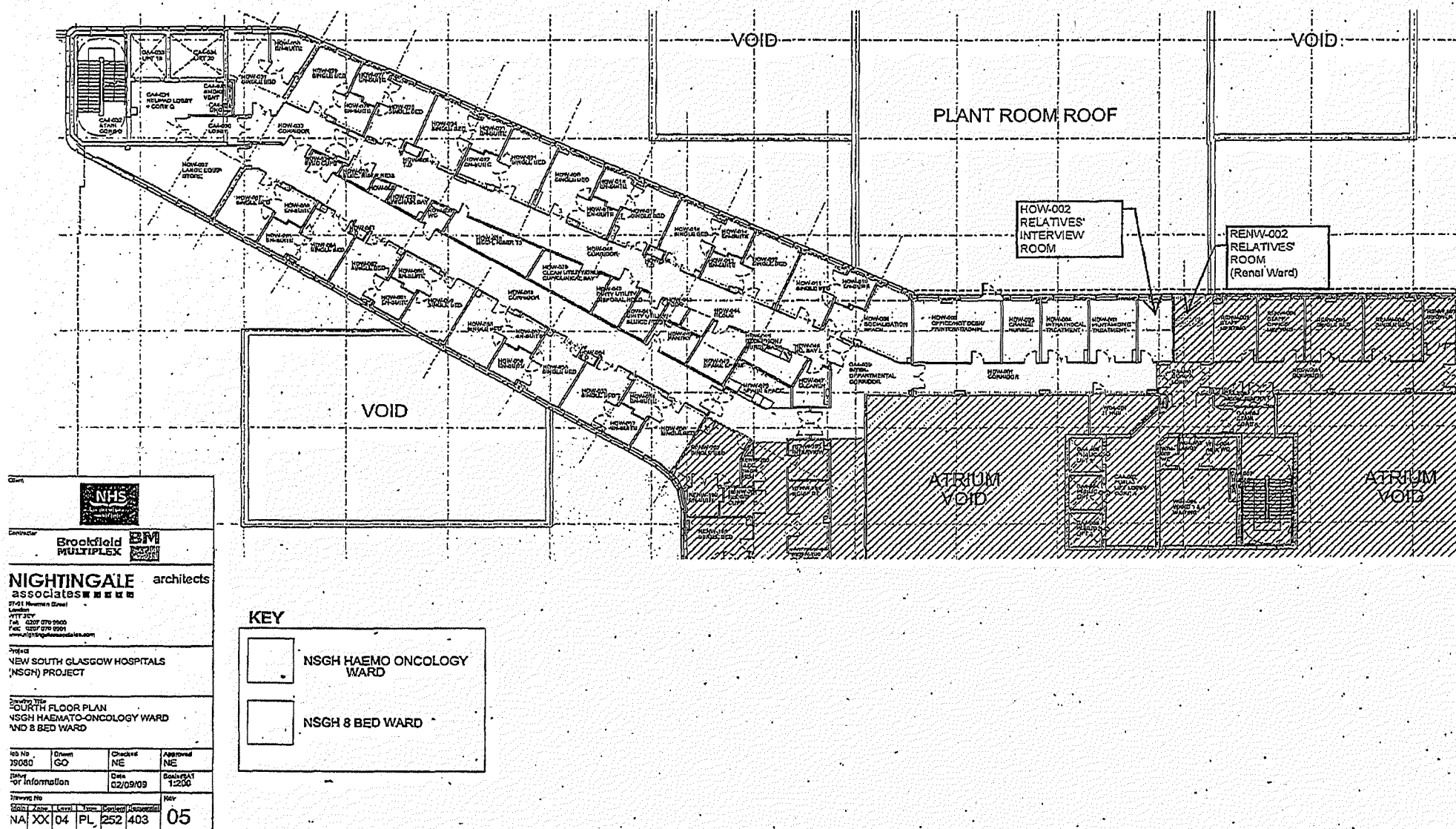
Appendix 2: 1:200 Drawing – Haemato-oncology Ward

Appendix 1

1:500 Drawing, 4th floor - Location and Co-locations



Appendix 2 **1:200 Drawing – Haemato-oncology Ward.**



QUEEN ELIZABETH UNIVERSITY HOSPITAL
ADULTS – RENAL WARD 4C

CRITICAL VENTILATION ANNUAL VERIFICATION & INSPECTION

QEUH – ADULTS RENAL WARD 4C



Client:	NHS Greater Glasgow & Clyde	Client Contact:	James Guthrie
Hospital:	Queen Elizabeth University Hospital	Site Address:	1345 Govan Road, Glasgow G51 4TF
Area:	Adults – Level 4	Report No:	A0056927 & A0056928
Date of Test:	16 th & 17 th January 2020	Date of Last Test:	N/A
Test Engineer & Report Preparation:	Paul McShee	Signature:	
CSSL. Reviewed By:	Ian McKenzie	Signature:	
Client Reviewed By:	James Guthrie	Clients Signature:	

QUEEN ELIZABETH UNIVERSITY HOSPITAL
ADULTS – RENAL WARD 4C

Table of Contents

1. Scope of Works
2. Definition of terms
3. Executive Summary/Observations
4. Supply & Extract airflow rates and air change rates
5. Room Pressure Differentials
6. Schematic Drawing Layouts of All Rooms
7. Equipment Used
8. Calibration Certificates

QUEEN ELIZABETH UNIVERSITY HOSPITAL

ADULTS – RENAL WARD 4C

Section 1 – Scope of Works

Adults - Ward 4C is located on the 4th floor in Queen Elizabeth University Hospital.

Adults Ward 4C is supplied by 3 Air Handling Units located on level 12 plant room, just one level below from the department.

To ensure compliance with the SHTM03-01, the following tests will be carried out;

- 1) Record room differential pressures. Room to Corridor and room to en-suite.
- 2) Record supply air volumes and calculate room air change rates.
- 3) Record Extract air volumes and calculate en-suite air change rates.

QUEEN ELIZABETH UNIVERSITY HOSPITAL

ADULTS – RENAL WARD 4C

Section 2 – Definition of terms

Assessment of compliance with SHPN 04 Supplement 1

Poor

Air volumes and hence air-change rate is less than 75% of the design. Room pressure differentials do not ensure a flow from clean to less clean areas; supply or extract air diffusers are not clean; pressure stabilisers not clean and/or not operating correctly; visible faults in the fabric of the suite; doors unable to close completely; general air of neglect.

Action: Urgent management action required.

Average

Air volumes and room pressure differentials approximate to the original design values; supply air diffusers clean but extracts visibly fouled; most pressure stabilisers clean and operating correctly; minor faults in the fabric and décor of the suite.

Action: Maintenance action required.

Good

Better than average.

Action: None.

Maintenance quality

Poor

More than three answers are negative.

Action: Management action required by estates/facilities department.

Average

No more than three answers are negative

Action: Maintenance action required.

Good

No answers are negative.

Action: None.

QUEEN ELIZABETH UNIVERSITY HOSPITAL

ADULTS – RENAL WARD 4C

Section 3 – Executive Summary

All rooms within Adults - Ward 4C comply with the client's specification.

Derogated client's specification:

- 1) Room ACRs = 3AC/HR
- 2) En-suite ACRs = 6AC/HR
- 3) Room Differential pressures to corridor to be nominally positive (+ve)
- 4) En-suite toilet to be -ve to the room.

CVG (Ceiling Ventilation Grilles x10) removed and replaced with a standard ceiling tile.

Total area of Ward 4C is 955.8m³.

Pressure across door exiting 4C at Core K is was +2.4Pa and across the door at Core A being +1Pa.

QUEEN ELIZABETH UNIVERSITY HOSPITAL

ADULTS – RENAL WARD 4C

Section 4 – Supply & Extract Airflow Rates & Air Change Rates

Adults – Rooms to Corridor - AHU Ref.: 124AHU04						
Room Reference	Design Volume l/s	Recorded Air Volume l/s	Percentage of Design	Room Volume m ³	Recorded AC/HR	ACRs (AC/HR)
RENW-125	+160	+163	102	135.4	4.3	6
RENW-125						
RENW-125						
RENW-125						
RENW-130	+40	+44	110	44.7	3.5	6
RENW-131	+40	+41	102	52.7	2.8	6
RENW-134	+40	+40	100	46.9	3.1	6
RENW-135	+40	+41	102	47.0	3.1	6
RENW-138	+40	+40	100	47.1	3.1	6
RENW-140	+40	+41	102	46.9	3.1	6
RENW-143	+40	+41	102	47.9	3.1	6
RENW-144	+40	+42	105	47.1	3.2	6
RENW-147	+40	+42	105	47.1	3.2	6
RENW-149	+40	+41	102	46.9	3.1	6
RENW-152	+40	+41	102	47.1	3.1	6
RENW-154	+40	+40	100	52.9	2.7	6
Comments:						

QUEEN ELIZABETH UNIVERSITY HOSPITAL

ADULTS – RENAL WARD 4C

Section 4 – Supply & Extract Airflow Rates & Air Change Rates – *Continued...*

Adults Ward 4C –Rooms to Corridor - AHU Ref.: 124AHU05						
Room Reference	Design Volume l/s	Recorded Air Volume l/s	Percentage of Design	Room Volume m ³	Recorded AC/HR	ACRs (AC/HR)
RENW-155	+40	+37	92	53.1	2.5	6
RENW-157	+40	+35	87	47.3	2.7	6
RENW-160	+40	+36	90	46.8	2.8	6
RENW-162	+40	+36	90	47.1	2.8	6
RENW-165	+40	+37	92	47.1	2.8	6
RENW-166	+40	+54	135	47.2	4.1	6
RENW-170	+40	+49	122	47.3	3.7	6
RENW-172	+40	+38	95	47.1	2.9	6
RENW-175	+40	N/A	N/A	N/A	N/A	6
RENW-180	+40	+38	95	47.1	2.9	6
RENW-183	+40	+37	92	46.9	2.8	6
RENW-185	+40	+38	95	47.1	2.9	6
RENW-188	+40	+37	92	47.2	2.9	6
RENW-214	+160	+148	92	134.6	4.0	6
Comments: No access to Room 71 Door Ref: RENW-175 as patient was seriously ill.						

QUEEN ELIZABETH UNIVERSITY HOSPITAL

ADULTS – RENAL WARD 4C

Section 4 – Supply & Extract Airflow Rates & Air Change Rates – *Continued...*

Adults Ward 4C –Rooms to Corridor - AHU Ref.: 124AHU06						
Room Reference	Design Volume l/s	Recorded Air Volume l/s	Percentage of Design	Room Volume m ³	Recorded AC/HR	ACRs (AC/HR)
RENW-127	+40	+37	92	44.6	3.0	N/A
RENW-127	-40	-28	70	44.6	N/A	N/A
RENW-239	+24	+23	96	N/A	N/A	N/A
RENW-237	+10	+12	120	16.2	2.7	N/A
RENW-235	+40	+38	95	29.2	4.7	N/A
RENW-235	-40	-28	70	29.2	N/A	N/A
RENW-234	+40	+37	92	29.2	4.6	N/A
RENW-234	-40	-29	72	29.2	N/A	N/A
RENW-323	+24	+28	116	N/A	N/A	N/A
RENW-227	+45	+38	95	31.0	4.4	N/A
RENW-227	-54	-43	80	31.0	N/A	N/A
RENW-230	+10	+12	120	21.4	2.0	N/A
RENW-226	+49	+49	100	21.4	8.5	6
RENW-225	-45	+18	40	20.8	N/A	N/A
RENW-225	+78	+40	51	20.8	6.9	6
RENW-224	+25	+86	344	38.4	8.0	6
RENW-224	-65	-44	68	38.4	N/A	N/A
Comments:						

QUEEN ELIZABETH UNIVERSITY HOSPITAL

ADULTS – RENAL WARD 4C

Section 4 – Supply & Extract Airflow Rates & Air Change Rates – *Continued...*

Adults Ward 4C –Rooms to Corridor - AHU Ref.: 124AHU06						
Room Reference	Design Volume l/s	Recorded Air Volume l/s	Percentage of Design	Room Volume m ³	Recorded AC/HR	ACRs (AC/HR)
RENW-213	+18	+18	100	45.7	1.4	N/A
RENW-210	N/A	+45	N/A	16.4	9.9	N/A
RENW-210	N/A	-25	N/A	16.4	N/A	N/A
RENW-176	+150	+70	63	45.0	7.6	10
		+25				
RENW-179	+10	+13	130	14.8	3.2	N/A
Comments:						

QUEEN ELIZABETH UNIVERSITY HOSPITAL

ADULTS – RENAL WARD 4C

Section 4 – Supply & Extract Airflow Rates & Air Change Rates – *Continued...*

Adults Ward 4C – Rooms to En Suite - AHU Ref.: 124AHU04						
Room Reference	Design Volume l/s	Recorded Air Volume l/s	Percentage of Design	Room Volume m ³	Recorded AC/HR	ACRs (AC/HR)
RENW-128	-45	-37	82	13.7	9.7	10
RENW-132	-45	-36	80	13.7	9.5	10
RENW-133	-45	-38	84	13.8	9.9	10
RENW-136	-45	-54	120	14.1	13.8	10
RENW-139	-45	-48	106	13.8	12.5	10
RENW-141	-45	-38	84	14.2	9.6	10
RENW-142	-45	-52	115	15.6	12.0	10
RENW-145	-45	-51	113	14.9	12.3	10
RENW-146	-45	-51	113	14.7	12.5	10
RENW-150	-45	-49	108	14.4	12.3	10
RENW-151	-45	-46	102	14.7	11.3	10
RENW-153	-45	-55	122	17.8	11.1	10
Comments:						

QUEEN ELIZABETH UNIVERSITY HOSPITAL

ADULTS – RENAL WARD 4C

Section 4 – Supply & Extract Airflow Rates & Air Change Rates – *Continued...*

Adults Ward 4C – Rooms to En Suite - AHU Ref.: 124AHU05						
Room Reference	Design Volume l/s	Recorded Air Volume l/s	Percentage of Design	Room Volume m ³	Recorded AC/HR	ACRs (AC/HR)
RENW-156	-45	-42	93	17.5	8.6	10
RENW-158	-45	-40	88	13.7	10.5	10
RENW-159	-45	-41	91	13.8	10.7	10
RENW-163	-45	-40	88	13.9	10.4	10
RENW-164	-45	-42	93	13.7	11	10
RENW-167	-45	-42	93	13.9	10.9	10
RENW-168	-45	-38	84	13.6	10.1	10
RENW-171	-45	-40	88	13.7	10.5	10
RENW-181	-45	-44	97	13.6	11.6	10
RENW-182	-45	-43	96	13.6	11.4	10
RENW-184	-45	-41	91	13.7	10.8	10
RENW-188	-45	-41	91	13.7	10.8	10
Comments:						

QUEEN ELIZABETH UNIVERSITY HOSPITAL

ADULTS – RENAL WARD 4C

Section 5 – Room Pressure Differentials

Adults Ward 4C – Bedrooms			
Room Reference	Target Bed Room Pressure (Pa)	Recorded Bed Room Pressures (Pa)	En-Suite Recorded Pressure (Pa)
RENW-125	+ve	0.9	N/A
RENW-130	+ve	0	-1.1
RENW-131	+ve	0	-1.2
RENW-134	+ve	0	-1.4
RENW-135	+ve	0	-2.3
RENW-138	+ve	0	-2.2
RENW-140	+ve	0	-1.7
RENW-143	+ve	0	-2.6
RENW-144	+ve	0	-2.7
RENW-147	+ve	0	-2.3
RENW-149	+ve	0	-2.3
RENW-152	+ve	0	-2.4
RENW-154	+ve	0	-2.8
RENW-155	+ve	0	-1.2
RENW-157	+ve	0	-1.8
RENW-160	+ve	0	-1.9
Comments:			

QUEEN ELIZABETH UNIVERSITY HOSPITAL

ADULTS – RENAL WARD 4C

Section 5 – Room Pressure Differentials *Continued...*

Adults Ward 4C – Bedrooms			
Room Reference	Target Bed Room Pressure (Pa)	Recorded Bed Room Pressures (Pa)	En-Suite Recorded Pressure (Pa)
RENW-164	+ve	0	-1.9
RENW-165	+ve	0	-2.0
RENW-166	+ve	0	-1.6
RENW-170	+ve	0	-1.8
RENW-172	+ve	0	-1.8
RENW-175	+ve	+0.7	N/A
RENW-180	+ve	0	-2.0
RENW-183	+ve	0	-2.1
RENW-185	+ve	0	-2.0
RENW-188	+ve	0	-2.0
Comments:			

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ADULTS – RENAL WARD 4C

Section 5 – Room Pressure Differentials *Continued...*

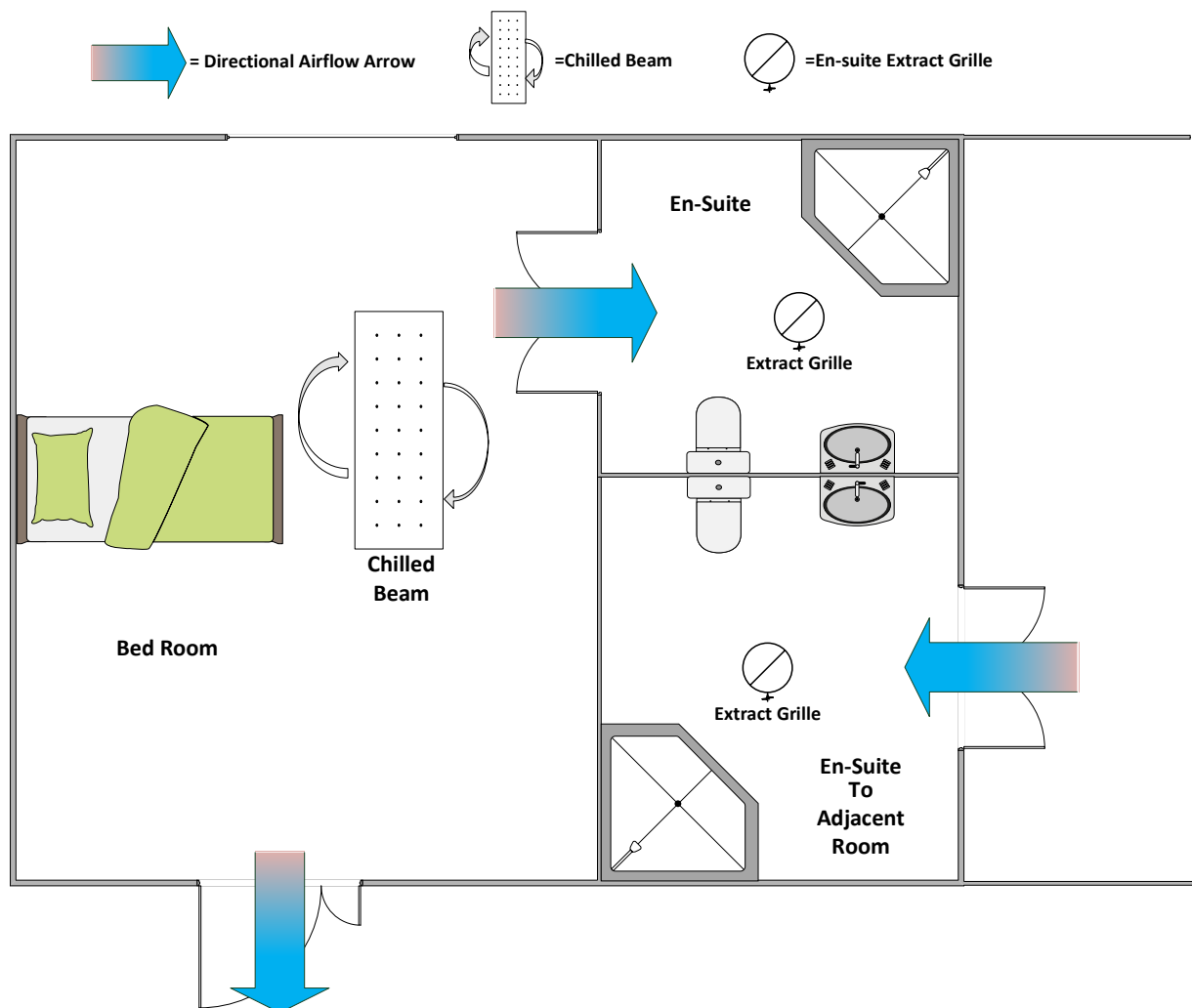
Adults Ward 4C – Other Rooms

Room Reference	Room Description	Target Pressures (Pa)	Recorded Room Pressures (Pa)
RENW-227	Staff Kitchen	n/a	+1.5Pa
RENW-224	Clean Utility	+ve	+1.2Pa
RENW-218	Staff W/C	-ve	-3.0Pa
RENW-225	Dialysis Store	n/a	+1.7Pa
RENW-226	Dirty Utility	-ve	+1.6Pa
RENW-230	Store	n/a	+0.8Pa
RENW-210	Facilities	n/a	+0.6Pa
RENW-214	Dialysis	n/a	+1.1Pa
RENW-213	Store	n/a	0Pa
RENW-176	Procedures	n/a	+5.0Pa
RENW-179	Procedures Store	n/a	-1.0Pa

Comments:

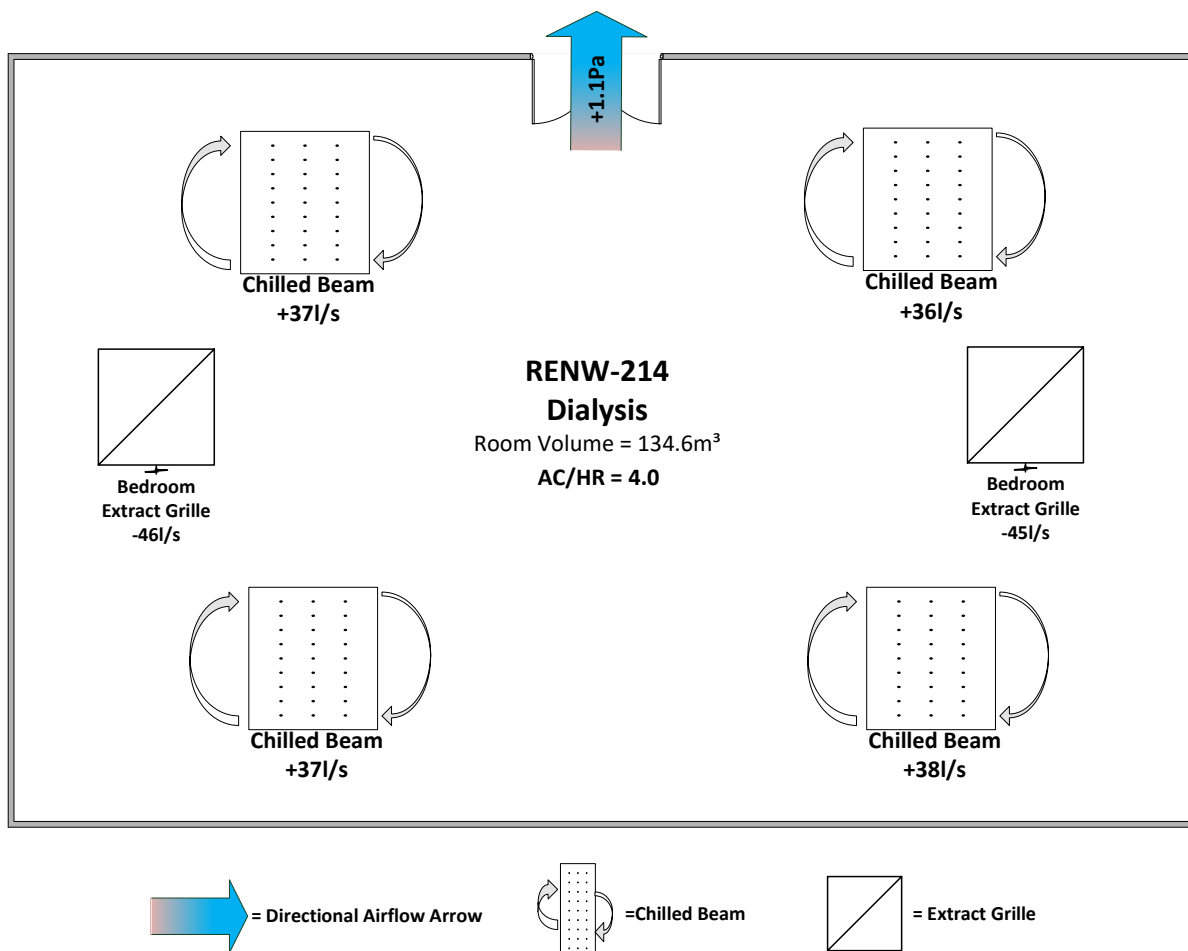
QUEEN ELIZABETH UNIVERSITY HOSPITAL ADULTS – RENAL WARD 4C

Section 6 – Typical Schematic of all Bed Room Layouts out for Ward 4C – Door References; [RENW-130](#), [RENW-131](#), [RENW-134](#), [RENW-135](#), [RENW-138](#), [RENW-140](#), [RENW-130](#), [RENW-144](#), [RENW-147](#), [RENW-149](#), [RENW-152](#), [RENW-154](#), [RENW-155](#), [RENW-157](#), [RENW-160](#), [RENW-162](#), [RENW-165](#), [RENW-166](#), [RENW-170](#), [RENW-172](#), [RENW-180](#), [RENW183](#), [RENW-185](#).



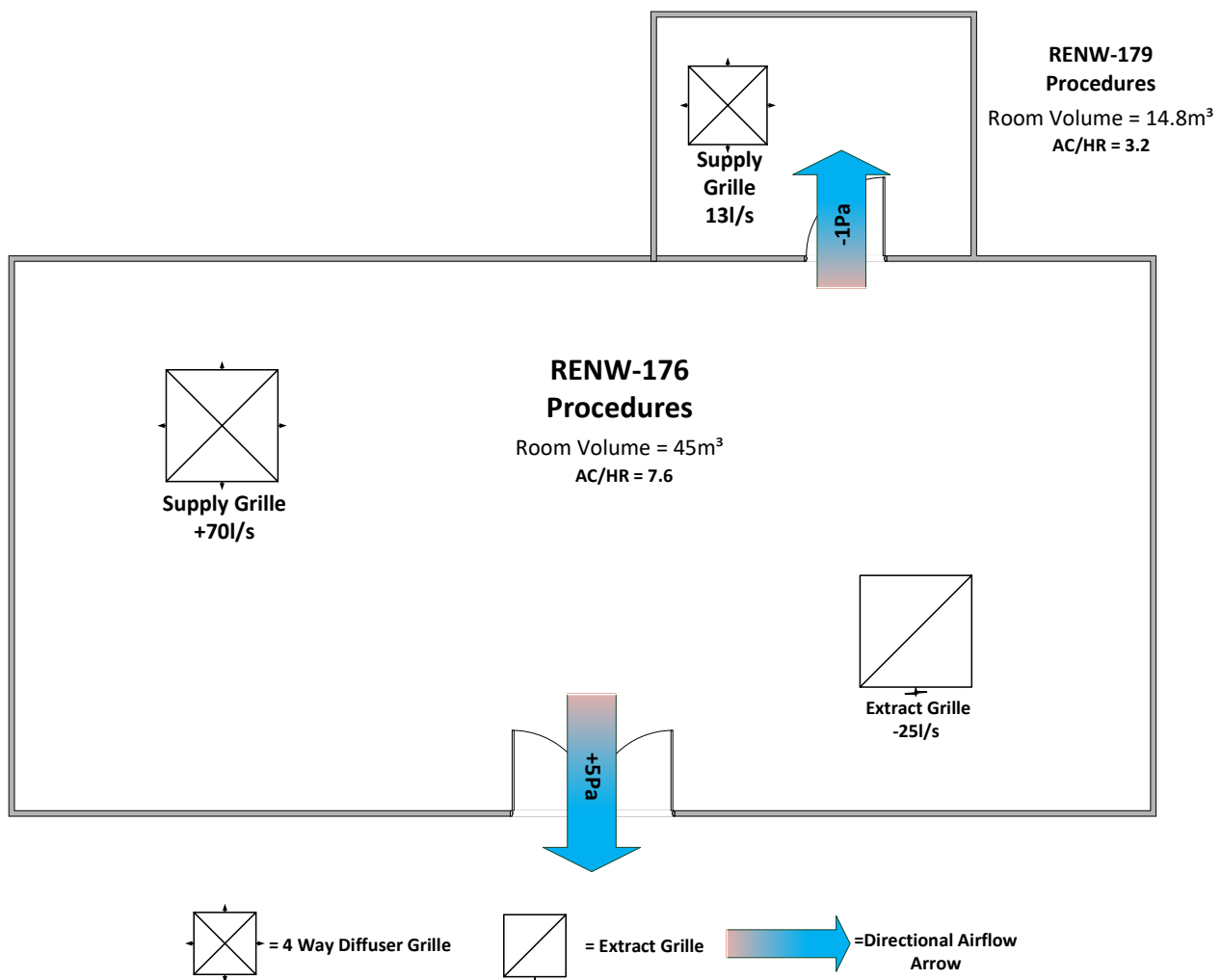
QUEEN ELIZABETH UNIVERSITY HOSPITAL ADULTS – RENAL WARD 4C

Section 6 – Schematic of Dialysis Door Ref; RENW-214



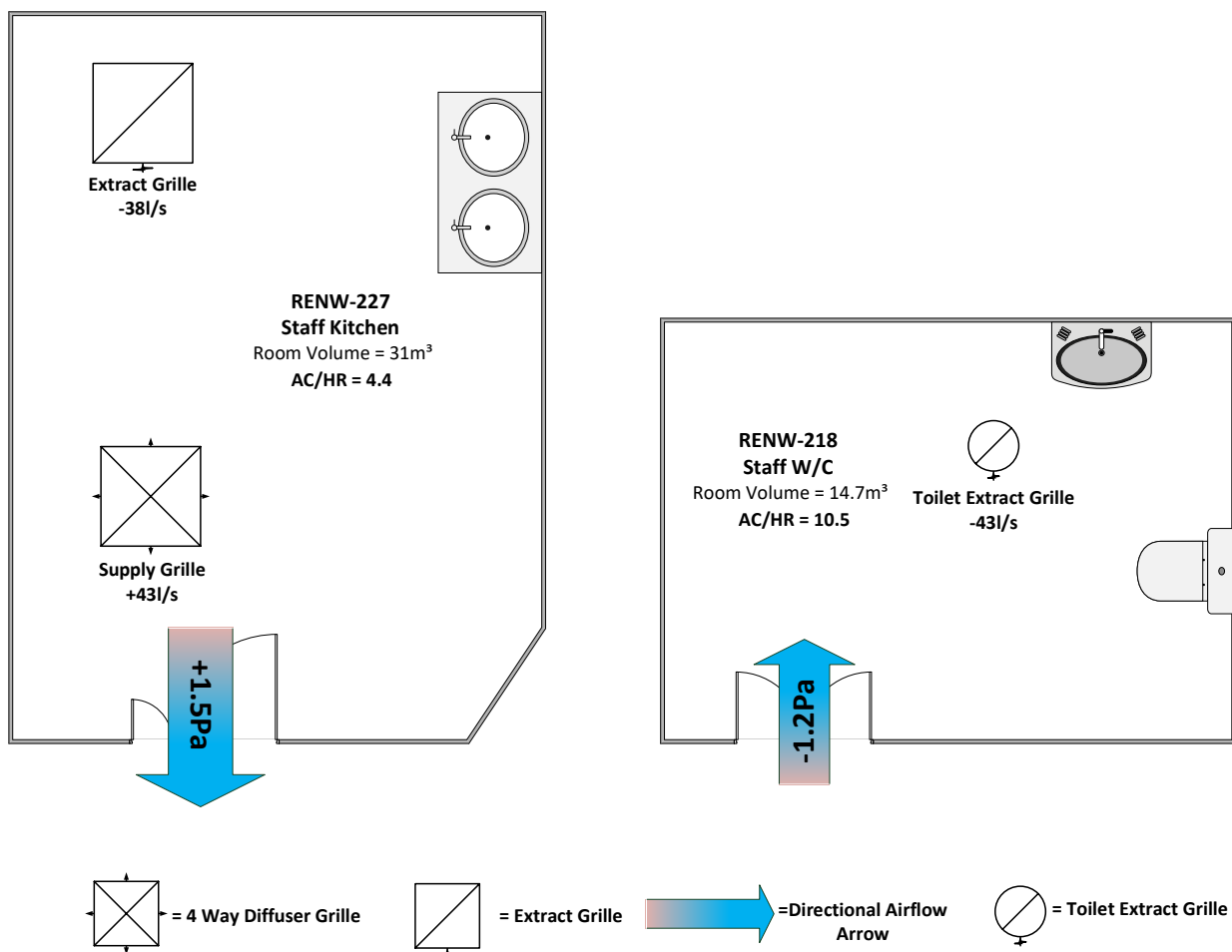
QUEEN ELIZABETH UNIVERSITY HOSPITAL
ADULTS – RENAL WARD 4C

Section 6 – Schematic of Procedures Door Ref; RENW-176 & Procedures Store Door Ref; Renw-179



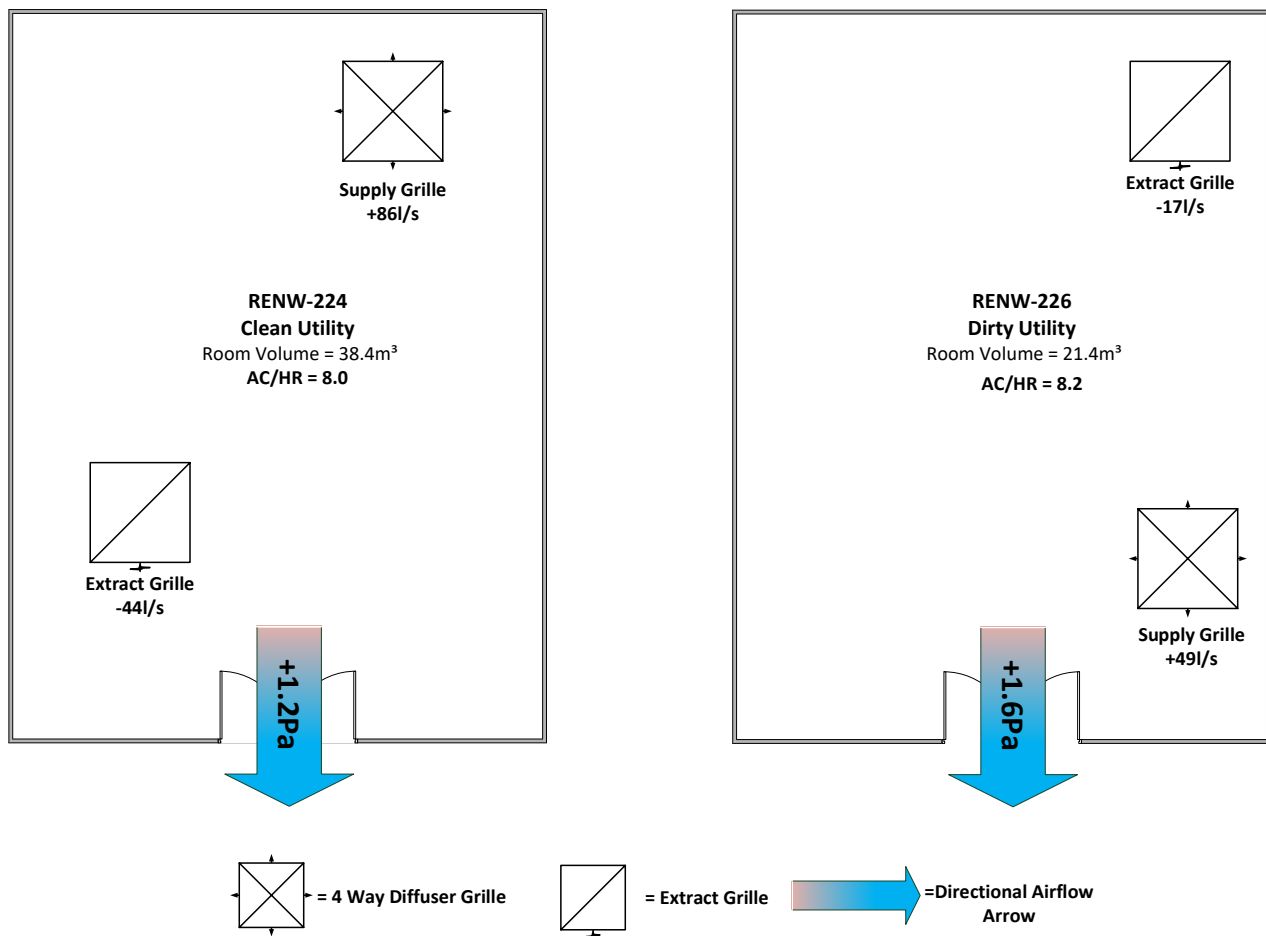
QUEEN ELIZABETH UNIVERSITY HOSPITAL ADULTS – RENAL WARD 4C

Section 6 – Schematic of Staff Kitchen Door Ref; RENW-227 & Staff W/C Door Ref; RENW-218



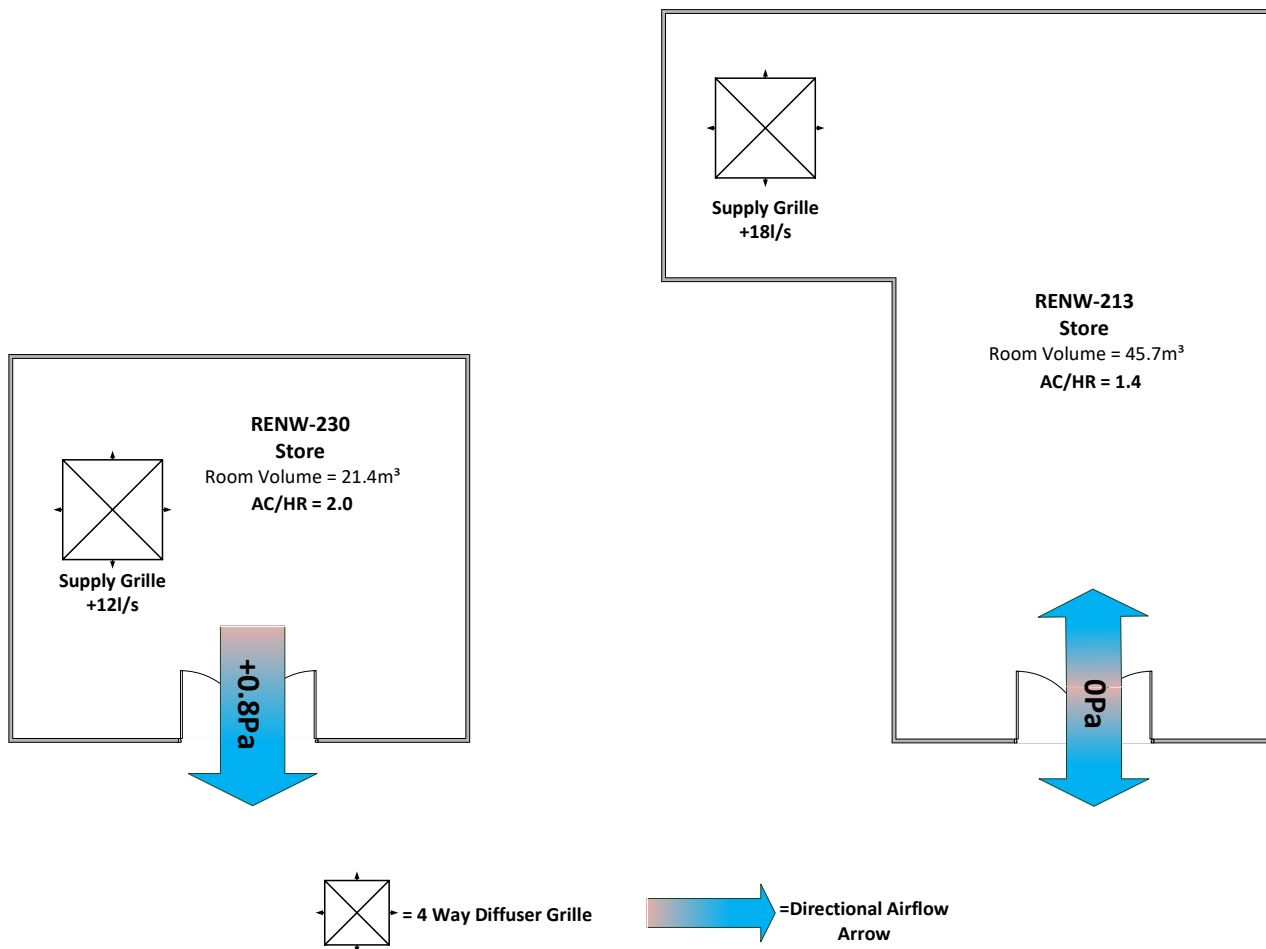
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ADULTS – RENAL WARD 4C

Section 6 – Schematic of Dirty Utility Door Ref; RENW-226 & Clean Utility Door Ref; RENW-224.



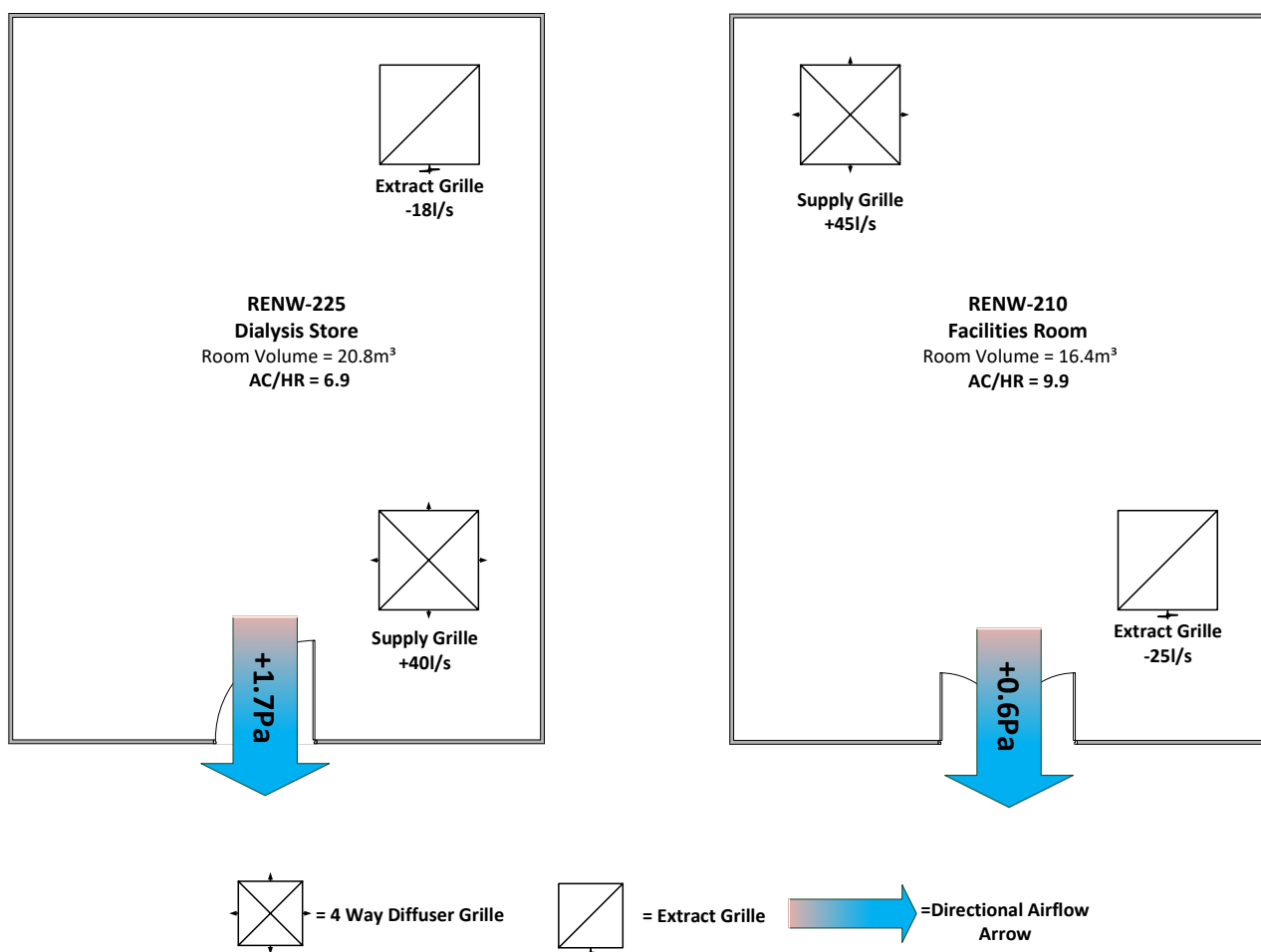
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Section 6 – Schematic of Store Door Ref; RENW-213 & Store Door Ref; RENW-230



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ADULTS – RENAL WARD 4C

Section 6 – Schematic of Dialysis Store Door Ref; RENW-225 & Facilities Room Door Ref; Renw-210



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ADULTS – RENAL WARD 4C

Section 7 – Test Equipment Used

Type of Equipment	Serial No	Cal Due Date
Micro-manometer	8651	June 2020
Balometer	PH7311809008	June 2020

QUEEN ELIZABETH UNIVERSITY HOSPITAL ADULTS – RENAL WARD 4C

Section 8 – Calibration Certificates

AIRFLOW INSTRUMENTS **CERTIFICATE OF CALIBRATION**
TSI Instruments Ltd., Stirling Road, Cressex Business Park,
High Wycombe, Bucks HP12 3RT England
Tel: (Int +44)(UK 0) 1494 459200 Fax: (Int +44)(UK 0) 1494 459700
http://www.tsiinc.co.uk

ENVIRONMENT CONDITION		
TEMPERATURE	67.3	° F
RELATIVE HUMIDITY	50.3	% RH
BAROMETRIC PRESSURE	29.3	inHg

MODEL	PROHOOD™ PH731
SERIAL NO.	PH7311809008

☒ AS LEFT	☒ IN TOLERANCE
☐ AS FOUND	☐ OUT OF TOLERANCE

CALIBRATION STANDARDS USED	
Capture Hood Calibration System UK1	

CALIBRATION DATA						
Tolerance: $\pm$ (3% of reading + 7.0 cfm)						
TESTING POINTS	SUPPLY DATA MEASURED IN ft ³ /min			RETURN DATA MEASURED IN ft ³ /min		
	CALIBRATION STANDARD	INSTRUMENT OUTPUT	ALLOWABLE RANGE	CALIBRATION STANDARD	INSTRUMENT OUTPUT	ALLOWABLE RANGE
1	1896	1937	1835 – 1961	1900	1856	1836 – 1964
2	1501	1519	1449 – 1553	1502	1458	1450 – 1554
3	1167	1206	1155 – 1239	1205	1170	1182 – 1248
4	900	904	866 – 934	901	862	867 – 935
5	601	604	576 – 626	601	594	576 – 626
6	302	300	286 – 318	297	294	282 – 312
7	99	102	90 – 108	100	101	90 – 110

* Indicates out of tolerance condition

TSI does hereby certify that the above described instrument conforms to the original manufacturer's specification (not applicable to As Found items) and has been calibrated using standards whose accuracies are traceable to members of the European co-operation for Accreditation (EAC) or is derived from accepted values of physical constants. TSI's calibration system meets ISO-9001:2008 and meets the requirements of ISO 10012:2003.

Measurement Variable	System ID Number	Date Last Calibrated	Calibration Due Date
DC Voltage	E006072	04-25-19	04-25-20
Thermometer	E006103	04-25-19	04-25-20
Pressure	E006155	04-24-19	04-24-20
Pressure	E006095	04-24-19	04-24-20
Flow	E004015	08-14-15	08-14-19
Flow	E004017	08-12-15	08-12-19
Barometric Pressure	E006061	04-24-19	04-24-20

Calibration procedure used: 9011156

Jun. 12, 2019
Calibration Date

1063903A

QUEEN ELIZABETH UNIVERSITY HOSPITAL

ADULTS – RENAL WARD 4C



DP MEASUREMENT

Unit 11, Top Angel, Buckingham Industrial Park, Buckingham, MK18 1TH
Tel/Fax: 01280 817122 e-mail: dpm@ttseries.com www.ttseries.com

CALIBRATION CERTIFICATE

CUSTOMER DETAILS:

Customer: Correctair Solutions Ltd
Customer Serial Number: N/A

INSTRUMENT DETAILS:

Model: TT570 S
Serial Number: 8651

CONDITION ON RECEIPT New

- 1 Required repair:
- 2 In spec:
- 3 If yes to 2 adjustment:
- 4 If no to 2 adjustment:

CALIBRATION DETAILS:

Date Of Calibration: 12/06/19
Due Date: 12/06/20
Certificate Number: 45518

TEST ROOM CONDITIONS:

Temperature: 22°C ± 2°C

Manufacturers Specification Readings less than 100 counts ± 2 counts

Readings greater than 100 counts ± 1% of reading ± 1 count

Manufacturer: DP Measurement

	0	40	80	160	400	800	kPa	kPa	kPa
TEST RESULTS:							1.60	3.00	6.00
Calibration Points Pa:	0	40	80	160	399	800	1.60	3.00	6.00
Indicated Readings:	0	-0.50%	-0.37%	0.00%	-0.25%	0.00%	0.00%	0.00%	0.00%
Percentage Error:									
TEST RESULTS:		-40	-80	-160	-400	-800	kPa	kPa	kPa
Calibration Points Pa:	0	-40	-80	-160	-400	-800	-1.60	-3.00	-6.00
Indicated Readings:	0	0.25%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Percentage Error:									

Calibration Points m/sec:	0	5.0	8.2	11.5	15.0	16.3	25.8	36.5	50.0
Indicated Readings:	0	5.0	8.2	11.5	15.0	16.3	25.8	36.5	50.0
Percentage Error:	0	0.0	0.0	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%

Notes:

Equipment:

The instrument detailed above has been calibrated against equipment serial number 0047368 which in turn has been calibrated against instruments and equipment that are traceable to National Standards. (UKAS Calibration Laboratory N° 0157). The above results are obtained on the date of calibration. The percentage error quoted refers to the measured values only, with no account being taken of the instruments ability to maintain its calibration.

Velocity Range

Is calibrated for the ellipsoidal nose (NPL Type) Pitot Static Tubes used at air density 1.20kg/m³. Air stream temperature set at 16°C and barometric pressure set at 1000 mbar on the instrument.

Calibrated by Hussein Khimji:

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Version 2
07.06.2017

Associated Instrument Repairs Ltd. Trading as DP Measurement.
Company Reg. No: 3485904 VAT No: 685 868 755
Registered Office: Ebenezer House, Poole Road, Bournemouth, Dorset. BH12 5QJ.

SHTM 03-01 CRITICAL VENTILATION VERIFICATION & INSPECTION
ADULTS WARD – 4C RENAL



Client:	NHS Greater Glasgow & Clyde	Client Contact:	Connor Stepney
Hospital:	Queen Elizabeth University Hospital	Site Address:	1345 Govan Road, Glasgow G51 4TF
Area:	Adults – Ward 4C – Level 4	AHU:	124AHU04 (S&E) & 124AHU05 (S&E)
Report No:	A-5704	Condition:	N/A
Date of Test:	8 th – 16 th September 2022	Date of Last Test:	24 th September 2021
Test Engineer & Report Preparation:	Paul McShee	Signature:	
CSSL. Reviewed By:	Daniel Kane	Signature:	
Client Reviewed By:	Connor Stepney	Clients Signature:	



HVAC - Hospital & Cleanroom Validation Experts

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A48946859

DOCUMENT NUMBER – A-5704

Table of Contents

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2. DEFINITION OF TERMS
3. EXECUTIVE SUMMARY & OBSERVATIONS
4. SUPPLY & EXTRACT AIRFLOW, AIR CHANGE RATES & SCHEMATIC LAYOUT & ROOM PRESSURE DIFFERENTIAL RATES, TEMPERATURE & NOISE LEVELS
5. TEST EQUIPMENT USED
6. CALIBRATION CERTIFICATES

Section 1.0 – Scope of Works

Annual Inspection of Critical Ventilation Systems

To carry out a compliance and performance inspection of all critical path ventilation systems in accordance with - Heating and Ventilation Systems - SHTM – Scottish Health Technical Memorandum 03-01: Specialised Ventilation for Healthcare Premises.

(Interim Version – Additional guidance related to COVID 19 to be added in an update in 2022)

Part B: The management, operating, maintenance and routine testing of existing healthcare ventilation systems.

The verification of the rooms was carried out to record an annual verification record for these rooms. This work followed post fitting of recirculation fans (Camfil Camcleaner 400 concealed fan units) located within the ceiling of the toilet of bedrooms in Adults – Ward 4C. The Camcleaner consists of a pre-filter (bag) and a secondary HEPA filter. See report details of fan settings, air volumes, room pressures and noise levels achieved while maintaining SHTM03-01 compliance.

Section 2.0 – Definition of Terms

Definition of terms used on survey form Assessment of compliance with Health Building Note 10-01 and Scottish Health Technical Memorandum 03-01 (all questions relevant to the type of theatre)

Poor

Air volumes and hence air-change rate is less than 80% of the design; room pressure differentials do not ensure a flow from clean to less clean areas; supply or extract air diffusers are not clean; pressure stabilisers not clean and/or not operating correctly; significant faults or failures of indicators on surgeon's panel; visible faults in the fabric of the suite; doors unable to close completely; general air of neglect.

Action: Urgent management action required.

Average

Air volumes and room pressure differentials approximate to the original design values; supply air diffusers clean but extracts visibly fouled; most pressure stabilisers clean and operating correctly; some of the indicators on the surgeon's panel not working; minor faults in the fabric and décor of the suite.

Action: Maintenance action required.

Good

Better than average.

Action: None.

Maintenance quality (all questions relevant to the type of theatre)

Poor

More than three answers are negative.

Action: Management action required by estates/facilities department.

Average

No more than three answers are negative

Action: Maintenance action required.

Good

No answers are negative.

Action: None.

Section 3.0 – Executive Summary & Observations

The evaluation of Adults – Ward 4C on level 4.

- To make sure the noise levels in the bedroom and en suite were compliant with SHTM03-01 which are bedroom 35dB(A) & en-suite 45dB(A)
- Noise levels and air volumes were measured to the various fan power levels on the recirculation unit in the en-suite (speed control setting level 1-6) Speed controller at setting 3 when all compliant and final values recorded within this report.

Observations

- All fabric issues have been reported to John Hetherton & Connor Stepney via email.
- Scrubber fan filter both F7 & H13 were changed prior to room verification for each room.
- Each room has their own separate condition which would refer to the chart below.

Values noted in colour relate to the table below		
Poor	Average	Good
Ventilation system should achieve not less than 80% of the design air change rate in accordance to the SHTM.	Air volumes and room pressure differentials approximate to the original design values.	Better than average.
Comments: Reference section 2.0 for more information.		

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Section 3.0 – Executive Summary & Observations

Fan Detail:

Adults Ward 4C – Renal – AHU Ref: 122AHU04 (S&E)				
Supply Fan Hz	Extract Fan Hz	Supply Pre-Filter DP	Supply Secondary Filter DP	Extract Filter DP
48.8	60.0	70Pa	50Pa	15Pa
Inlet Pressure	-111Pa	Discharge Pressure	+310Pa	

Adults Ward 4C – Renal – AHU Ref: 122AHU05 (S&E)				
Supply Fan Hz	Extract Fan Hz	Supply Pre-Filter DP	Supply Secondary Filter DP	Extract Filter DP
53.5	40.0	60Pa	50Pa	20Pa
Inlet Pressure	-223Pa	Discharge Pressure	+337Pa	

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Section 4.0 – Supply & Extract Airflow Rates & Air Change Rates & Schematic layout

Adults Ward 4C – Room 51 – Door Ref: RENW-138					
Room Reference	Design Volume l/s	Recorded Air Volume l/s	Room Volume m³	Recorded (AC/HR)	*SHTM ACRs (AC/HR)
Bedroom (Supply Chilled Beam)	+40	+45	46.0	3.52	*2.5 – 3.0
En-Suite (Extract)	-45	-22	13.68	5.78	3.0
Room Condition:	GOOD				
Comments: Room was occupied while carrying out annual verification and inspection.					

Adults Ward 4C – Room 51 – Door Ref: RENW-137				
Fan Speed Setting	En-Suite dB(A) SHTM 45dB(A)	Bedroom dB(A) SHTM 35dB(A)	Air Volume l/s	*Increased scrub value for the en-suite (ACRs)
1	-	-	-	-
2	-	-	-	-
3	43.3	34.9	-68	23.67
4	-	-	-	-
5	-	-	-	-
6	-	-	-	-
Comments: Speed for the en-suite is SHTM03-01 compliant – Speed is SHTM03-01 compliant for the bedroom noise levels.				

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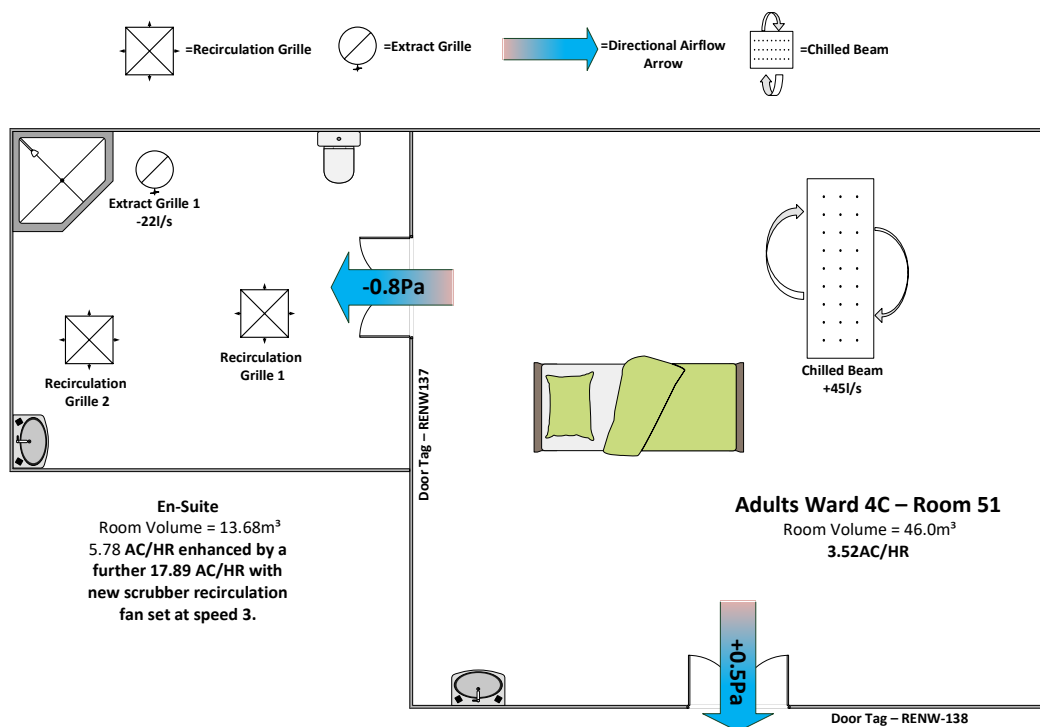
Section 4.0 – Supply & Extract Airflow Rates & Air Change Rates & Schematic layout

Room Pressure Differentials

Adults Ward 4C – Room 51 – Door Ref: RENW-130				
Room Reference	Target Room Pressure (Pa)	Recorded Room Pressures (Pa)	Magnehelic Gauge pre reading (Pa)	Magnehelic Gauge post reading (Pa)
Bedroom to Corridor	+ve	+0.5	n/a	n/a
Bedroom to En-Suite	-ve	-0.8	n/a	n/a
Comments: Room pressure is as requested for room type SHTM03-01 should be 0Pa or -ve to corridor.				

Temperature & Noise Levels

Room Reference	Door TAG Ref.:	Temperature Target 18 - 25°C	Noise Level Target <35dB(A)
Bedroom	RENW-138	23.3	34.8
En-Suite	RENW-137	23.2	43.3
Comments: Noise levels SHTM03-01 compliant set on speed 3 Camfil fan speed set at speed 3 when values recorded on above table. WC noise level target 45dB(A)			



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Section 4.0 – Supply & Extract Airflow Rates & Air Change Rates & Schematic layout

Adults Ward 4C – Room 52 – Door Ref: RENW-131					
Room Reference	Design Volume l/s	Recorded Air Volume l/s	Room Volume m³	Recorded (AC/HR)	*SHTM ACRs (AC/HR)
Bedroom (Supply Chilled Beam)	+40	+42	54.1	2.79	*2.5 – 3.0
En-Suite (Extract)	-45	-45	13.8	11.73	3.0
Room Condition:	GOOD				
Comments: * derogated ACRs for the bedroom – SHTM03-01 is 6 air change rates.					

Adults Ward 4C – Room 52 – Door Ref: RENW-132				
Fan Speed Setting	En-Suite dB(A) SHTM 45dB(A)	Bedroom dB(A) SHTM 35db(A)	Air Volume l/s	*Increased scrub value for the en-suite (ACRs)
1	-	-	-	-
2	-	-	-	-
3	44.5	34.8	-58	26.86
4	-	-	-	-
5	-	-	-	-
6	-	-	-	-
Comments: Speed for the en-suite is SHTM03-01 compliant – Speed is SHTM03-01 compliant for the bedroom noise levels.				

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Section 4.0 – Supply & Extract Airflow Rates & Air Change Rates & Schematic layout

Room Pressure Differentials

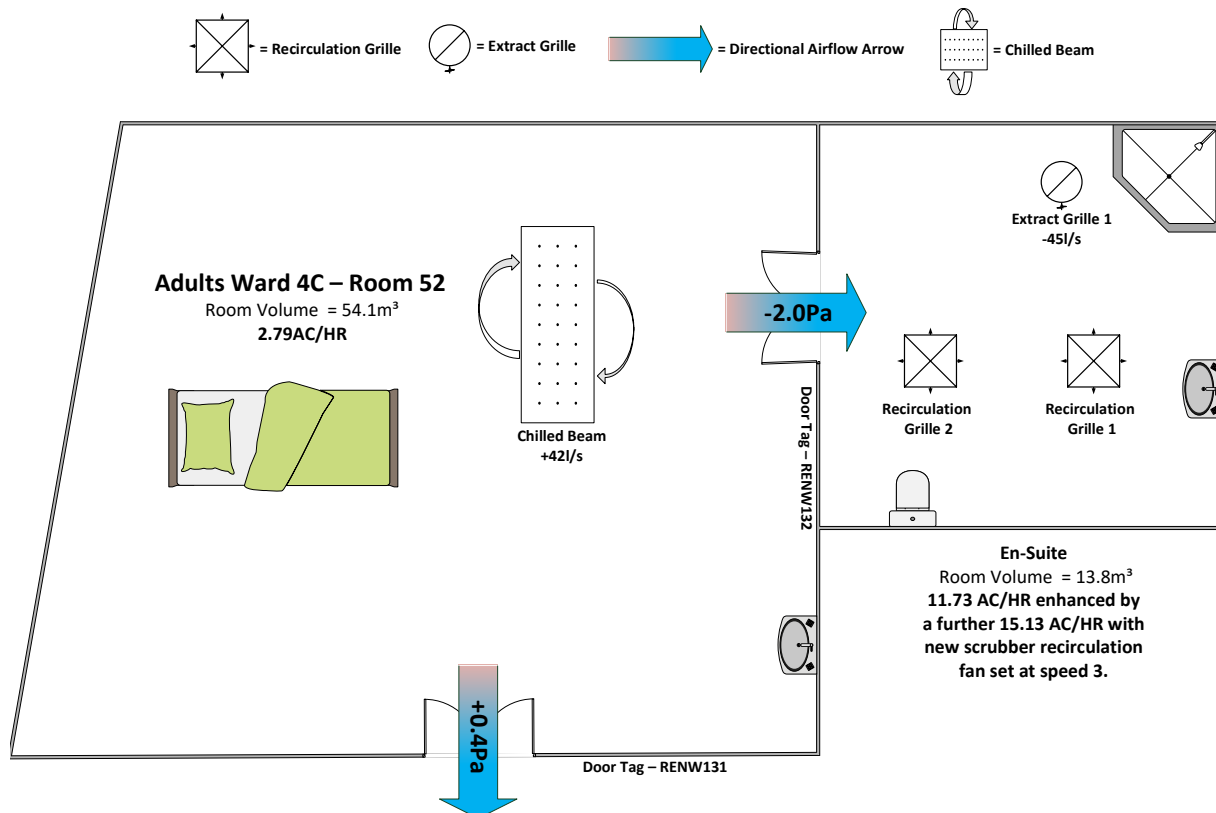
Adults Ward 4C – Room 52 – Door Ref: RENW-131				
Room Reference	Target Room Pressure (Pa)	Recorded Room Pressures (Pa)	Magnehelic Gauge pre reading (Pa)	Magnehelic Gauge post reading (Pa)
Bedroom to Corridor	+ve	+0.4	n/a	n/a
Bedroom to En-Suite	-ve	-2.0	n/a	n/a

Comments: Room pressure is as requested for room type SHTM03-01 should be 0Pa or -ve to corridor.

Temperature & Noise Levels

Room Reference	Door TAG Ref.:	Temperature Target 18 - 25°C	Noise Level Target <35dB(A)
Bedroom	RENW-131	23.5	34.8
En-Suite	RENW-132	23.8	44.5

Comments: Noise levels SHTM03-01 compliant set on speed 3 Camfil fan speed set at speed 3 when values recorded on above table. WC noise level target 45dB(A)



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Section 4.0 – Supply & Extract Airflow Rates & Air Change Rates & Schematic layout

Adults Ward 4C – Room 53 – Door Ref: RENW-134					
Room Reference	Design Volume l/s	Recorded Air Volume l/s	Room Volume m³	Recorded (AC/HR)	*SHTM ACRs (AC/HR)
Bedroom (Supply Chilled Beam)	+40	+41	46.25	3.19	*2.5 – 3.0
En-Suite (Extract)	-45	-47	16.36	10.34	3.0
Room Condition:	GOOD				
Comments: * derogated ACRs for the bedroom – SHTM03-01 is 6 air change rates.					

Adults Ward 4C – Room 53– Door Ref: RENW-133				
Fan Speed Setting	En-Suite dB(A) SHTM 45dB(A)	Bedroom dB(A) SHTM 35db(A)	Air Volume l/s	*Increased scrub value for the en-suite (ACRs)
1	-	-	-	-
2	-	-	-	-
3	44.7	34.7	-60	23.54
4	-	-	-	-
5	-	-	-	-
6	-	-	-	-
Comments: Speed for the en-suite is SHTM03-01 compliant – Speed is SHTM03-01 compliant for the bedroom noise levels.				

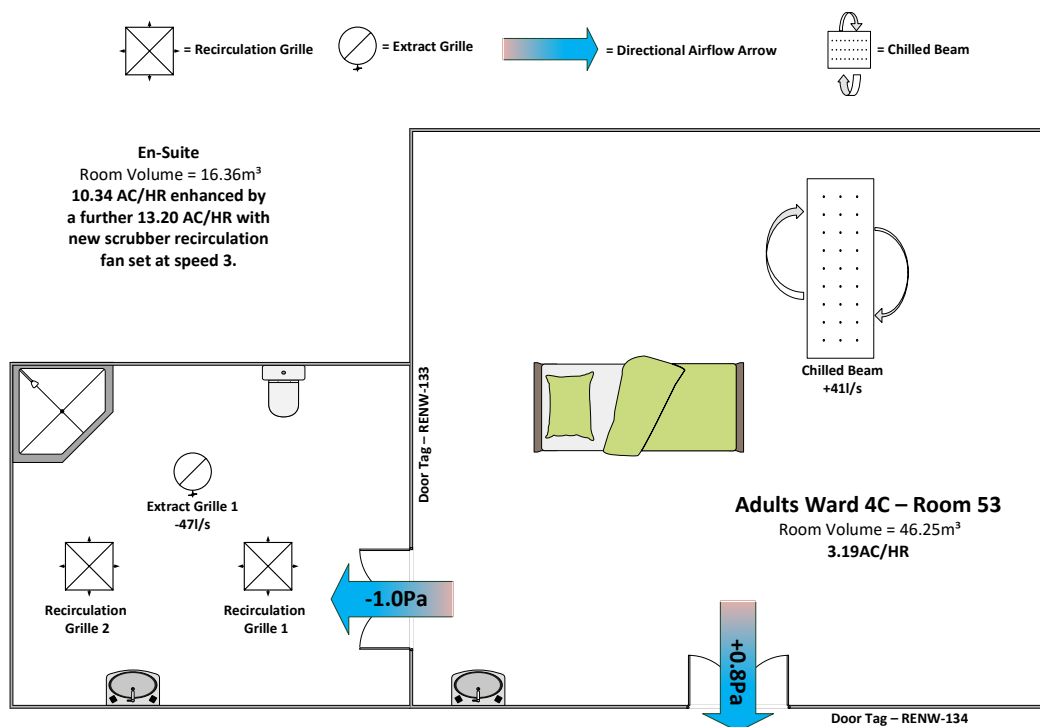
Section 4.0 – Supply & Extract Airflow Rates & Air Change Rates & Schematic layout

Room Pressure Differentials

Adults Ward 4C – Room 53 – Door Ref: RENW-134				
Room Reference	Target Room Pressure (Pa)	Recorded Room Pressures (Pa)	Magnehelic Gauge pre reading (Pa)	Magnehelic Gauge post reading (Pa)
Bedroom to Corridor	+ve	+0.8	n/a	n/a
Bedroom to En-Suite	-ve	-1.0	n/a	n/a
Comments: Room pressure is as requested for room type SHTM03-01 should be 0Pa or -ve to corridor.				

Temperature & Noise Levels

Room Reference	Door TAG Ref.:	Temperature Target 18 - 25°C	Noise Level Target <35dB(A)
Bedroom	RENW-134	24.3	34.7
En-Suite	RENW-133	24.1	44.7
Comments: Noise levels SHTM03-01 compliant set n speed 3 Camfil fan speed set at speed 3 when values recorded on above table. WC noise level target 45dB(A)			



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Section 4.0 – Supply & Extract Airflow Rates & Air Change Rates & Schematic layout

Adults Ward 4C – Room 54 – Door Ref: RENW-135					
Room Reference	Design Volume l/s	Recorded Air Volume l/s	Room Volume m³	Recorded (AC/HR)	*SHTM ACRs (AC/HR)
Bedroom (Supply Chilled Beam)	+40	+40	48.1	2.99	*2.5 – 3.0
En-Suite (Extract)	-45	-43	13.1	11.81	3.0
Room Condition:	GOOD				
Comments: * derogated ACRs for the bedroom – SHTM03-01 is 6 air change rates.					

Adults Ward 4C – Room 54 – Door Ref: RENW-136				
Fan Speed Setting	En-Suite dB(A) SHTM 45dB(A)	Bedroom dB(A) SHTM 35dB(A)	Air Volume l/s	*Increased scrub value for the en-suite (ACRs)
1	-	-	-	-
2	-	-	-	-
3	44.1	34.1	-59	28.02
4	-	-	-	-
5	-	-	-	-
6	-	-	-	-
Comments: Speed for the en-suite is SHTM03-01 compliant – Speed is SHTM03-01 compliant for the bedroom noise levels.				

Section 4.0 – Supply & Extract Airflow Rates & Air Change Rates & Schematic layout

Room Pressure Differentials

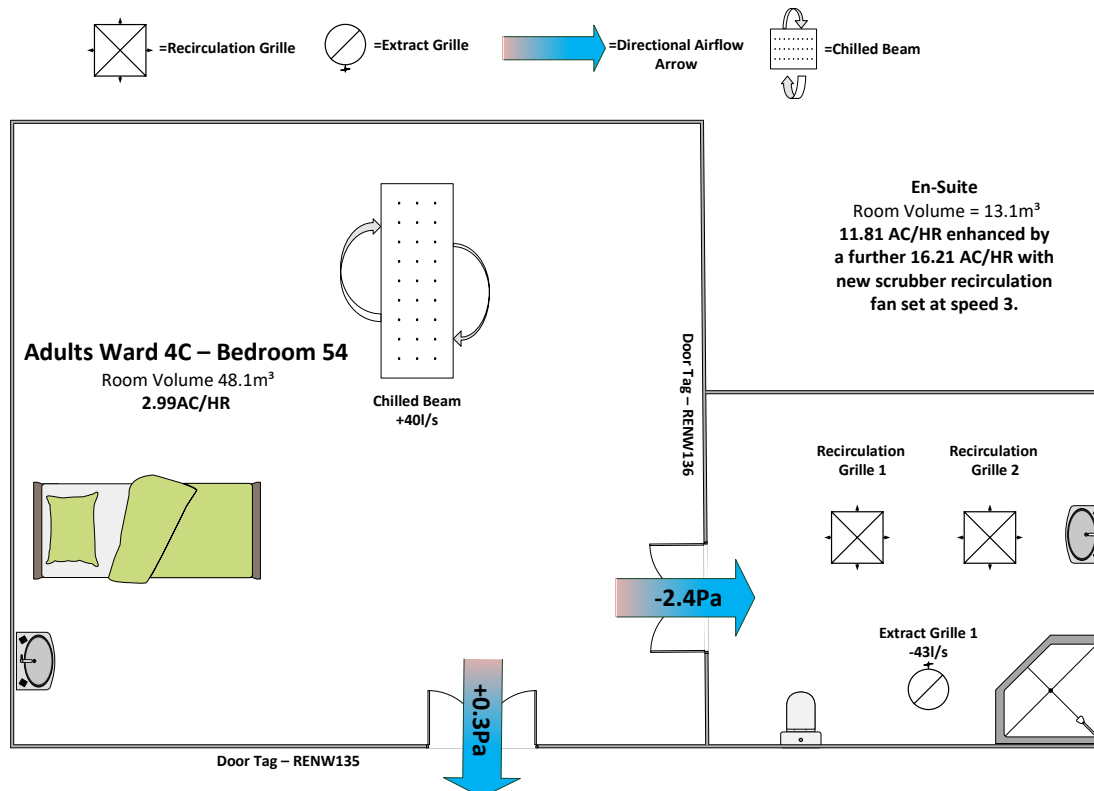
Adults Ward 4C – Room 54 – Door Ref: RENW-135				
Room Reference	Target Room Pressure (Pa)	Recorded Room Pressures (Pa)	Magnehelic Gauge pre reading (Pa)	Magnehelic Gauge post reading (Pa)
Bedroom to Corridor	+ve	+0.3	n/a	n/a
Bedroom to En-Suite	-ve	-2.4	n/a	n/a

Comments: Room pressure is as requested for room type SHTM03-01 should be 0Pa or -ve to corridor.

Temperature & Noise Levels

Room Reference	Door TAG Ref.:	Temperature Target 18 - 25°C	Noise Level Target <35dB(A)
Bedroom	RENW-135	24.1	34.1
En-Suite	RENW-136	24.1	44.1

Comments: Noise levels SHTM03-01 compliant set on speed 3 Camfil fan speed set at speed 3 when values recorded on above table. WC noise level target 45dB(A)



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Section 4.0 – Supply & Extract Airflow Rates & Air Change Rates & Schematic layout

Adults Ward 4C – Room 55 – Door Ref: RENW-138					
Room Reference	Design Volume l/s	Recorded Air Volume l/s	Room Volume m³	Recorded (AC/HR)	*SHTM ACRs (AC/HR)
Bedroom (Supply Chilled Beam)	+40	+40	48.09	2.99	*2.5 – 3.0
En-Suite (Extract)	-45	-45	14.08	11.50	3.0
Room Condition:	GOOD				
Comments: * derogated ACRs for the bedroom – SHTM03-01 is 6 air change rates.					

Adults Ward 4C – Room 55 – Door Ref: RENW-137				
Fan Speed Setting	En-Suite dB(A) SHTM 45dB(A)	Bedroom dB(A) SHTM 35dB(A)	Air Volume l/s	*Increased scrub value for the en-suite (ACRs)
1	-	-	-	-
2	-	-	-	-
3	44.9	37.4	-62	27.35
4	-	-	-	-
5	-	-	-	-
6	-	-	-	-
Comments: Speed for the en-suite is SHTM03-01 compliant – Speed is SHTM03-01 compliant for the bedroom noise levels.				

Section 4.0 – Supply & Extract Airflow Rates & Air Change Rates & Schematic layout

Room Pressure Differentials

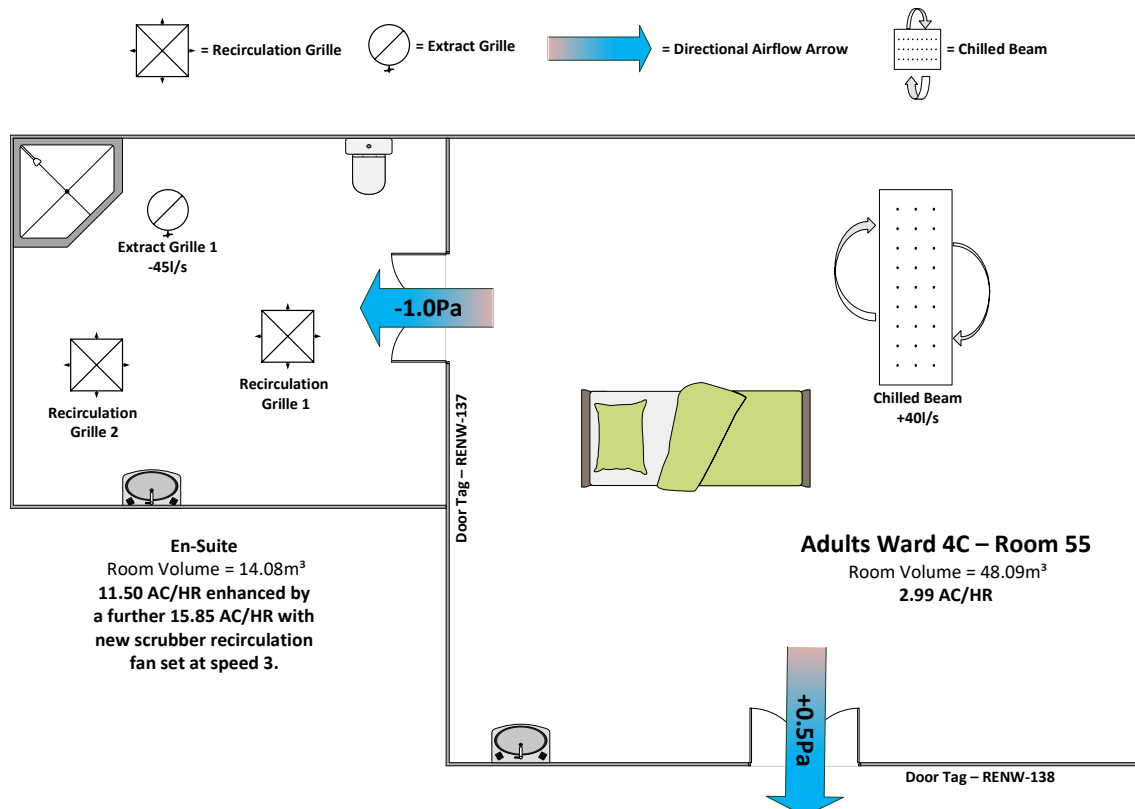
Adults Ward 4C – Room 55 – Door Ref: RENW-138				
Room Reference	Target Room Pressure (Pa)	Recorded Room Pressures (Pa)	Magnehelic Gauge pre reading (Pa)	Magnehelic Gauge post reading (Pa)
Bedroom to Corridor	+ve	+0.5	n/a	n/a
Bedroom to En-Suite	-ve	-1.0	n/a	n/a

Comments: Room pressure is as requested for room type SHTM03-01 should be 0Pa or -ve to corridor.

Temperature & Noise Levels

Room Reference	Door TAG Ref.:	Temperature Target 18 - 25°C	Noise Level Target <35dB(A)
Bedroom	RENW-138	24.9	34.7
En-Suite	RENW-137	24.7	44.9

Comments: Noise levels SHTM03-01 compliant set n speed 3 Camfil fan speed set at speed 3 when values recorded on above table. WC noise level target 45dB(A)



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Adults Ward 4C – Room 56 – Door Ref: RENW-140					
Room Reference	Design Volume l/s	Recorded Air Volume l/s	Room Volume m³	Recorded (AC/HR)	*SHTM ACRs (AC/HR)
Bedroom (Supply Chilled Beam)	+40	+40	46.59	3.09	*2.5 – 3.0
En-Suite (Extract)	-45	-44	15.24	10.39	3.0
Room Condition:	Good				
Comments: * derogated ACRs for the bedroom – SHTM03-01 is 6 air change rates.					

Adults Ward 4C – Room 56 – Door Ref: RENW-140				
Fan Speed Setting	En-Suite dB(A) SHTM 45dB(A)	Bedroom dB(A) SHTM 35dB(A)	Air Volume l/s	*Increased scrub value for the en-suite (ACRs)
1	-	-	-	-
2	-	-	-	-
3	44.8	34.8	-55	23.38
4	-	-	-	-
5	-	-	-	-
6	-	-	-	-
Comments: Speed for the en-suite is SHTM03-01 compliant – Speed is SHTM03-01 compliant for the bedroom noise levels.				

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Section 4.0 – Supply & Extract Airflow Rates & Air Change Rates & Schematic layout

Room Pressure Differentials

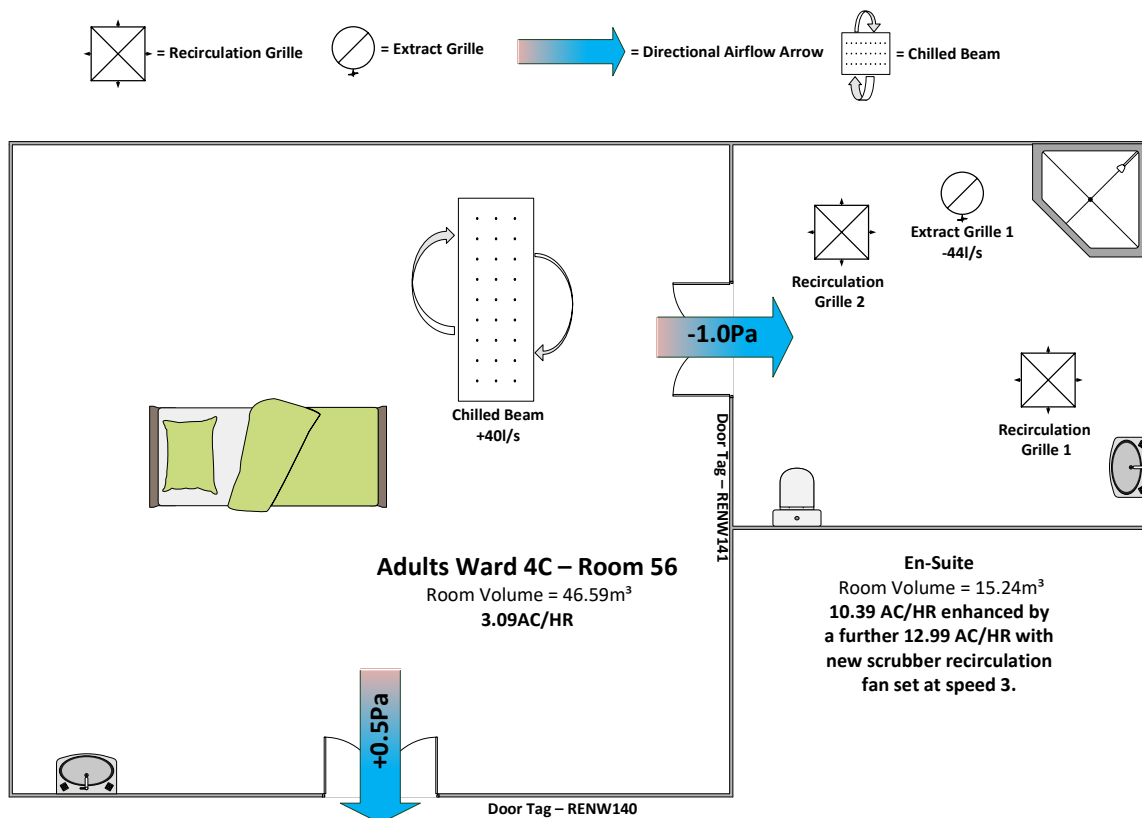
Adults Ward 4C – Room 56 – Door Ref: RENW-140				
Room Reference	Target Room Pressure (Pa)	Recorded Room Pressures (Pa)	Magnehelic Gauge pre reading (Pa)	Magnehelic Gauge post reading (Pa)
Bedroom to Corridor	+ve	+0.5	n/a	n/a
Bedroom to En-Suite	-ve	-1.0	n/a	n/a

Comments: Room pressure is as requested for room type SHTM03-01 should be 0Pa or -ve to corridor.

Temperature & Noise Levels

Room Reference	Door TAG Ref.:	Temperature Target 18 - 25°C	Noise Level Target <35dB(A)
Bedroom	RENW-140	24.9	34.8
En-Suite	RENW-141	24.7	44.8

Comments: Noise levels SHTM03-01 compliant set n speed 3 Camfil fan speed set at speed 3 when values recorded on above table. WC noise level target 45dB(A)



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Section 4.0 – Supply & Extract Airflow Rates & Air Change Rates & Schematic layout

Adults Ward 4C – Room 57 – Door Ref: RENW-143					
Room Reference	Design Volume l/s	Recorded Air Volume l/s	Room Volume m³	Recorded (AC/HR)	*SHTM ACRs (AC/HR)
Bedroom (Supply Chilled Beam)	+40	+41	48.4	3.04	*2.5 – 3.0
En-Suite (Extract)	-45	-39	13.4	10.47	3.0
Room Condition:	GOOD				
Comments: * derogated ACRs for the bedroom – SHTM03-01 is 6 air change rates.					

Adults Ward 4C – Room 57 – Door Ref: RENW-142				
Fan Speed Setting	En-Suite dB(A) SHTM 45dB(A)	Bedroom dB(A) SHTM 35db(A)	Air Volume l/s	*Increased scrub value for the en-suite (ACRs)
1	-	-	-	-
2	-	-	-	-
3	44.5	34.8	-53	24.7
4	-	-	-	-
5	-	-	-	-
6	-	-	-	-
Comments: Speed for the en-suite is SHTM03-01 compliant – Speed is SHTM03-01 compliant for the bedroom noise levels.				

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Section 4.0 – Supply & Extract Airflow Rates & Air Change Rates & Schematic layout

Room Pressure Differentials

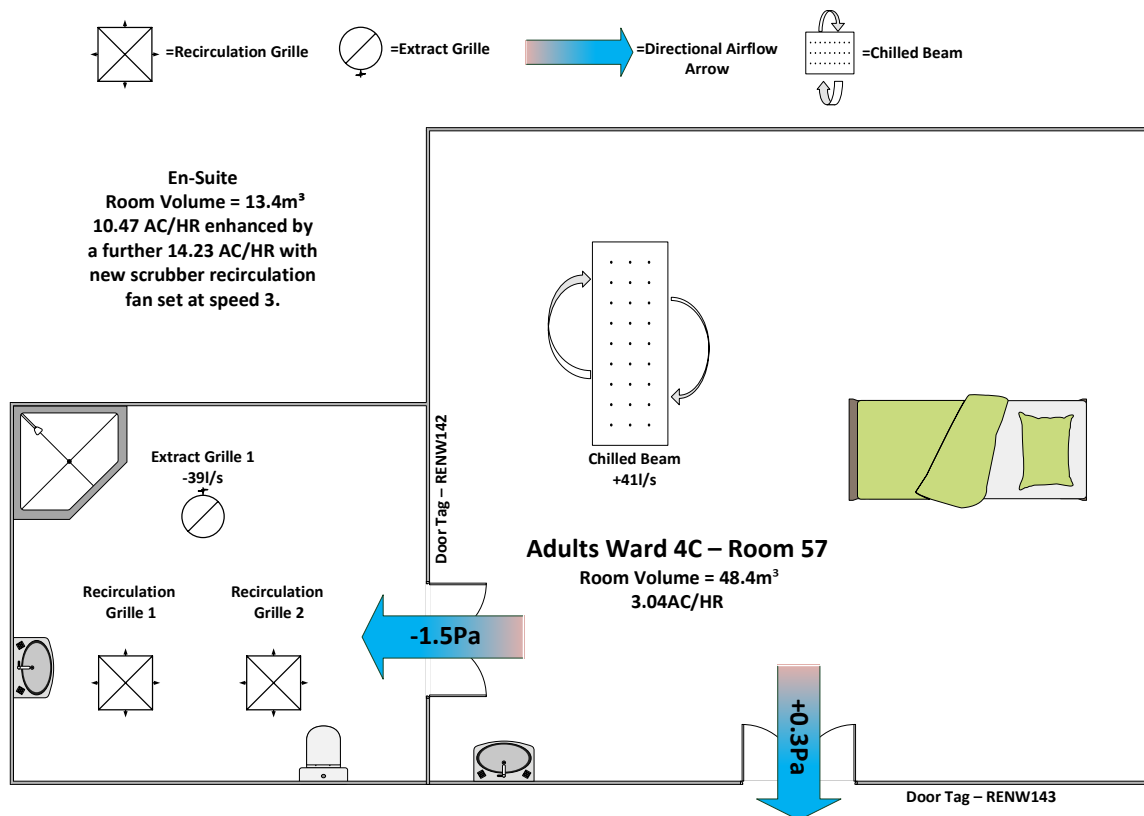
Adults Ward 4C – Room 57 – Door Ref: RENW-143				
Room Reference	Target Room Pressure (Pa)	Recorded Room Pressures (Pa)	Magnehelic Gauge pre reading (Pa)	Magnehelic Gauge post reading (Pa)
Bedroom to Corridor	+ve	+0.3	n/a	n/a
Bedroom to En-Suite	-ve	-1.5	n/a	n/a

Comments: Room pressure is as requested for room type SHTM03-01 should be 0Pa or -ve to corridor.

Temperature & Noise Levels

Room Reference	Door TAG Ref.:	Temperature Target 18 - 25°C	Noise Level Target <35dB(A)
Bedroom	RENW-143	21.9	34.8
En-Suite	RENW-142	22.0	44.5

Comments: Noise levels SHTM03-01 compliant set on speed 3 Camfil fan speed set at speed 3 when values recorded on above table. WC noise level target 45dB(A)



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Section 4.0 – Supply & Extract Airflow Rates & Air Change Rates & Schematic layout

Adults Ward 4C – Room 58 – Door Ref: RENW-144					
Room Reference	Design Volume l/s	Recorded Air Volume l/s	Room Volume m³	Recorded (AC/HR)	*SHTM ACRs (AC/HR)
Bedroom (Supply Chilled Beam)	+40	+42	49.07	3.08	*2.5 – 3.0
En-Suite (Extract)	-45	-47	13.53	12.50	3.0
Room Condition:	GOOD				
Comments: * derogated ACRs for the bedroom – SHTM03-01 is 6.0 air change rates.					

Adults Ward 4C – Room 58– Door Ref: RENW-145				
Fan Speed Setting	En-Suite dB(A) SHTM 45dB(A)	Bedroom dB(A) SHTM 35dBA)	Air Volume l/s	*Increased scrub value for the en-suite (ACRs)
1	-	-	-	-
2	-	-	-	-
3	44.4	34.8	63	29.26
4	-	-	-	-
5	-	-	-	-
6	-	-	-	-
Comments: Speed for the en-suite is SHTM03-01 compliant – Speed is SHTM03-01 compliant for the bedroom noise levels.				

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Room Pressure Differentials

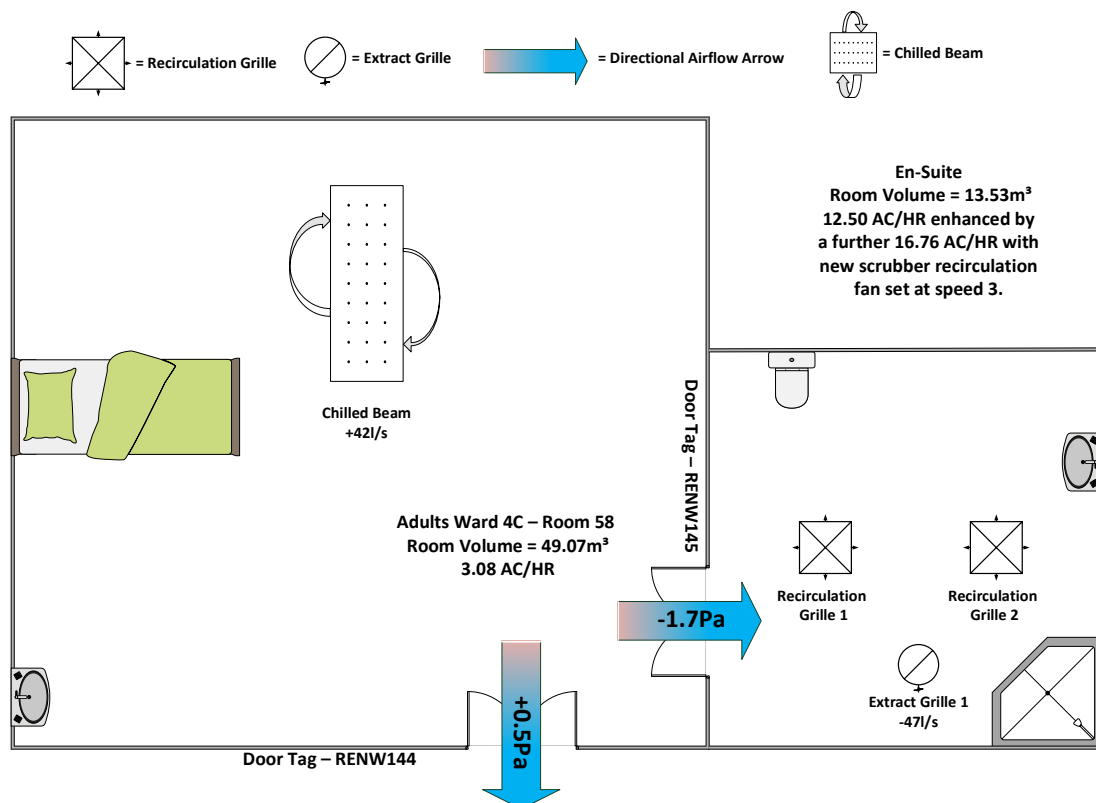
Adults Ward 4C – Room 58 – Door Ref: RENW-144				
Room Reference	Target Room Pressure (Pa)	Recorded Room Pressures (Pa)	Magnehelic Gauge pre reading (Pa)	Magnehelic Gauge post reading (Pa)
Bedroom to Corridor	+ve	+0.5	n/a	n/a
Bedroom to En-Suite	-ve	-1.7	n/a	n/a

Comments: Room pressure is as requested for room type SHTM03-01 should be 0Pa or -ve to corridor.

Temperature & Noise Levels

Room Reference	Door TAG Ref.:	Temperature Target 18 - 25°C	Noise Level Target <35dB(A)
Bedroom	RENW-144	24.9	34.8
En-Suite	RENW-145	24.7	44.4

Comments: Noise levels SHTM03-01 compliant set n speed 3 Camfil fan speed set at speed 3 when values recorded on above table. WC noise level target 45dB(A)



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Adults Ward 4C – Room 59 – Door Ref: RENW-147					
Room Reference	Design Volume l/s	Recorded Air Volume l/s	Room Volume m³	Recorded (AC/HR)	*SHTM ACRs (AC/HR)
Bedroom (Supply Chilled Beam)	+40	+41	48.3	2.98	*2.5 – 3.0
En-Suite (Extract)	-45	-37	13.8	9.65	3.0
Room Condition:	GOOD				
Comments: * derogated ACRs for the bedroom – SHTM03-01 is 6 air change rates.					

Adults Ward 4C – Room 59 – Door Ref: RENW-146				
Fan Speed Setting	En-Suite dB(A) SHTM 45dB(A)	Bedroom dB(A) SHTM 35db(A)	Air Volume l/s	*Increased scrub value for the en-suite (ACRs)
1	-	-	-	-
2	-	-	-	-
3	44.1	34.7	-60	25.3
4	-	-	-	-
5	-	-	-	-
6	-	-	-	-
Comments: Speed for the en-suite is SHTM03-01 compliant – Speed is SHTM03-01 compliant for the bedroom noise levels.				

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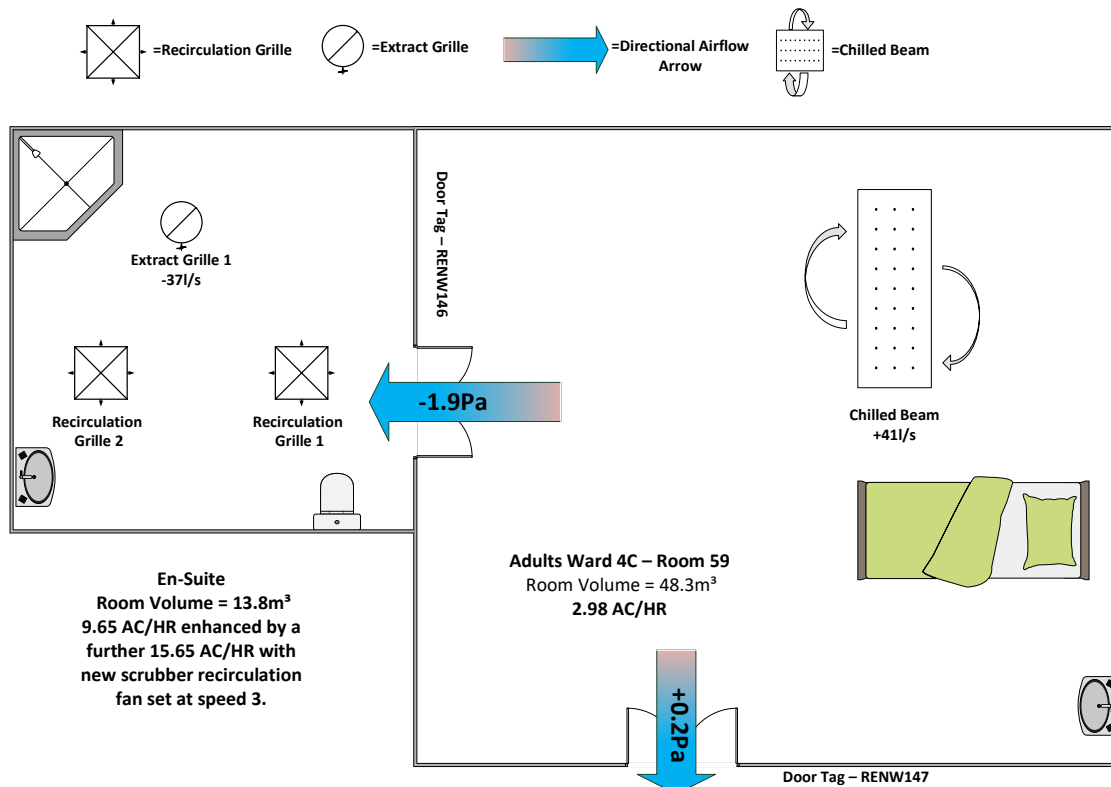
Section 4.0 – Supply & Extract Airflow Rates & Air Change Rates & Schematic layout

Room Pressure Differentials

Adults Ward 4C – Room 59 – Door Ref: RENW-147				
Room Reference	Target Room Pressure (Pa)	Recorded Room Pressures (Pa)	Magnehelic Gauge pre reading (Pa)	Magnehelic Gauge post reading (Pa)
Bedroom to Corridor	+ve	+0.2	n/a	n/a
Bedroom to En-Suite	-ve	-1.9	n/a	n/a
Comments: Room pressure is as requested for room type SHTM03-01 should be 0Pa or -ve to corridor.				

Temperature & Noise Levels

Room Reference	Door TAG Ref.:	Temperature Target 18 - 25°C	Noise Level Target <35dB(A)
Bedroom	RENW-147	21.7	34.7
En-Suite	RENW-146	22.1	44.1
Comments: Noise levels SHTM03-01 compliant set on speed 3 Camfil fan speed set at speed 3 when values recorded on above table. WC noise level target 45dB(A)			



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Adults Ward 4C – Room 60 – Door Ref: RENW-149					
Room Reference	Design Volume l/s	Recorded Air Volume l/s	Room Volume m³	Recorded (AC/HR)	*SHTM ACRs (AC/HR)
Bedroom (Supply Chilled Beam)	+40	+41	48.55	3.04	*2.5 – 3.0
En-Suite (Extract)	-45	-39	13.56	10.35	3.0
Room Condition:	GOOD				
Comments: * derogated ACRs for the bedroom – SHTM03-01 is 6.0 air change rates.					

Adults Ward 4C – Room 60 – Door Ref: RENW-150				
Fan Speed Setting	En-Suite dB(A) SHTM 45dB(A)	Bedroom dB(A) SHTM 35db(A)	Air Volume l/s	*Increased scrub value for the en-suite (ACRs)
1	-	-	-	-
2	-	-	-	-
3	44.1	34.7	-59	26.01
4	-	-	-	-
5	-	-	-	-
6	-	-	-	-
Comments: Speed for the en-suite is SHTM03-01 compliant – Speed is SHTM03-01 compliant for the bedroom noise levels.				

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Section 4.0 – Supply & Extract Airflow Rates & Air Change Rates & Schematic layout

Room Pressure Differentials

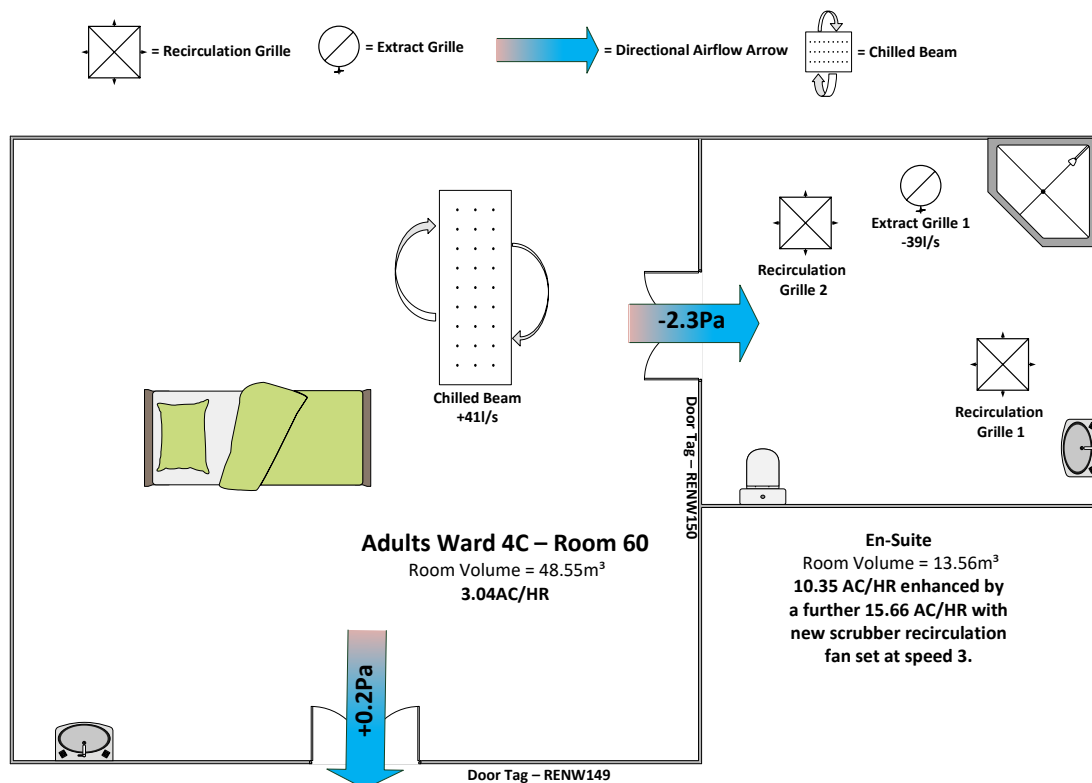
Adults Ward 4C – Room 60 – Door Ref: RENW-149				
Room Reference	Target Room Pressure (Pa)	Recorded Room Pressures (Pa)	Magnehelic Gauge pre reading (Pa)	Magnehelic Gauge post reading (Pa)
Bedroom to Corridor	+ve	+0.2	n/a	n/a
Bedroom to En-Suite	-ve	-2.3	n/a	n/a

Comments: Room pressure is as requested for room type SHTM03-01 should be 0Pa or -ve to corridor.

Temperature & Noise Levels

Room Reference	Door TAG Ref.:	Temperature Target 18 - 25°C	Noise Level Target <35dB(A)
Bedroom	RENW-149	24.7	34.7
En-Suite	RENW-150	24.1	44.1

Comments: Noise levels SHTM03-01 compliant set n speed 3 Camfil fan speed set at speed 3 when values recorded on above table. WC noise level target 45dB(A)



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Section 4.0 – Supply & Extract Airflow Rates & Air Change Rates & Schematic layout

Adults Ward 4C – Room 61 – Door Ref: RENW-152					
Room Reference	Design Volume l/s	Recorded Air Volume l/s	Room Volume m³	Recorded (AC/HR)	*SHTM ACRs (AC/HR)
Bedroom (Supply Chilled Beam)	+40	+42	48.9	3.09	*2.5 – 3.0
En-Suite (Extract)	-45	-41	13.4	11.01	3.0
Room Condition:	GOOD				
Comments: * derogated ACRs for the bedroom – SHTM03-01 is 6.0 air change rates.					

Adults Ward 4C – Room 61 – Door Ref: RENW-151				
Fan Speed Setting	En-Suite dB(A) SHTM 45dB(A)	Bedroom dB(A) SHTM 35db(A)	Air Volume l/s	*Increased scrub value for the en-suite (ACRs)
1	-	-	-	-
2	-	-	-	-
3	44.3	34.6	-63	27.93
4	-	-	-	-
5	-	-	-	-
6	-	-	-	-
Comments: Speed for the en-suite is SHTM03-01 compliant – Speed is SHTM03-01 compliant for the bedroom noise levels.				

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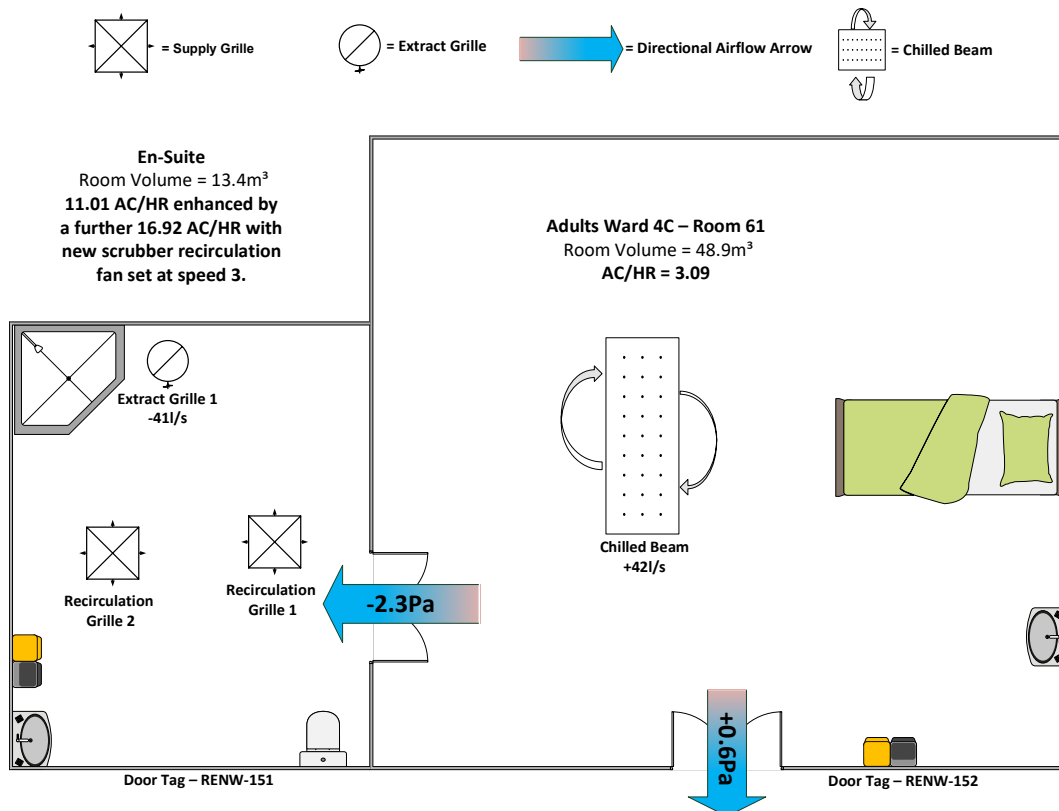
Section 4.0 – Supply & Extract Airflow Rates & Air Change Rates & Schematic layout

Room Pressure Differentials

Adults Ward 4C – Room 61 – Door Ref: RENW-152				
Room Reference	Target Room Pressure (Pa)	Recorded Room Pressures (Pa)	Magnehelic Gauge pre reading (Pa)	Magnehelic Gauge post reading (Pa)
Bedroom to Corridor	+ve	+0.6	n/a	n/a
Bedroom to En-Suite	-ve	-2.3	n/a	n/a
Comments: Room pressure is as requested for room type SHTM03-01 should be 0Pa or -ve to corridor.				

Temperature & Noise Levels

Room Reference	Door TAG Ref.:	Temperature Target 18 - 25°C	Noise Level Target <35dB(A)
Bedroom	RENW-152	23.8	34.6
En-Suite	RENW-151	23.4	44.3
Comments: Noise levels SHTM03-01 compliant set n speed 3 Camfil fan speed set at speed 3 when values recorded on above table. WC noise level target 45dB(A)			



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Section 4.0 – Supply & Extract Airflow Rates & Air Change Rates & Schematic layout

Adults Ward 4C – Room 62 – Door Ref: RENW-154					
Room Reference	Design Volume l/s	Recorded Air Volume l/s	Room Volume m³	Recorded (AC/HR)	*SHTM ACRs (AC/HR)
Bedroom (Supply Chilled Beam)	+40	+41	53.04	2.78	*2.5 – 3.0
En-Suite (Extract)	-45	-55	17.91	11.06	3.0
Room Condition:	GOOD				
Comments: Room was occupied while carrying out annual verification and inspection.					

Adults Ward 4C – Room 62 – Door Ref: RENW-153				
Fan Speed Setting	En-Suite dB(A) SHTM 45dB(A)	Bedroom dB(A) SHTM 35dB(A)	Air Volume l/s	*Increased scrub value for the en-suite (ACRs)
1	-	-	-	-
2	-	-	-	-
3	43.3	34.9	-62	23.52
4	-	-	-	-
5	-	-	-	-
6	-	-	-	-
Comments: Speed for the en-suite is SHTM03-01 compliant – Speed is SHTM03-01 compliant for the bedroom noise levels.				

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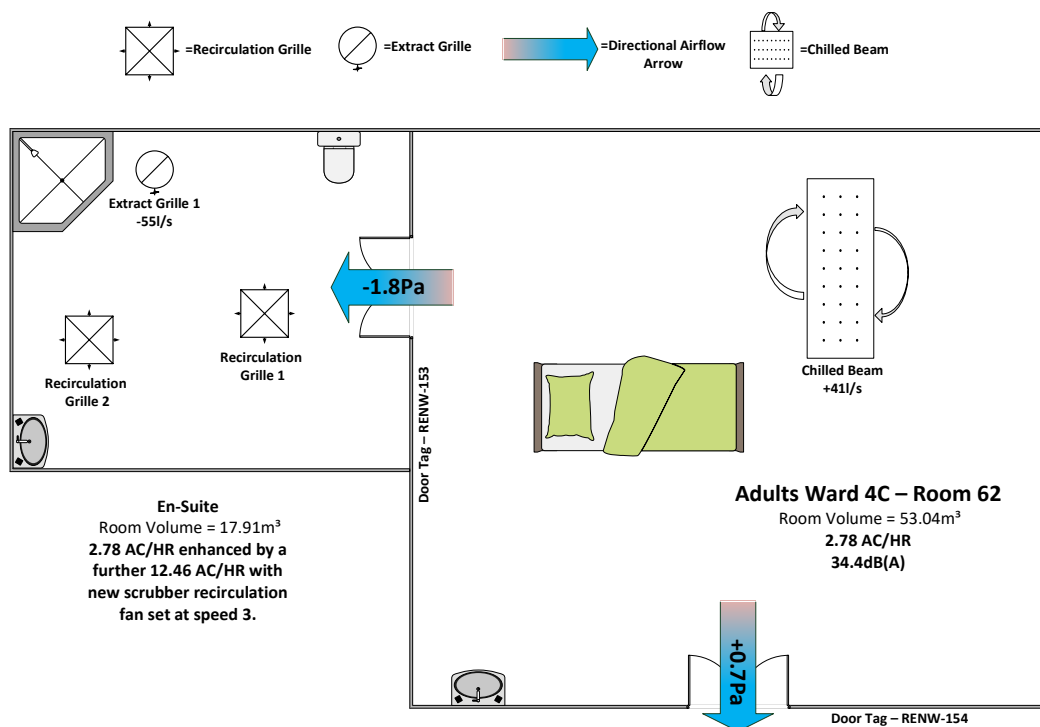
Section 4.0 – Supply & Extract Airflow Rates & Air Change Rates & Schematic layout

Room Pressure Differentials

Adults Ward 4C – Room 62 – Door Ref: RENW-154				
Room Reference	Target Room Pressure (Pa)	Recorded Room Pressures (Pa)	Magnehelic Gauge pre reading (Pa)	Magnehelic Gauge post reading (Pa)
Bedroom to Corridor	+ve	+0.7	n/a	n/a
Bedroom to En-Suite	-ve	-1.8	n/a	n/a
Comments: Room pressure is as requested for room type SHTM03-01 should be 0Pa or -ve to corridor.				

Temperature & Noise Levels

Room Reference	Door TAG Ref.:	Temperature Target 18 - 25°C	Noise Level Target <35dB(A)
Bedroom	RENW-154	23.3	34.4
En-Suite	RENW-153	23.4	43.2
Comments: Noise levels SHTM03-01 compliant set on speed 3 Camfil fan speed set at speed 3 when values recorded on above table. WC noise level target 45dB(A)			



Section 4.0 – Supply & Extract Airflow Rates & Air Change Rates & Schematic layout

Adults Ward 4C – Room 63 – Door Ref: RENW-155					
Room Reference	Design Volume l/s	Recorded Air Volume l/s	Room Volume m³	Recorded (AC/HR)	*SHTM ACRs (AC/HR)
Bedroom (Supply Chilled Beam)	+40	+40	47.1	3.05	*2.5 – 3.0
En-Suite (Extract)	-45	-45	16.8	9.64	3.0
Room Condition:	GOOD				
Comments: * derogated ACRs for the bedroom – SHTM03-01 is 6 air change rates.					

Adults Ward 4C – Room 63 – Door Ref: RENW-156				
Fan Speed Setting	En-Suite dB(A) SHTM 45dB(A)	Bedroom dB(A) SHTM 35dB(A)	Air Volume l/s	*Increased scrub value for the en-suite (ACRs)
1	-	-	-	-
2	-	-	-	-
3	44.4	34.1	-55	21.42
4	-	-	-	-
5	-	-	-	-
6	-	-	-	-
Comments: Speed for the en-suite is SHTM03-01 compliant – Speed is SHTM03-01 compliant for the bedroom noise levels.				

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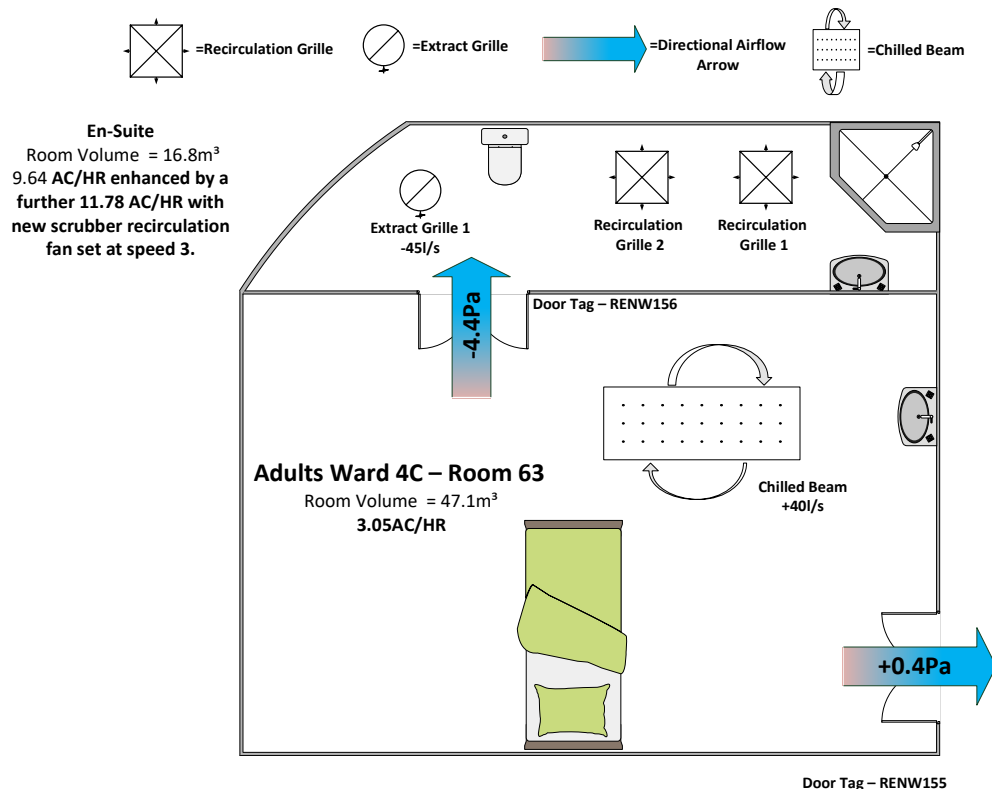
Section 4.0 – Supply & Extract Airflow Rates & Air Change Rates & Schematic layout

Room Pressure Differentials

Adults Ward 4C – Room 63 – Door Ref: RENW-155				
Room Reference	Target Room Pressure (Pa)	Recorded Room Pressures (Pa)	Magnehelic Gauge pre reading (Pa)	Magnehelic Gauge post reading (Pa)
Bedroom to Corridor	+ve	+0.4	n/a	n/a
Bedroom to En-Suite	-ve	-4.4	n/a	n/a
Comments: Room pressure is as requested for room type SHTM03-01 should be 0Pa or -ve to corridor.				

Temperature & Noise Levels

Room Reference	Door TAG Ref.:	Temperature Target 18 - 25°C	Noise Level Target <35dB(A)
Bedroom	RENW-155	21.9	34.1
En-Suite	RENW-156	21.9	44.4
Comments: Noise levels SHTM03-01 compliant set on speed 3 Camfil fan speed set at speed 3 when values recorded on above table. WC noise level target 45dB(A)			



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Adults Ward 4C – Room 64 – Door Ref: RENW-157					
Room Reference	Design Volume l/s	Recorded Air Volume l/s	Room Volume m³	Recorded (AC/HR)	*SHTM ACRs (AC/HR)
Bedroom (Supply Chilled Beam)	+40	+39	46.42	3.02	*2.5 – 3.0
En-Suite (Extract)	-45	-48	13.96	12.37	3.0
Room Condition:	GOOD				
Comments: Room was occupied while carrying out annual verification and inspection.					

Adults Ward 4C – Room 64– Door Ref: RENW-158				
Fan Speed Setting	En-Suite dB(A) SHTM 45dB(A)	Bedroom dB(A) SHTM 35dB(A)	Air Volume l/s	*Increased scrub value for the en-suite (ACRs)
1	-	-	-	-
2	-	-	-	-
3	43.6	34.5	44	23.71
4	-	-	-	-
5	-	-	-	-
6	-	-	-	-
Comments: Speed for the en-suite is SHTM03-01 compliant – Speed is SHTM03-01 compliant for the bedroom noise levels.				

Section 4.0 – Supply & Extract Airflow Rates & Air Change Rates & Schematic layout

Room Pressure Differentials

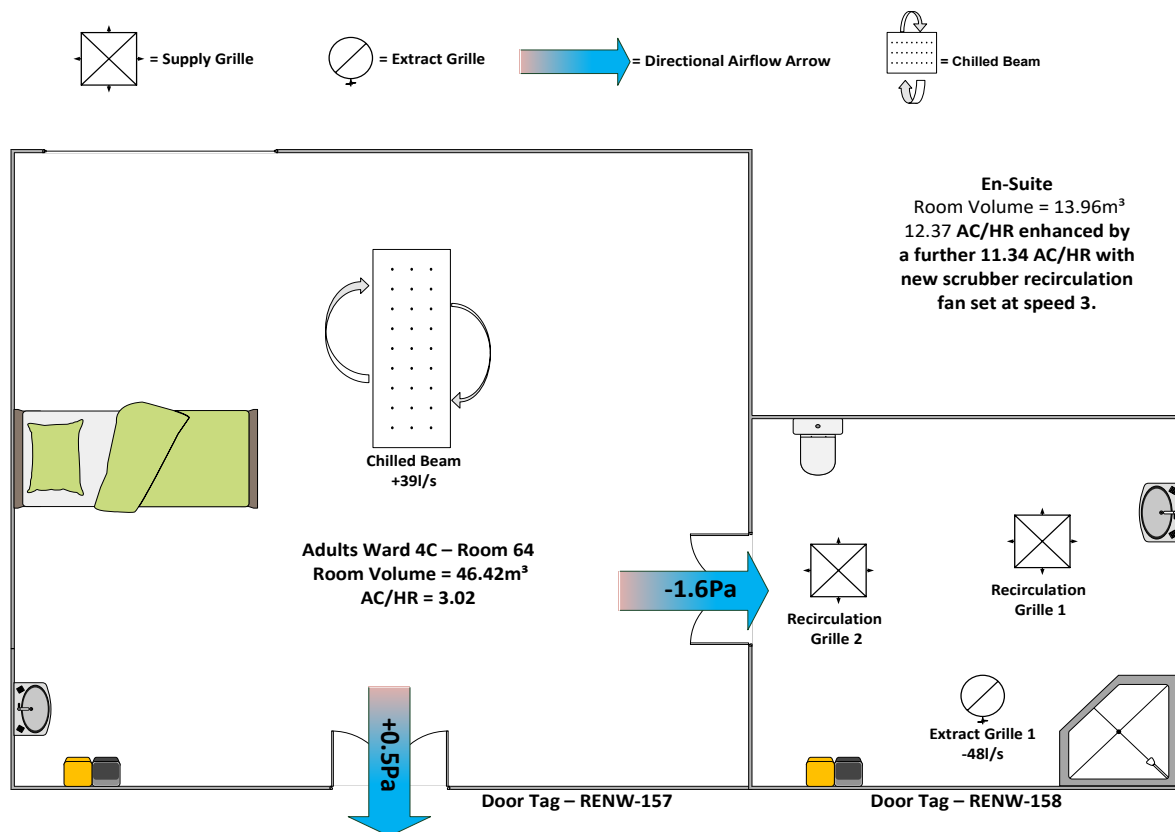
Adults Ward 4C – Room 64 – Door Ref: RENW-157				
Room Reference	Target Room Pressure (Pa)	Recorded Room Pressures (Pa)	Magnehelic Gauge pre reading (Pa)	Magnehelic Gauge post reading (Pa)
Bedroom to Corridor	+ve	+0.5	n/a	n/a
Bedroom to En-Suite	-ve	-1.6	n/a	n/a

Comments: Room pressure is as requested for room type SHTM03-01 should be 0Pa or -ve to corridor.

Temperature & Noise Levels

Room Reference	Door TAG Ref.:	Temperature Target 18 - 25°C	Noise Level Target <35dB(A)
Bedroom	RENW-157	23.2	34.5
En-Suite	RENW-158	23.1	43.6

Comments: Noise levels SHTM03-01 compliant set on speed 3 Camfil fan speed set at speed 3 when values recorded on above table. WC noise level target 45dB(A)



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Adults Ward 4C – Room 65 – Door Ref: RENW-160					
Room Reference	Design Volume l/s	Recorded Air Volume l/s	Room Volume m³	Recorded (AC/HR)	*SHTM ACRs (AC/HR)
Bedroom (Supply Chilled Beam)	+40	+39	48.4	2.90	*2.5 – 3.0
En-Suite (Extract)	-45	-42	13.6	11.11	3.0
Room Condition:	GOOD				
Comments: * derogated ACRs for the bedroom – SHTM03-01 is 6 air change rates.					

Adults Ward 4C – Room 65 – Door Ref: RENW-159				
Fan Speed Setting	En-Suite dB(A) SHTM 45dB(A)	Bedroom dB(A) SHTM 35db(A)	Air Volume l/s	*Increased scrub value for the en-suite (ACRs)
1	-	-	-	-
2	-	-	-	-
3	44.6	34.8	-57	26.19
4	-	-	-	-
5	-	-	-	-
6	-	-	-	-
Comments: Speed for the en-suite is SHTM03-01 compliant – Speed is SHTM03-01 compliant for the bedroom noise levels.				

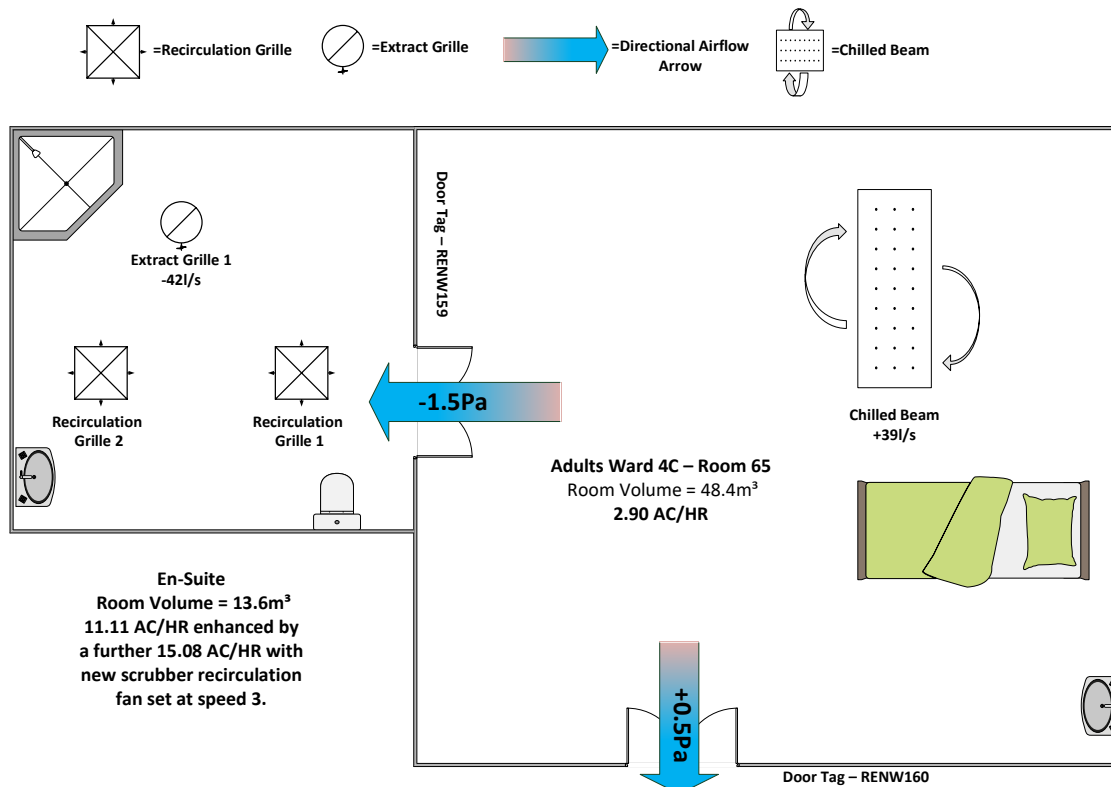
Section 4.0 – Supply & Extract Airflow Rates & Air Change Rates & Schematic layout

Room Pressure Differentials

Adults Ward 4C – Room 65 – Door Ref: RENW-160				
Room Reference	Target Room Pressure (Pa)	Recorded Room Pressures (Pa)	Magnehelic Gauge pre reading (Pa)	Magnehelic Gauge post reading (Pa)
Bedroom to Corridor	+ve	+0.4	n/a	n/a
Bedroom to En-Suite	-ve	-1.5	n/a	n/a
Comments: Room pressure is as requested for room type SHTM03-01 should be 0Pa or -ve to corridor.				

Temperature & Noise Levels

Room Reference	Door TAG Ref.:	Temperature Target 18 - 25°C	Noise Level Target <35dB(A)
Bedroom	RENW-160	22.5	34.8
En-Suite	RENW-159	22.4	44.6
Comments: Noise levels SHTM03-01 compliant set on speed 3 Camfil fan speed set at speed 3 when values recorded on above table. WC noise level target 45db(A)			



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Section 4.0 – Supply & Extract Airflow Rates & Air Change Rates & Schematic layout

Adults Ward 4C – Room 66 – Door Ref: RENW-162					
Room Reference	Design Volume l/s	Recorded Air Volume l/s	Room Volume m³	Recorded (AC/HR)	*SHTM ACRs (AC/HR)
Bedroom (Supply Chilled Beam)	+40	+41	48.2	3.06	*2.5 – 3.0
En-Suite (Extract)	-45	-40	13.4	10.74	3.0
Room Condition:	GOOD				
Comments: * derogated ACRs for the bedroom – SHTM03-01 is 6 air change rates.					

Adults Ward 4C – Room 66 – Door Ref: RENW-163				
Fan Speed Setting	En-Suite dB(A) SHTM 45dB(A)	Bedroom dB(A) SHTM 35db(A)	Air Volume l/s	*Increased scrub value for the en-suite (ACRs)
1	-	-	-	-
2	-	-	-	-
3	43.5	34.4	-56	25.78
4	-	-	-	-
5	-	-	-	-
6	-	-	-	-
Comments: Speed for the en-suite is SHTM03-01 compliant – Speed is SHTM03-01 compliant for the bedroom noise levels.				

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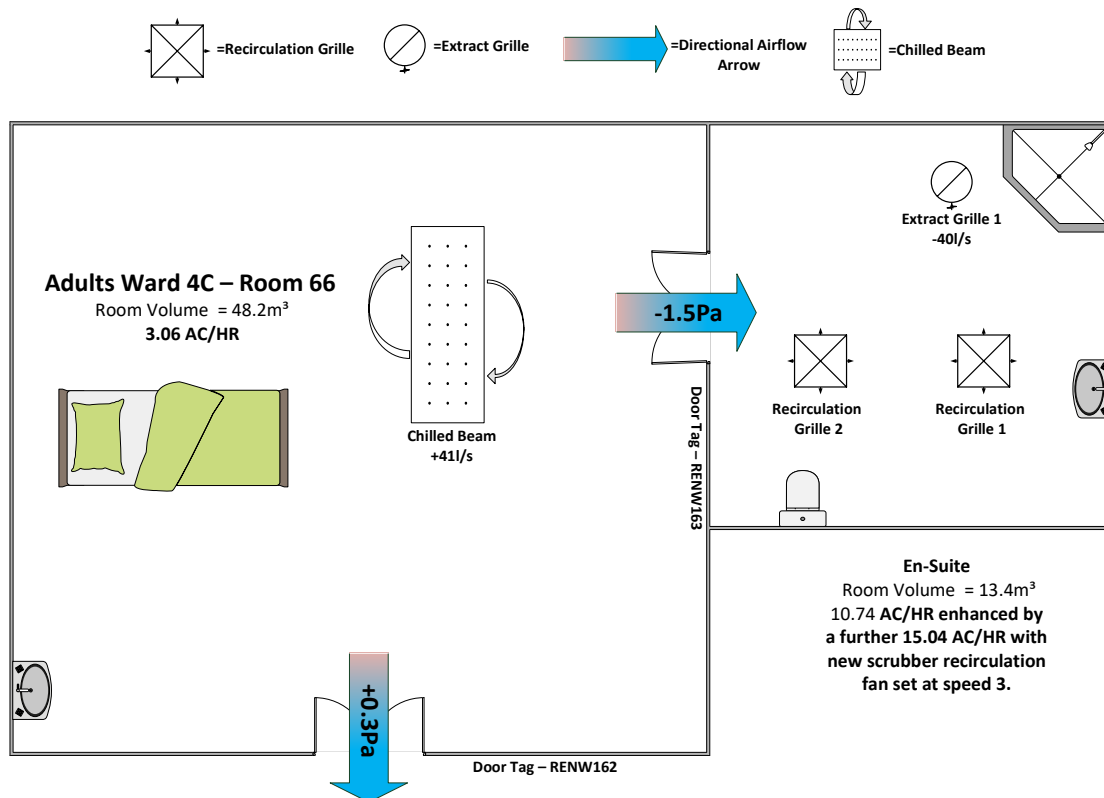
Section 4.0 – Supply & Extract Airflow Rates & Air Change Rates & Schematic layout

Room Pressure Differentials

Adults Ward 4C – Room 66 – Door Ref: RENW-162				
Room Reference	Target Room Pressure (Pa)	Recorded Room Pressures (Pa)	Magnehelic Gauge pre reading (Pa)	Magnehelic Gauge post reading (Pa)
Bedroom to Corridor	+ve	+0.3	n/a	n/a
Bedroom to En-Suite	-ve	-1.5	n/a	n/a
Comments: Room pressure is as requested for room type SHTM03-01 should be 0Pa or -ve to corridor.				

Temperature & Noise Levels

Room Reference	Door TAG Ref.:	Temperature Target 18 - 25°C	Noise Level Target <35dB(A)
Bedroom	RENW-162	22.5	34.4
En-Suite	RENW-163	22.3	43.5
Comments: Noise levels SHTM03-01 compliant set on speed 3 Camfil fan speed set at speed 3 when values recorded on above table. WC noise level target 45db(A)			



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Adults Ward 4C – Room 67 – Door Ref: RENW-165					
Room Reference	Design Volume l/s	Recorded Air Volume l/s	Room Volume m³	Recorded (AC/HR)	*SHTM ACRs (AC/HR)
Bedroom (Supply Chilled Beam)	+40	+39	49.07	2.86	*2.5 – 3.0
En-Suite (Extract)	-45	-47	13.60	12.44	3.0
Room Condition:	GOOD				
Comments: Room was occupied while carrying out annual verification and inspection.					

Adults Ward 4C – Room 67 – Door Ref: RENW-165				
Fan Speed Setting	En-Suite dB(A) SHTM 45dB(A)	Bedroom dB(A) SHTM 35dB(A)	Air Volume l/s	*Increased scrub value for the en-suite (ACRs)
1	-	-	-	-
2	-	-	-	-
3	43.9	34.9	59	28.05
4	-	-	-	-
5	-	-	-	-
6	-	-	-	-
Comments: Speed for the en-suite is SHTM03-01 compliant – Speed is SHTM03-01 compliant for the bedroom noise levels.				

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Section 4.0 – Supply & Extract Airflow Rates & Air Change Rates & Schematic layout

Room Pressure Differentials

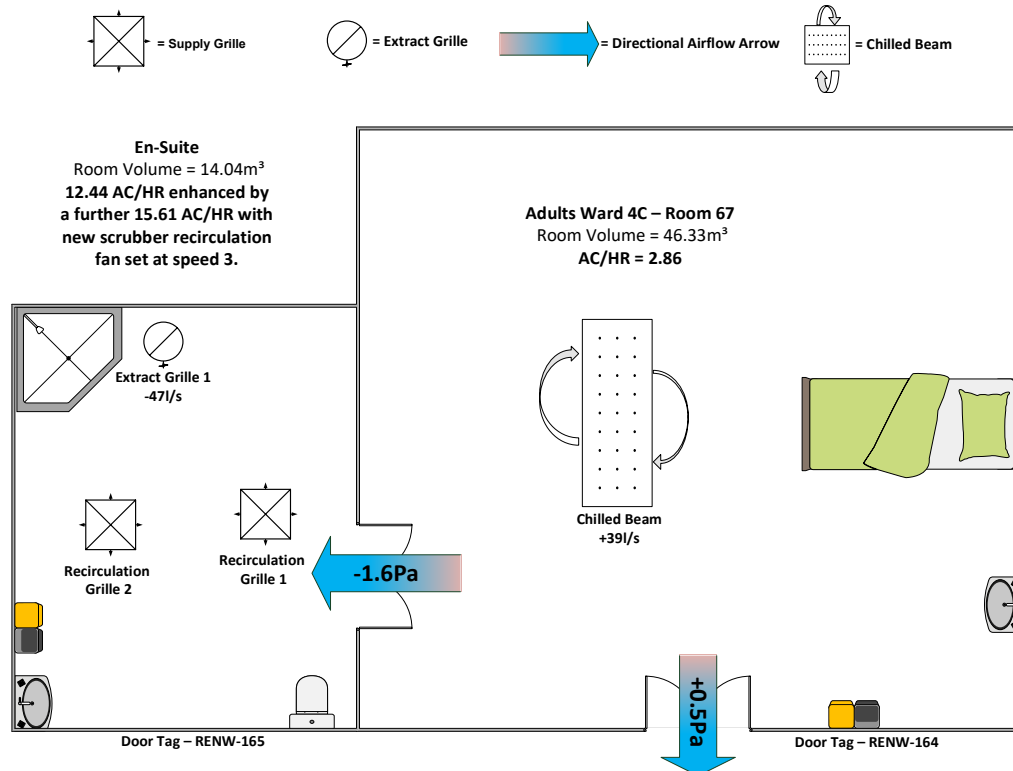
Adults Ward 4C – Room 67 – Door Ref: RENW-165				
Room Reference	Target Room Pressure (Pa)	Recorded Room Pressures (Pa)	Magnehelic Gauge pre reading (Pa)	Magnehelic Gauge post reading (Pa)
Bedroom to Corridor	+ve	+0.5	n/a	n/a
Bedroom to En-Suite	-ve	-1.6	n/a	n/a

Comments: Room pressure is as requested for room type SHTM03-01 should be 0Pa or -ve to corridor.

Temperature & Noise Levels

Room Reference	Door TAG Ref.:	Temperature Target 18 - 25°C	Noise Level Target <35dB(A)
Bedroom	RENW-165	24.5	34.9
En-Suite	RENW-164	24.6	43.9

Comments: Noise levels SHTM03-01 compliant set on speed 3 Camfil fan speed set at speed 3 when values recorded on above table. WC noise level target 45dB(A)



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Section 4.0 – Supply & Extract Airflow Rates & Air Change Rates & Schematic layout

Adults Ward 4C – Room 68 – Door Ref: RENW-166					
Room Reference	Design Volume l/s	Recorded Air Volume l/s	Room Volume m³	Recorded (AC/HR)	*SHTM ACRs (AC/HR)
Bedroom (Supply Chilled Beam)	+40	+41	48.4	3.04	*2.5 – 3.0
En-Suite (Extract)	-45	-44	13.8	11.47	3.0
Room Condition:	GOOD				
Comments: * derogated ACRs for the bedroom – SHTM03-01 is 6 air change rates.					

Adults Ward 4C – Room 68 – Door Ref: RENW-167				
Fan Speed Setting	En-Suite dB(A) SHTM 45dB(A)	Bedroom dB(A) SHTM 35dB(A)	Air Volume l/s	*Increased scrub value for the en-suite (ACRs)
1	-	-	-	-
2	-	-	-	-
3	44.7	34.5	-64	28.16
4	-	-	-	-
5	-	-	-	-
6	-	-	-	-
Comments: Speed for the en-suite is SHTM03-01 compliant – Speed is SHTM03-01 compliant for the bedroom noise levels.				

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Room Pressure Differentials

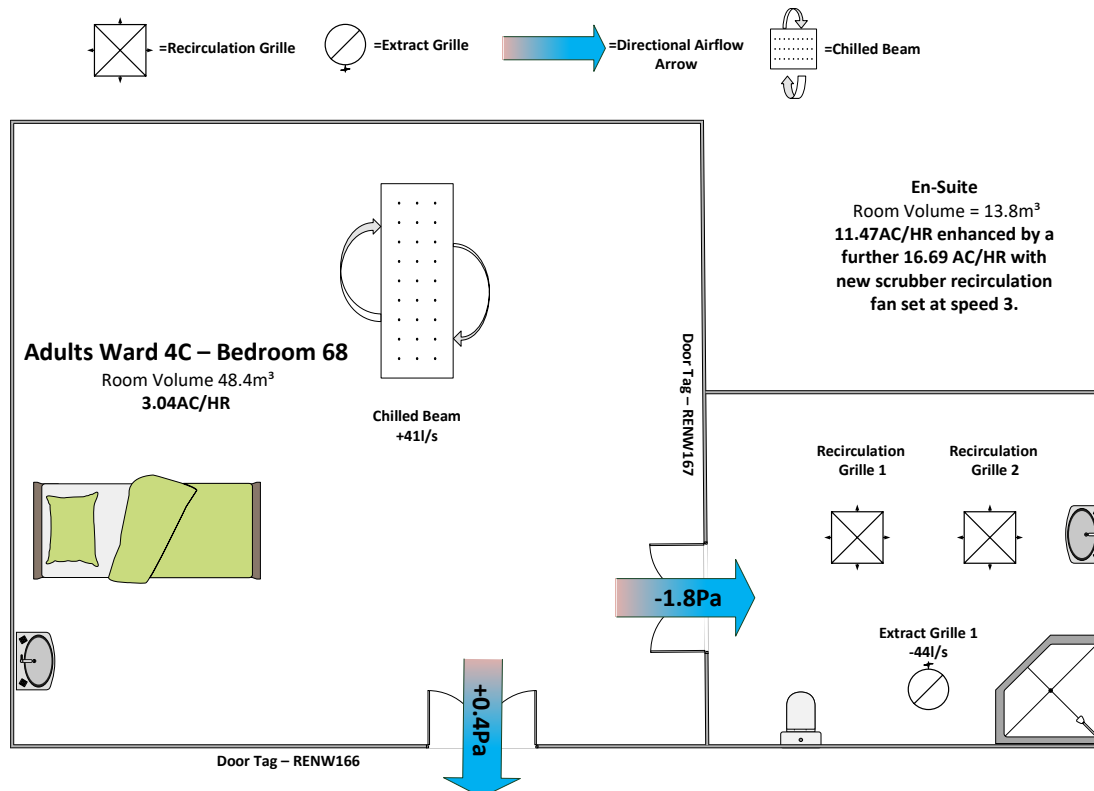
Adults Ward 4C – Room 68 – Door Ref: RENW-166				
Room Reference	Target Room Pressure (Pa)	Recorded Room Pressures (Pa)	Magnehelic Gauge pre reading (Pa)	Magnehelic Gauge post reading (Pa)
Bedroom to Corridor	+ve	+0.4	n/a	n/a
Bedroom to En-Suite	-ve	-1.8	n/a	n/a

Comments: Room pressure is as requested for room type SHTM03-01 should be 0Pa or -ve to corridor.

Temperature & Noise Levels

Room Reference	Door TAG Ref.:	Temperature Target 18 - 25°C	Noise Level Target <35dB(A)
Bedroom	RENW-166	22.0	34.5
En-Suite	RENW-167	22.0	44.7

Comments: Noise levels SHTM03-01 compliant set on speed 3 Camfil fan speed set at speed 3 when values recorded on above table. WC noise level target 45dB(A)



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Adults Ward 4C – Room 69 – Door Ref: RENW-170					
Room Reference	Design Volume l/s	Recorded Air Volume l/s	Room Volume m³	Recorded (AC/HR)	*SHTM ACRs (AC/HR)
Bedroom (Supply Chilled Beam)	+40	+45	48.42	3.34	*2.5 – 3.0
En-Suite (Extract)	-45	-44	14.04	11.28	3.0
Room Condition:	GOOD				
Comments: Room was occupied while carrying out annual verification and inspection.					

Adults Ward 4C – Room 69 – Door Ref: RENW-168				
Fan Speed Setting	En-Suite dB(A) SHTM 45dB(A)	Bedroom dB(A) SHTM 35dB(A)	Air Volume l/s	*Increased scrub value for the en-suite (ACRs)
1	-	-	-	-
2	-	-	-	-
3	43.4	34.6	61	26.92
4	-	-	-	-
5	-	-	-	-
6	-	-	-	-
Comments: Speed for the en-suite is SHTM03-01 compliant – Speed is SHTM03-01 compliant for the bedroom noise levels.				

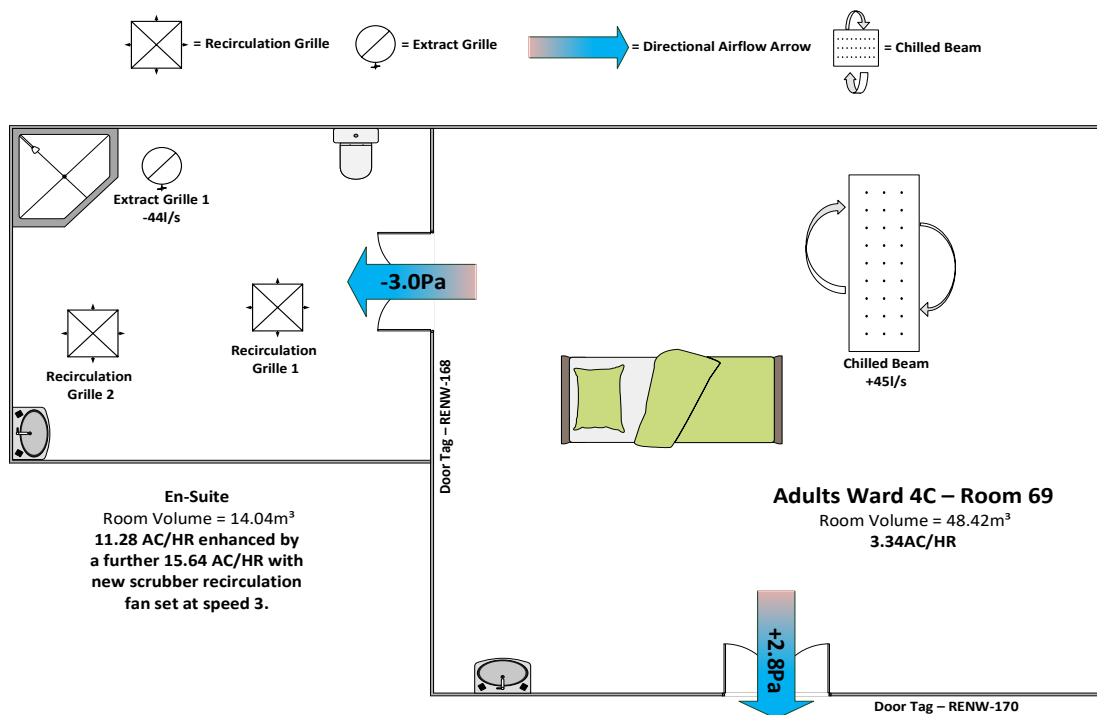
Section 4.0 – Supply & Extract Airflow Rates & Air Change Rates & Schematic layout

Room Pressure Differentials

Adults Ward 4C – Room 69 – Door Ref: RENW-170				
Room Reference	Target Room Pressure (Pa)	Recorded Room Pressures (Pa)	Magnehelic Gauge pre reading (Pa)	Magnehelic Gauge post reading (Pa)
Bedroom to Corridor	+ve	+2.8	n/a	n/a
Bedroom to En-Suite	-ve	-3.0	n/a	n/a
Comments: Room pressure is as requested for room type SHTM03-01 should be 0Pa or -ve to corridor.				

Temperature & Noise Levels

Room Reference	Door TAG Ref.:	Temperature Target 18 - 25°C	Noise Level Target <35dB(A)
Bedroom	RENW-170	24.1	34.6
En-Suite	RENW-168	24.4	43.4
Comments: Noise levels SHTM03-01 compliant set on speed 3 Camfil fan speed set at speed 3 when values recorded on above table. WC noise level target 45dB(A)			



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Adults Ward 4C – Room 70 – Door Ref: RENW-172					
Room Reference	Design Volume l/s	Recorded Air Volume l/s	Room Volume m³	Recorded (AC/HR)	*SHTM ACRs (AC/HR)
Bedroom (Supply Chilled Beam)	+40	+39	48.4	2.90	*2.5 – 3.0
En-Suite (Extract)	-45	-40	14.3	10.06	3.0
Room Condition:	GOOD				
Comments: * derogated ACRs for the bedroom – SHTM03-01 is 6 air change rates.					

Adults Ward 4C – Room 70 – Door Ref: RENW-173				
Fan Speed Setting	En-Suite dB(A) SHTM 45dB(A)	Bedroom dB(A) SHTM 35db(A)	Air Volume l/s	*Increased scrub value for the en-suite (ACRs)
1	-	-	-	-
2	-	-	-	-
3	44.3	34.4	61	25.41
4	-	-	-	-
5	-	-	-	-
6	-	-	-	-
Comments: Speed for the en-suite is SHTM03-01 compliant – Speed is SHTM03-01 compliant for the bedroom noise levels.				

Section 4.0 – Supply & Extract Airflow Rates & Air Change Rates & Schematic layout

Room Pressure Differentials

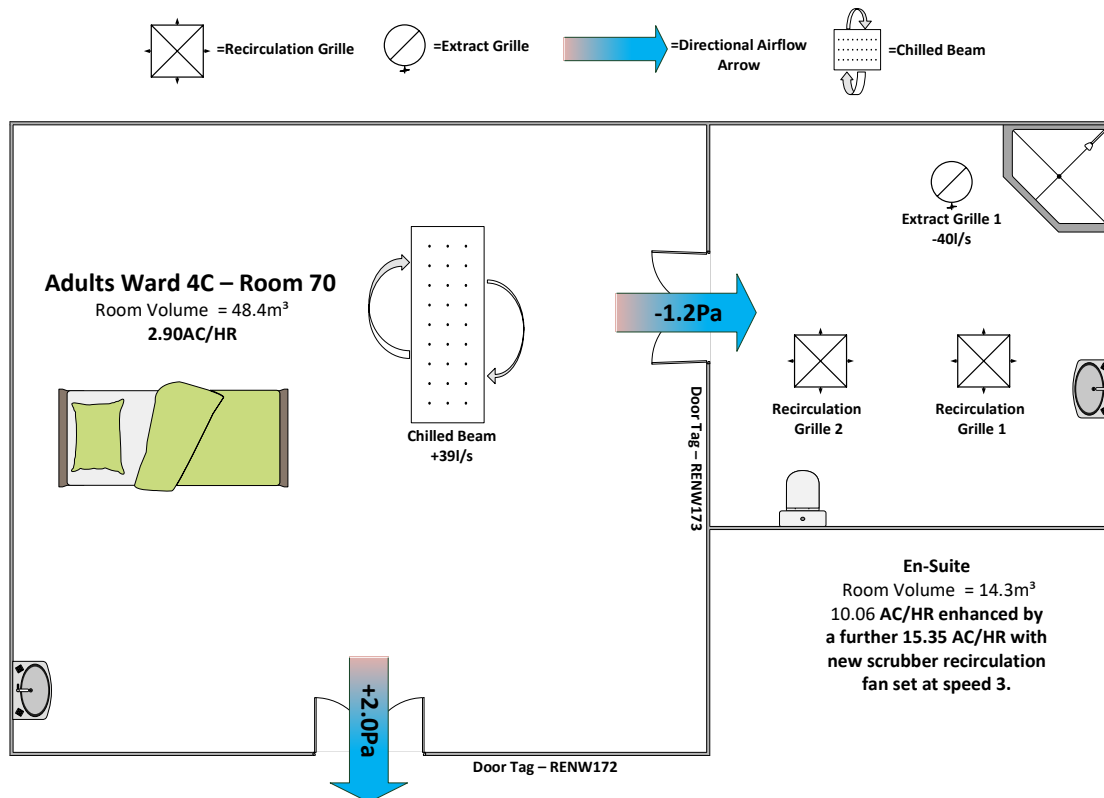
Adults Ward 4C – Room 70 – Door Ref: RENW-172				
Room Reference	Target Room Pressure (Pa)	Recorded Room Pressures (Pa)	Magnehelic Gauge pre reading (Pa)	Magnehelic Gauge post reading (Pa)
Bedroom to Corridor	+ve	+2.0	n/a	n/a
Bedroom to En-Suite	-ve	-1.2	n/a	n/a

Comments: Room pressure is as requested for room type SHTM03-01 should be 0Pa or -ve to corridor.

Temperature & Noise Levels

Room Reference	Door TAG Ref.:	Temperature Target 18 - 25°C	Noise Level Target <35dB(A)
Bedroom	RENW-172	22.0	34.4
En-Suite	RENW-173	21.8	44.3

Comments: Noise levels SHTM03-01 compliant set on speed 3 Camfil fan speed set at speed 3 when values recorded on above table. WC noise level target 45dB(A)



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Adults Ward 4C – Room 71 – Door Ref: RENW-175					
Room Reference	Design Volume l/s	Recorded Air Volume l/s	Room Volume m³	Recorded (AC/HR)	*SHTM ACRs (AC/HR)
Bedroom (Supply Chilled Beam)	+40	+38	48.2	2.83	*2.5 – 3.0
En-Suite (Extract)	-45	-48	13.1	13.19	3.0
Room Condition:	GOOD				
Comments: * derogated ACRs for the bedroom – SHTM03-01 is 6 air change rates.					

Adults Ward 4C – Room 71 – Door Ref: RENW-174				
Fan Speed Setting	En-Suite dB(A) SHTM 45dB(A)	Bedroom dB(A) SHTM 35dB(A)	Air Volume l/s	*Increased scrub value for the en-suite (ACRs)
1	-	-	-	-
2	-	-	-	-
3	44.6	34.9	57	28.85
4	-	-	-	-
5	-	-	-	-
6	-	-	-	-
Comments: Speed for the en-suite is SHTM03-01 compliant – Speed is SHTM03-01 compliant for the bedroom noise levels.				

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Section 4.0 – Supply & Extract Airflow Rates & Air Change Rates & Schematic layout

Room Pressure Differentials

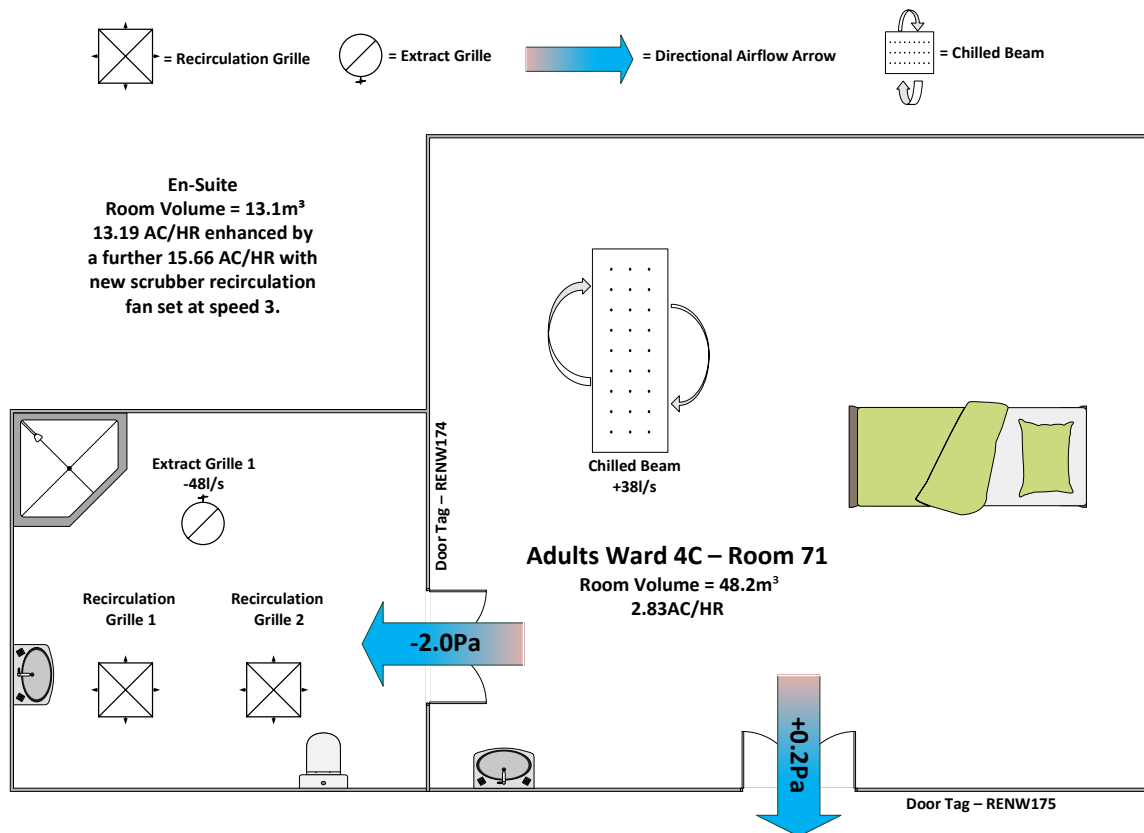
Adults Ward 4C – Room 71 Door Ref: RENW-175				
Room Reference	Target Room Pressure (Pa)	Recorded Room Pressures (Pa)	Magnehelic Gauge pre reading (Pa)	Magnehelic Gauge post reading (Pa)
Bedroom to Corridor	+ve	+0.2	n/a	n/a
Bedroom to En-Suite	-ve	-2.0	n/a	n/a

Comments: Room pressure is as requested for room type SHTM03-01 should be 0Pa or -ve to corridor.

Temperature & Noise Levels

Room Reference	Door TAG Ref.:	Temperature Target 18 - 25°C	Noise Level Target <35dB(A)
Bedroom	RENW-175	22.1	34.9
En-Suite	RENW-174	21.9	44.6

Comments: Noise levels SHTM03-01 compliant set on speed 3 Camfil fan speed set at speed 3 when values recorded on above table. WC noise level target 45db(A)



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Adults Ward 4C – Room 72 – Door Ref: RENW-180					
Room Reference	Design Volume l/s	Recorded Air Volume l/s	Room Volume m³	Recorded (AC/HR)	*SHTM ACRs (AC/HR)
Bedroom (Supply Chilled Beam)	+40	+44	48.4	3.27	*2.5 – 3.0
En-Suite (Extract)	-45	-46	13.5	12.26	3.0
Room Condition:	GOOD				
Comments: * derogated ACRs for the bedroom – SHTM03-01 is 6 air change rates.					

Adults Ward 4C – Room 72 – Door Ref: RENW-181				
Fan Speed Setting	En-Suite dB(A) SHTM 45dB(A)	Bedroom dB(A) SHTM 35dB(A)	Air Volume l/s	*Increased scrub value for the en-suite (ACRs)
1	-	-	-	-
2	-	-	-	-
3	44.2	34.6	-58	27.74
4	-	-	-	-
5	-	-	-	-
6	-	-	-	-
Comments: Speed for the en-suite is SHTM03-01 compliant – Speed is SHTM03-01 compliant for the bedroom noise levels.				

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Room Pressure Differentials

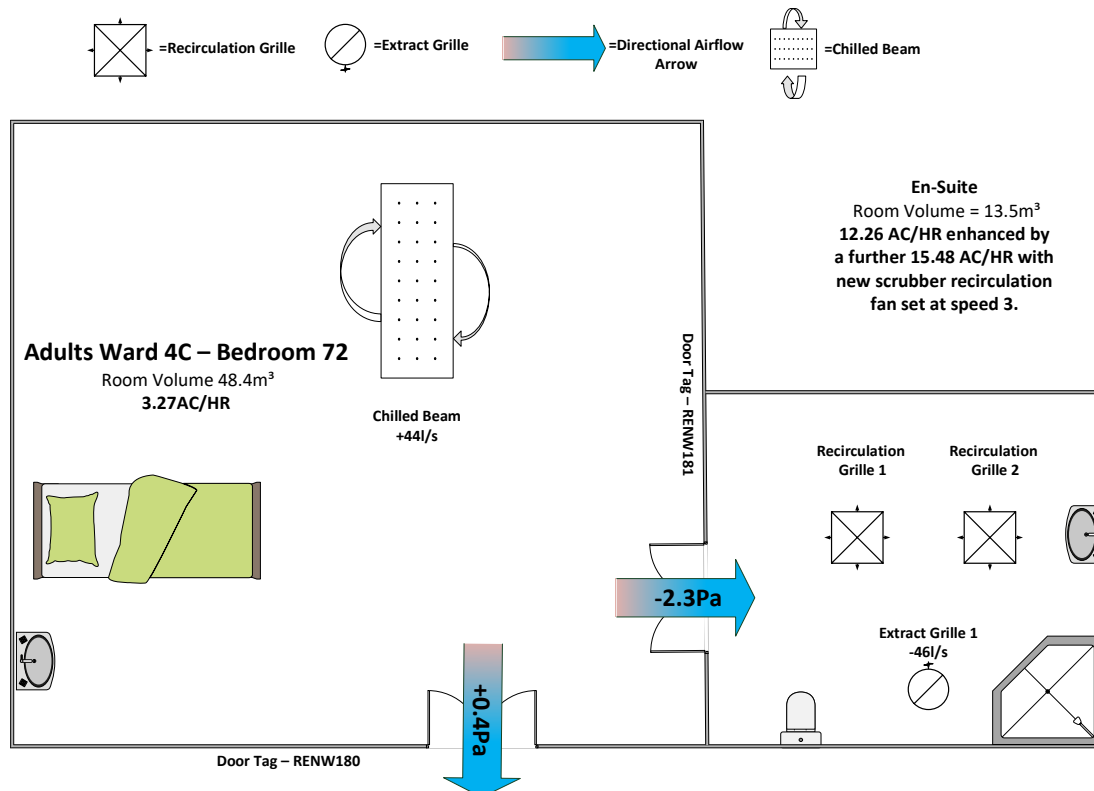
Adults Ward 4C – Room 72 – Door Ref: RENW-180				
Room Reference	Target Room Pressure (Pa)	Recorded Room Pressures (Pa)	Magnehelic Gauge pre reading (Pa)	Magnehelic Gauge post reading (Pa)
Bedroom to Corridor	+ve	+0.4	n/a	n/a
Bedroom to En-Suite	-ve	-2.3	n/a	n/a

Comments: Room pressure is as requested for room type SHTM03-01 should be 0Pa or -ve to corridor.

Temperature & Noise Levels

Room Reference	Door TAG Ref.:	Temperature Target 18 - 25°C	Noise Level Target <35dB(A)
Bedroom	RENW-180	21.9	34.6
En-Suite	RENW-181	22.0	44.2

Comments: Noise levels SHTM03-01 compliant set on speed 3 Camfil fan speed set at speed 3 when values recorded on above table. WC noise level target 45dB(A)



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Section 4.0 – Supply & Extract Airflow Rates & Air Change Rates & Schematic layout

Adults Ward 4C – Room 73 – Door Ref: RENW-183					
Room Reference	Design Volume l/s	Recorded Air Volume l/s	Room Volume m³	Recorded (AC/HR)	*SHTM ACRs (AC/HR)
Bedroom (Supply Chilled Beam)	+40	+38	47.9	2.85	*2.5 – 3.0
En-Suite (Extract)	-45	-47	13.2	12.81	3.0
Room Condition:	GOOD				
Comments: * derogated ACRs for the bedroom – SHTM03-01 is 6 air change rates.					

Adults Ward 4C – Room 73 – Door Ref: RENW-182				
Fan Speed Setting	En-Suite dB(A) SHTM 45dB(A)	Bedroom dB(A) SHTM 35dB(A)	Air Volume l/s	*Increased scrub value for the en-suite (ACRs)
1	-	-	-	-
2	-	-	-	-
3	44.8	34.9	57	28.35
4	-	-	-	-
5	-	-	-	-
6	-	-	-	-
Comments: Speed for the en-suite is SHTM03-01 compliant – Speed is SHTM03-01 compliant for the bedroom noise levels.				

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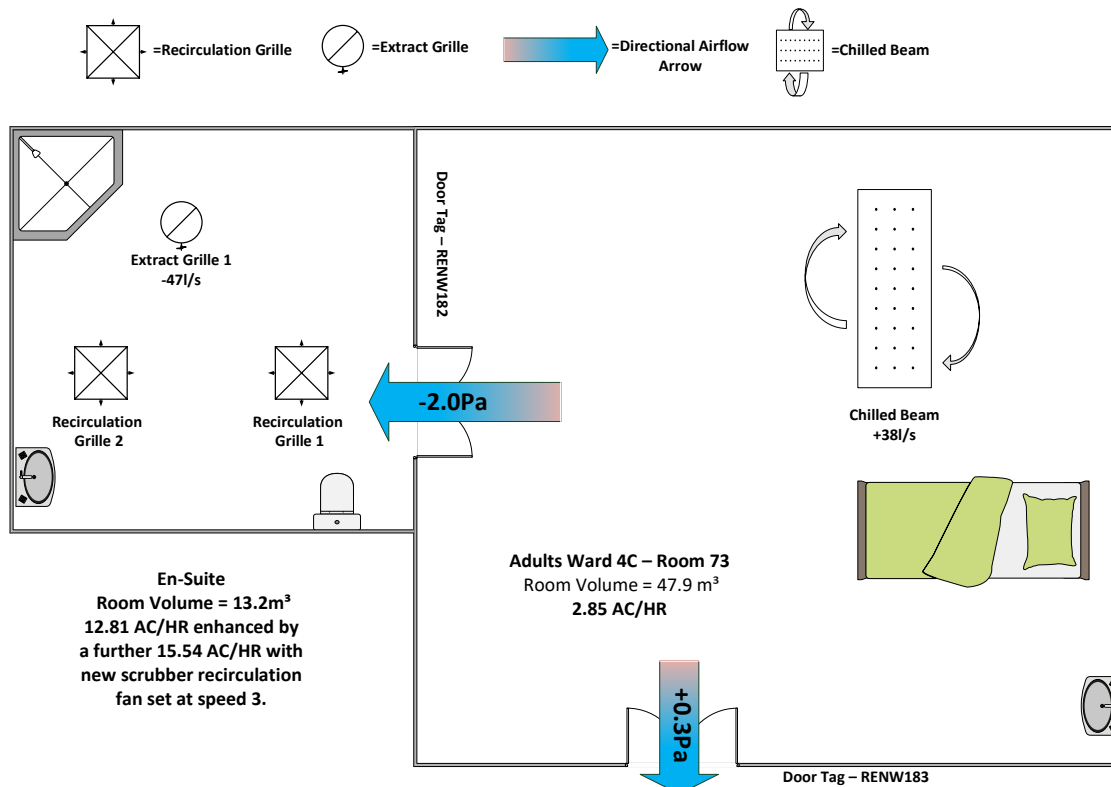
Section 4.0 – Supply & Extract Airflow Rates & Air Change Rates & Schematic layout

Room Pressure Differentials

Adults Ward 4C – Room 73 – Door Ref: RENW-183				
Room Reference	Target Room Pressure (Pa)	Recorded Room Pressures (Pa)	Magnehelic Gauge pre reading (Pa)	Magnehelic Gauge post reading (Pa)
Bedroom to Corridor	+ve	+0.3	n/a	n/a
Bedroom to En-Suite	-ve	-2.0	n/a	n/a
Comments: Room pressure is as requested for room type SHTM03-01 should be 0Pa or -ve to corridor.				

Temperature & Noise Levels

Room Reference	Door TAG Ref.:	Temperature Target 18 - 25°C	Noise Level Target <35dB(A)
Bedroom	RENW-183	22.3	34.9
En-Suite	RENW-182	22.2	44.8
Comments: Noise levels SHTM03-01 compliant set on speed 3 Camfil fan speed set at speed 3 when values recorded on above table. WC noise level target 45db(A)			



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Section 4.0 – Supply & Extract Airflow Rates & Air Change Rates & Schematic layout

Adults Ward 4C – Room 74 – Door Ref: RENW-185					
Room Reference	Design Volume l/s	Recorded Air Volume l/s	Room Volume m³	Recorded (AC/HR)	*SHTM ACRs (AC/HR)
Bedroom (Supply Chilled Beam)	+40	+42	48.1	3.14	*2.5 – 3.0
En-Suite (Extract)	-45	-48	14.3	12.08	3.0
Room Condition:	Good				
Comments: * derogated ACRs for the bedroom – SHTM03-01 is 6 air change rates.					

Adults Ward 4C – Room 74 – Door Ref: RENW-186				
Fan Speed Setting	En-Suite dB(A) SHTM 45dB(A)	Bedroom dB(A) SHTM 35dB(A)	Air Volume l/s	*Increased scrub value for the en-suite (ACRs)
1	-	-	-	-
2	-	-	-	-
3	44.8	34.9	65	28.44
4	-	-	-	-
5	-	-	-	-
6	-	-	-	-
Comments: Speed for the en-suite is SHTM03-01 compliant – Speed is SHTM03-01 compliant for the bedroom noise levels.				

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Section 4.0 – Supply & Extract Airflow Rates & Air Change Rates & Schematic layout

Room Pressure Differentials

Adults Ward 4C – Room 74 – RENW-186

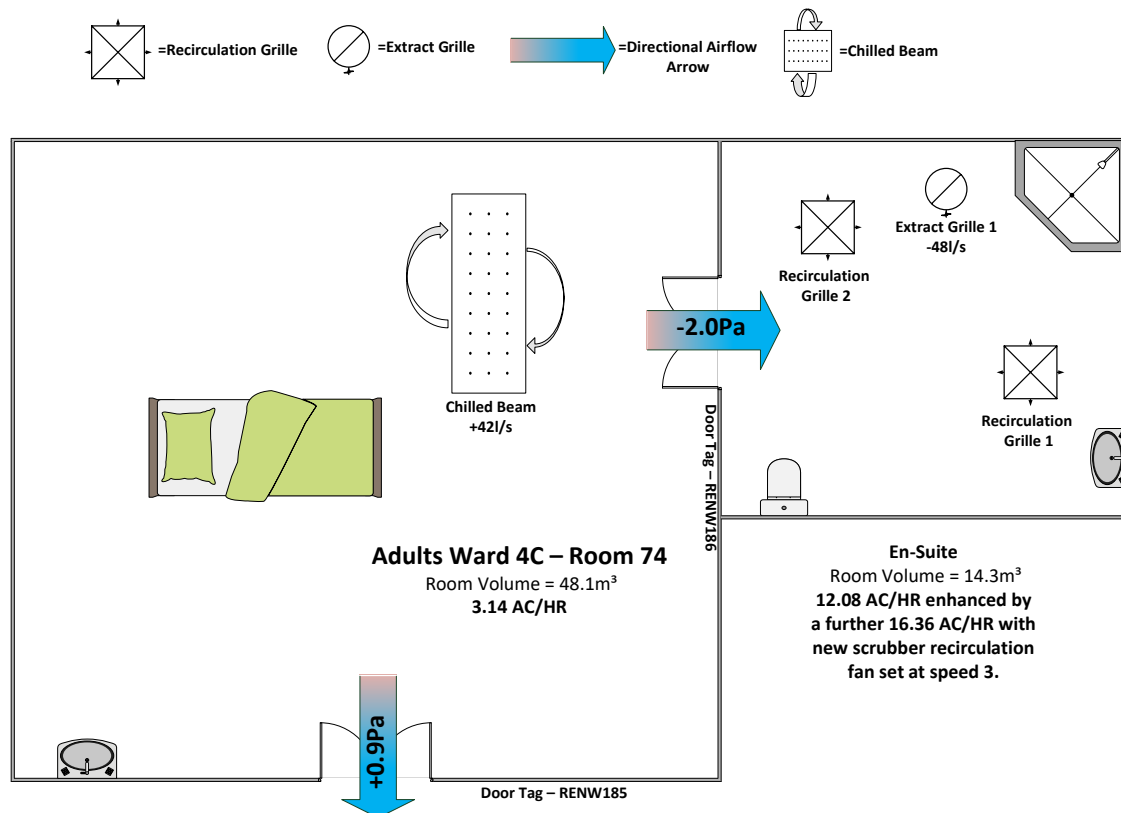
Room Reference	Target Room Pressure (Pa)	Recorded Room Pressures (Pa)	Magnehelic Gauge pre reading (Pa)	Magnehelic Gauge post reading (Pa)
Bedroom to Corridor	+ve	+0.9	n/a	n/a
Bedroom to En-Suite	-ve	-2.0	n/a	n/a

Comments: Room pressure is as requested for room type SHTM03-01 should be 0Pa or -ve to corridor.

Temperature & Noise Levels

Room Reference	Door TAG Ref.:	Temperature Target 18 - 25°C	Noise Level Target <35dB(A)
Bedroom	RENW-185	22.0	34.9
En-Suite	RENW-186	22.1	44.8

Comments: Noise levels SHTM03-01 compliant set on speed 3 Camfil fan speed set at speed 3 when values recorded on above table. WC noise level target 45dB(A).



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Section 4.0 – Supply & Extract Airflow Rates & Air Change Rates & Schematic layout

Adults Ward 4C – Room 75 – Door Ref: RENW-188					
Room Reference	Design Volume l/s	Recorded Air Volume l/s	Room Volume m³	Recorded (AC/HR)	*SHTM ACRs (AC/HR)
Bedroom (Supply Chilled Beam)	+40	+39	48.6	2.88	*2.5 – 3.0
En-Suite (Extract)	-45	-50	13.5	13.33	3.0
Room Condition:	GOOD				
Comments: * derogated ACRs for the bedroom – SHTM03-01 is 6 air change rates.					

Adults Ward 4C – Room 75 – Door Ref: RENW-187				
Fan Speed Setting	En-Suite dB(A) SHTM 45dB(A)	Bedroom dB(A) SHTM 35dB(A)	Air Volume l/s	*Increased scrub value for the en-suite (ACRs)
1	-	-	-	-
2	-	-	-	-
3	44.9	34.8	56	28.26
4	-	-	-	-
5	-	-	-	-
6	-	-	-	-
Comments: Speed for the en-suite is SHTM03-01 compliant – Speed is SHTM03-01 compliant for the bedroom noise levels.				

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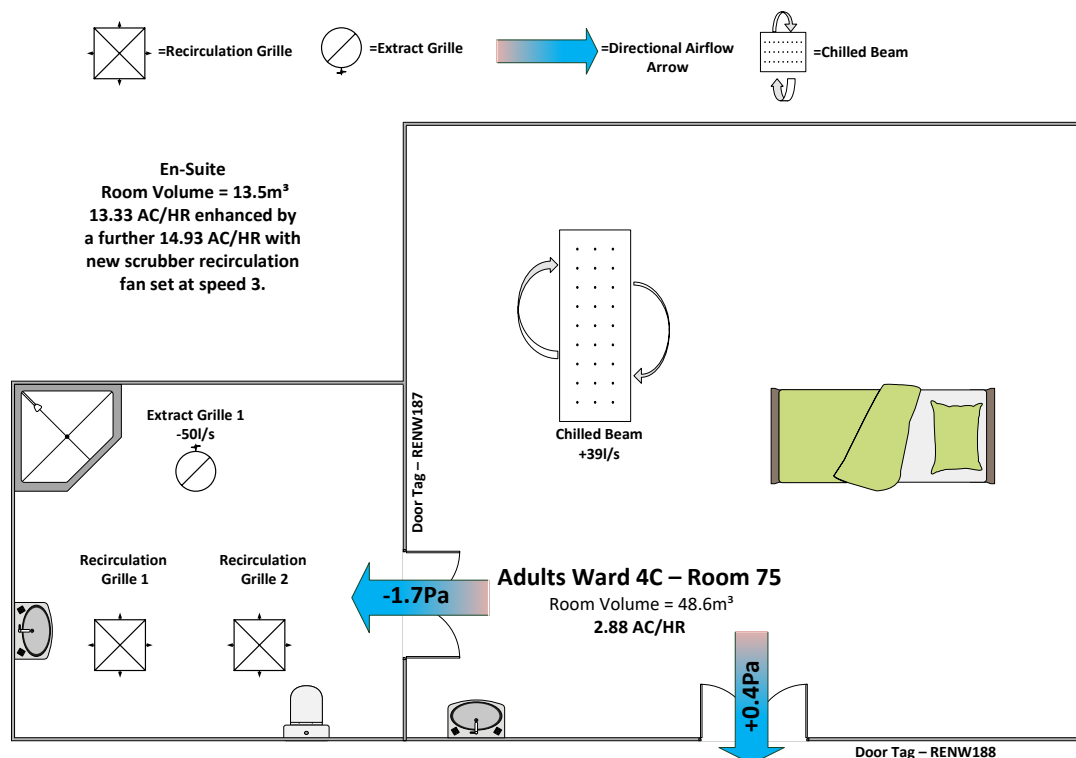
Section 4.0 – Supply & Extract Airflow Rates & Air Change Rates & Schematic layout

Room Pressure Differentials

Adults Ward 4C – Room 75 – Door Ref: RENW-188				
Room Reference	Target Room Pressure (Pa)	Recorded Room Pressures (Pa)	Magnehelic Gauge pre reading (Pa)	Magnehelic Gauge post reading (Pa)
Bedroom to Corridor	+ve	+0.4	n/a	n/a
Bedroom to En-Suite	-ve	-1.7	n/a	n/a
Comments: Room pressure is as requested for room type SHTM03-01 should be 0Pa or -ve to corridor.				

Temperature & Noise Levels

Room Reference	Door TAG Ref.:	Temperature Target 18 - 25°C	Noise Level Target <35dB(A)
Bedroom	RENW-188	21.7	34.8
En-Suite	RENW-187	21.9	44.9
Comments: Noise levels SHTM03-01 compliant set on speed 3 Camfil fan speed set at speed 3 when values recorded on above table. WC noise level target 45dB(A).			



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Section 4.0 – Supply & Extract Airflow Rates & Air Change Rates

Adults Ward 4C – Isolation Rooms – AHU Ref: 124AHU05 & 04						
Room Reference	Design Volume l/s	Recorded Air Volume l/s	Percentage of Design	Room Volume m³	Recorded AC/HR	ACRs (AC/HR)
51	+40	+45	112	46.0	3.52	2.5 – 3.0
52		+42	105	54.1	2.79	
53		+41	102	46.25	3.19	
54		+40	100	48.1	2.99	
55		+40	100	48.09	2.99	
56		+40	100	46.59	3.09	
57		+41	102	48.4	3.04	
58		+42	105	49.07	3.08	
59		+41	102	48.30	3.20	
60		+41	102	48.55	3.11	
61		+42	105	48.9	3.09	
62		+41	102	53.04	2.78	
Comments:						

Section 4.0 – Supply & Extract Airflow Rates & Air Change Rates

Adults Ward 4C – Bedrooms – AHU Ref: 124AHU05 & 04						
Room Reference	Design Volume l/s	Recorded Air Volume l/s	Percentage of Design	Room Volume m³	Recorded AC/HR	ACRs (AC/HR)
63	+40	+40	100	47.1	3.05	2.5 – 3.0
64		+39	97	46.42	3.02	
65		+39	97	48.4	2.90	
66		+41	102	48.2	3.06	
67		+39	97	49.07	2.86	
68		+41	102	48.4	3.04	
69		+45	112	48.42	3.34	
70		+39	97	48.4	2.90	
71		+38	95	48.2	2.83	
72		+44	110	48.4	3.27	
73		+38	95	47.9	2.85	
74		+42	105	48.1	3.14	
75		+39	97	48.6	2.88	
Comments:						

Section 4.0 – Supply & Extract Airflow Rates & Air Change Rates

Adults Ward 4C – En Suites – AHU Ref: 124AHU04 & 05						
Room Reference	Design Volume l/s	Recorded Air Volume l/s	Percentage of Design	Room Volume m³	Recorded AC/HR	ACRs (AC/HR)
51	-45	-22	48	13.68	5.78	3.0
52		-45	100	13.8	11.73	
53		-47	104	16.36	10.34	
54		-43	95	13.1	11.81	
55		-45	100	14.08	11.5	
56		-44	97	15.24	10.39	
57		-39	86	13.4	10.47	
58		-47	104	13.53	12.50	
59		-37	82	13.8	9.65	
60		-39	86	13.56	10.35	
61		-41	91	13.4	11.01	
62		-55	122	17.91	11.06	
Comments: None.						

Section 4.0 – Supply & Extract Airflow Rates & Air Change Rates

Adults Ward 4C – En Suites – AHU Ref: 124AHU04 & 05						
Room Reference	Design Volume l/s	Recorded Air Volume l/s	Percentage of Design	Room Volume m³	Recorded AC/HR	ACRs (AC/HR)
63	-45	-45	100	16.8	9.64	3.0
64		-48	106	13.96	12.37	
65		-42	93	13.6	11.11	
66		-40	88	13.4	10.74	
67		-47	104	13.6	12.44	
68		-44	97	13.8	11.47	
69		-44	97	14.04	11.28	
70		-40	88	14.3	10.06	
71		-48	106	13.1	13.19	
72		-46	102	13.5	12.26	
73		-47	104	13.2	12.81	
74		-48	106	14.3	12.08	
75		-50	111	13.5	13.33	
Comments: None.						

Section 5.0 – Test Equipment Used

Type of Equipment	Serial No	Cal Due Date
Micro-manometer	DCL5342/8651	6 th July 2023
Temperature Probe	42670651	20 th December 2022
Sound Meter	8089301	20 th December 2022
Balometer	PH7311945004	22 nd June 2023

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Section 6.0 – Calibration Certificates





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CERTIFICATE OF CALIBRATION

Certificate number :	44956-1-3	Page No:	1 of 1
Customer :	CORRECT AIR SOLUTIONS	Date of calibration:	06 July 2022

Instrument :	Description: DIGITAL MANOMETER Manufacturer: DP MEASUREMENT BUCKINGHAM Type: RS232/TT570 Serial Number: DCL5342/8651	Job number: 44956 1/3 Previous calibration: N/A Accuracy of U.U.T: +/- 0.2 % of Indication +/- LSD Condition recieved: Satisfactory
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Lab Conditions at time of calibration:	Temperature: 20.0 +/- 1.0 °C Supply Voltage: 230 +/- 12 Volts	Humidity: 50 % +/- 20 % Supply Frequency: 50 Hz +/- 1 Hz
--	--	---

Comments: The unit was allowed to stabilize for a period of 24 hours prior to calibration
 The unit was mounted in a horizontal position,
 The pressure medium was Dry Air,
 The unit was zeroed prior to calibration

The above instrument was calibrated using:

Plant No. G19 S/No. 221/96-5	UKAS Lab No. 0822	Certificate No. 94071
Plant No. G23 S/No. 85772	UKAS Lab No. 0690	Certificate No. 18204

Uncertainty of measurement & capabilities: +/- 0.02%

Calibration Information: This instrument was calibrated against laboratory standards whose values are traceable to National Standards.
 The uncertainty limits quoted refer to the measured values only, with no account being taken of the instruments ability to maintain its calibration
 The Calibration was carried out in accordance with BS EN ISO 17025 : 2017

Calibration readings:

Range (kPa)	Ind. on U.U.T. (kPa)	App. Std. (kPa)	% Deviation
7	0.00	0.000	0.0000
	0.50	0.490	2.0000
	1.00	0.990	1.0000
	2.00	2.005	-0.2500
	3.00	3.003	-0.1000
	4.00	3.998	0.0500
	5.00	4.996	0.0800
	6.00	5.993	0.1167
	7.00	6.990	0.1429

This calibration was carried out by: I. Green Date due for Re-calibration: 06 July 2023

Approved Signatories: B. C. Dowden ☐ I. Green ☐ C Dowden ☒ Signature [Redacted Signature]



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CERTIFICATE OF CALIBRATION

Certificate number : 44021-S-6

Page No: 1 of 1

Customer : CORRECT AIR SOLUTIONS LTD

Date of calibration: 20 December 2021

Instrument :	Description: SOUND LEVEL METER	Job number: 44021 S/6
	Manufacturer: ATP	Previous calibration: 20 January 2021
	Type: DT-805	Accuracy of U.U.T +/- 1 db
	Serial Number: 8089301	
		Condition received: Satisfactory

Lab Conditions	Temperature: 20.0 +/- 1.0 °C	Humidity: 50 % +/- 20 %
at time of calibration:	Supply Voltage: 230 +/- 12 Volts	Supply Frequency: 50 Hz +/- 1 Hz

Comments: The unit was allowed to stabilize for a period of 24 hours prior to calibration

This instrument was tested on all wavelengths and the accuracies found were within manufacturer specification.

The above instrument was calibrated using: Plant Number with reference to UKAS calibrated equipment below.

Plant No. G15 S/No. 407074 UKAS Lab: 0324 Certificate No. 34854

Uncertainty of measurement & capabilities: +/- 0.1 db | +/- 0.001 ppm

Calibration Information: This instrument was calibrated against laboratory standards whose values are traceable to National Standards.
The uncertainty limits quoted refer to the measured values only, with no account being taken of the instruments ability to maintain its calibration
The Calibration was carried out in accordance with BS EN ISO 17025 : 2017

Calibration readings:	Range	Indication on U.U.T	Applied Standard
	(DB)	(DB)	(DB)
	114	113.3	114.0
	94	93.4	94.0

This calibration was carried out by: K. Greene

Date due for Re-calibration: 20 December 2022

Approved Signatories: B. C. Dowden ☐ I. Green ☐ C Dowden ☒ Signature



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CERTIFICATE OF CALIBRATION

Certificate number : 44021-3-6

Page No: 1 of 1

Customer : CORRECT AIR SOLUTIONS

Date of calibration: 20 December 2021

Instrument :	Description: THERMOHYGROMETER	Job number: 44021 3/6
	Manufacturer: FLUKE	Previous calibration: 20 January 2021
	Type: 971	Accuracy of U.U.T TEMP = +/- 1°C
	Serial Number: 42670651	HUMIDITY = +/- 5%RH
		Condition received: Satisfactory

Lab Conditions	Temperature: 20.0 +/- 1.0 °C	Humidity: 50 % +/- 20 %
at time of calibration:	Supply Voltage: 230 +/- 12 Volts	Supply Frequency: 50 Hz +/- 1 Hz

Comments: The unit was allowed to stabilize for a period of 24 hours prior to calibration

The above instrument was calibrated using:

Plant No. A13, A40 with reference to UKAS calibrated equipment below.
Plant No. G8 S/No. 6509010118 UKAS Lab No. 0601 Certificate No. 021116/N2

Uncertainty of measurement & capabilities: Temp : +/- 0.06 °C / 0.01% | Humidity : +/- 0.5%

Calibration Information: This instrument was calibrated against laboratory standards whose values are traceable to National Standards.
The uncertainty limits quoted refer to the measured values only,
with no account being taken of the instruments ability to maintain its calibration
The Calibration was carried out in accordance with BS EN ISO 17025 : 2017 & 6789 : 2003

Calibration readings:	Range (°C)	Indication U.U.T. (°C)	Applied Standard (°C)	% Deviation
	-20 to 60	-9.8	-10.00	-2.0408
		0.1	0.00	0.0000
		20.1	20.00	0.4975
		30.1	30.00	0.3322
		40.2	40.00	0.4975
		60.3	60.00	0.4975

	Range (%RH)	Indication U.U.T. (%RH)	Applied Standard (%RH)	% Deviation
	5 to 95	11.1	11.3	-1.8018
		32.5	33.0	-1.5385
		74.7	75.3	-0.8032

This calibration was carried out by: K. Greene

Date due for Re-calibration: 20 December 2022

Approved Signatories: B. C. Dowden ☐ I. Green ☐ C Dowden ☒ Signature





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CERTIFICATE OF CALIBRATION

Certificate number: 44894-2-2

Page No: 1 of 2

Customer: CORRECT AIR SOLUTIONS

Date of calibration: 22 June 2022

Instrument:

Description: BALOMETER
Manufacturer: AIRFLOW
Type: PROHOOD 731
Serial Number: PH7311945004

Job number: 44894 2/2

Previous calibration: 06 December 2021

Accuracy of U.U.T: +/- 1%

Condition received: Req. Adjustment

Lab Conditions

Temperature: 20.0 +/- 1.0 °C

Humidity: 50 % +/- 20 %

at time of calibration:

Supply Voltage: 230 +/- 12 Volts

Supply Frequency: 50 Hz +/- 1 Hz

Comments:

The unit was allowed to stabilize for a period of 24 hours prior to calibration

The above instrument was calibrated using:

Plant No. G23 S/No. 85772
Plant No. G19 S/No. 221/96-5

UKAS Lab No. 0690
UKAS Lab No. 0822

Certificate No. 18204
Certificate No. 94071

Uncertainty of measurement & capabilities:

Air Velocity = 0.1 to 25 m/s = +/- 0.5%

Temperature = Real -50 to 650 degC = +/- 0.06 degC / 0.02%

Calibration information:

This instrument was calibrated against laboratory standards whose values are traceable to National Standards.
The uncertainty limits quoted refer to the measured values only, with no account being taken of the instruments ability to maintain its calibration
The Calibration was carried out in accordance with BS EN ISO 17025 : 2017

This calibration was carried out by:

I. Green

Date due for Re-calibration: 22 June 2023

Approved Signatories:

B. C. Dowden ☐

I. Green ☐

C Dowden ☒

Signature



Risk Assessment Form – Airborne Pathogens

Activity being assessed:		Hazards identified: ✓					
The risk associated with exposure to airborne pathogens from the ventilation system, for immune compromised patients		Violence and aggression		Blood and body fluids		Radiation	
		Lone working		Machinery/equipment		Fire / Sources of ignition	
		Sharps		Hazardous substances		Ergonomic	
		Slips, trips, falls		Electricity		Work methodology	
		Manual Handling		Weather		Environment	X
Department:	Haemato- Oncology	Additional information: Ward 4C at the Queen Elizabeth University Hospital is a 10 single room unit caring for Haematooncology patients. A number of disease types are managed here but those most at risk of airborne fungal infections are patients with acute myeloid and lymphoblastic leukaemias. These patients typically endure long periods of neutropenia following intensive chemotherapy. Many of these patients are given anti-fungal prophylaxis medication which is highly effective. The other groups of patients treated for lymphoma, chronic leukaemias myeloma and autologous stem cell transplant are at low risk for fungal infection. Patients managed with allogeneic stem cell transplantation are not treated on ward 4C but are treated in the adjacent transplant unit, ward 4B. Patients undergoing treatment for acute leukaemia are normally confined to their room and only leave for essential imaging or diagnostic procedures. These patients are also high risk for bacterial infection, the source of which is normally the patient's own skin, lung and gut commensal flora during periods of severe neutropenia. We regularly monitor these patients for features suggestive of fungal infection; namely fevers refractory to broad spectrum antibiotics, new pulmonary infiltrates, skin lesions, serological testing and relevant cultures from blood, indwelling lines, sputum, tissue or body fluids. We have not noted any change in the background low incidence of these infections compared to those identified historically					
Location:	Ward 4C QEUH						
Person(s) exposed:		Patients with weakened immune systems					
Control measures currently in place:						Specific risk assessments or guidance to be referred to:	
1. NICE guidelines (2016) recommending the use of single rooms for accommodating high-risk patients. All accommodation in Ward 4C is in single rooms. https://www.nice.org.uk/guidance/ng47/resources/haematological-cancers-improving-outcomes-pdf-1837457868229						 haematological-cancers-improving-outcom	

Risk Assessment Form – Airborne Pathogens

2. **antimicrobial prophylaxis** medicines : The use of **antimicrobial prophylaxis** medicines are strongly recommended in patients being treated for acute leukaemia. Several classes of drugs are used for prophylaxis but the azoles, particularly posaconazole, are the most commonly used. Posaconazole has been shown in multi-centre, randomised controlled trials to be highly effective, in one trial published in the NEJM showing a reduction in overall mortality in addition to fungal related mortality. Furthermore, there is prospective, observational, single centre, real-life data showing significant clinical benefit. In addition there is a good understanding of how posaconazole works at the cellular level that explains its efficacy as a prophylactic agent. All international guidelines including IDSA and ESCMID recommend anti-fungal prophylaxis in high-risk patients.

3. Regular routine surveillance for possible fungal infection as noted above.

4. Management of patients in single rooms with movement outside this environment only for essential imaging or diagnostic/therapeutic procedures. Limited access by visitors.

5. Adults Ward 4C is located on the 4th floor of the Queen Elizabeth University Hospital and is supplied by 3 Air Handling Units located on level 12 plant room 124, these AH-units also serve adjacent ward levels 5, 6 & 7 for the C core and have thermal wheel recovery incorporated within them at source. The original filtration and pressure set up from building hand over for ward 4C was as follows :

General ward - G4 rated primary filtration and F7 Secondary filtration at source with an ambient (0pa) pressure cascade from room to corridor.

As an additional risk reducing measure within ward 4C, installation of recirculation air scrubber fans (Camfil Camcleaner 400 concealed fan units) located within the ceiling of each toilet bedroom on ward 4C was carried out and then each space validated to quantify the improvements achieved. The Cam cleaner consists of a pre-filter (bag) and a secondary HEPA filter. See report details of fan settings, air volumes, room pressures and noise levels achieved while maintaining SHTM03-01 compliance.

Subsequent improvement modifications include :

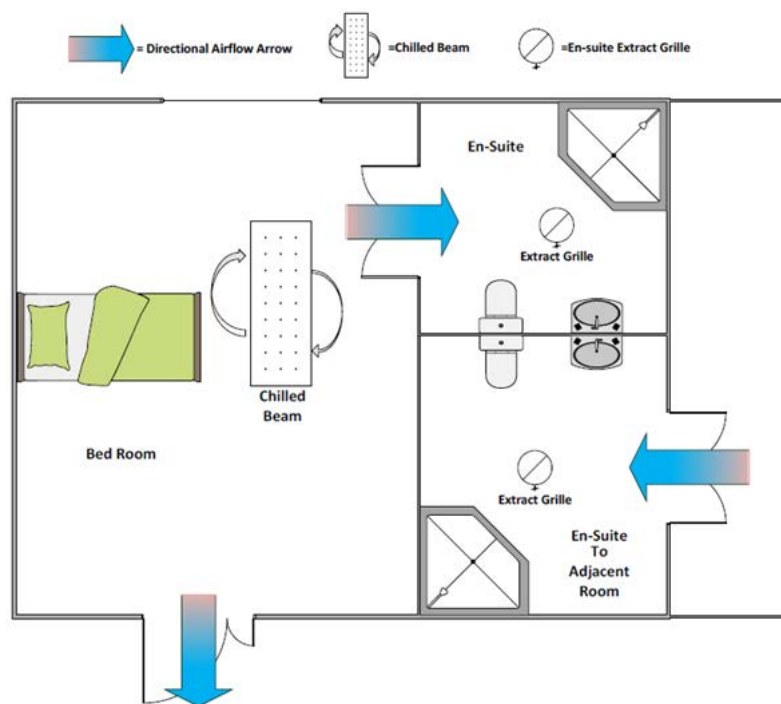
1. Oct/Nov 2018 plant re calibration and ventilation system re balance to change ward 4C Room Differential pressures to corridor to be nominally positive (+ve)
2. Jan 2019 Installation of F9 secondary filtration to improve the source air quality delivered to these departments.
3. Jan 2019 Deployment of mobile city M HEPPA air scrubbers to assist in reducing the existing particulate within the Air.
4. January 2020 CVG (Ceiling Ventilation Grilles x10) removed and replaced with a standard ceiling tile to reduce the risk of particulate moving from the corridor ceiling void into the corridor transfer area and rooms.

Risk Assessment Form – Airborne Pathogens

5. 4C, installation of recirculation air scrubber fans and particulate counts carried out in October 2020.

December 2020, Post Survey meaning verification completed on conclusion of works it is confirmed that the current example performance within ward 4C is reflective :

From :



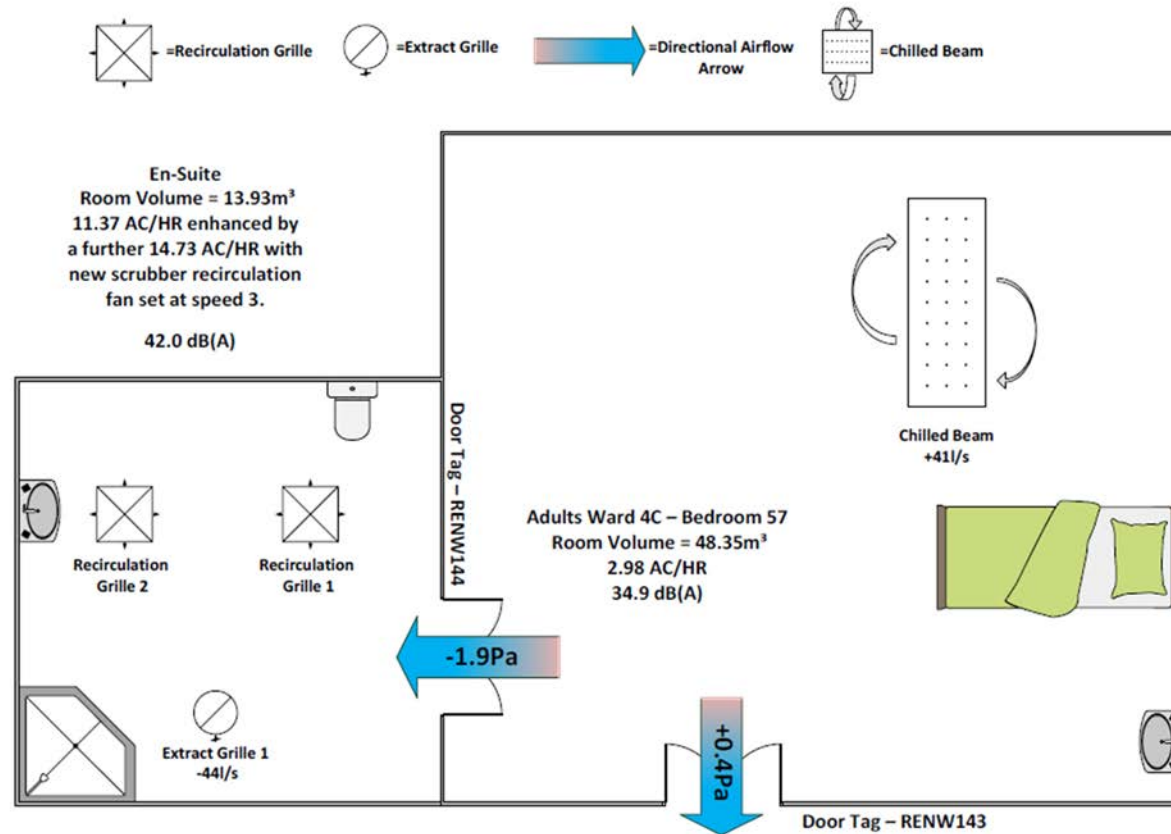
- 1) Room ACRs = 3AC/HR
- 2) EN-suite ACRs = 6AC/HR
- 3) Room Differential pressures to corridor to be nominally positive (+ve)
- 4) EN-suite toilet to be -ve to the room.

Risk Assessment Form – Airborne Pathogens

To:	
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Risk Assessment Form – Airborne Pathogens

Section 7 – Schematic Layout of Bedroom 57



Risk Assessment Form – Airborne Pathogens

Evaluation of Risk:						Additional Control Measures Required:																																											
<table border="1" style="width: 100%; border-collapse: collapse; margin: 10px;"> <thead> <tr> <th style="text-align: center;">Likelihood</th> <th colspan="5" style="text-align: center;">Severity</th> </tr> <tr> <th></th> <th style="text-align: center;">Negligible 1</th> <th style="text-align: center;">Minor 2</th> <th style="text-align: center;">Moderate 3</th> <th style="text-align: center;">Major 4</th> <th style="text-align: center;">Extreme 5</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">Almost Certain 5</td> <td style="background-color: yellow;">Medium</td> <td style="background-color: orange;">High</td> <td style="background-color: orange;">High</td> <td style="background-color: red;">V High</td> <td style="background-color: red;">V High</td> </tr> <tr> <td style="text-align: center;">Likely 4</td> <td style="background-color: yellow;">Medium</td> <td style="background-color: yellow;">Medium</td> <td style="background-color: orange;">High</td> <td style="background-color: orange;">High</td> <td style="background-color: red;">V High</td> </tr> <tr> <td style="text-align: center;">Possible 3</td> <td style="background-color: green;">Low</td> <td style="background-color: yellow;">Medium</td> <td style="background-color: yellow;">Medium</td> <td style="background-color: orange;">High</td> <td style="background-color: orange;">High</td> </tr> <tr> <td style="text-align: center;">Unlikely 2</td> <td style="background-color: green;">Low</td> <td style="background-color: yellow;">Medium</td> <td style="background-color: yellow;">Medium</td> <td style="background-color: orange;">Medium</td> <td style="background-color: orange;">High</td> </tr> <tr> <td style="text-align: center;">Rare 1</td> <td style="background-color: green;">Low</td> <td style="background-color: green;">Low</td> <td style="background-color: green;">Low</td> <td style="background-color: yellow;">Medium</td> <td style="background-color: yellow;">Medium</td> </tr> </tbody> </table>						Likelihood	Severity						Negligible 1	Minor 2	Moderate 3	Major 4	Extreme 5	Almost Certain 5	Medium	High	High	V High	V High	Likely 4	Medium	Medium	High	High	V High	Possible 3	Low	Medium	Medium	High	High	Unlikely 2	Low	Medium	Medium	Medium	High	Rare 1	Low	Low	Low	Medium	Medium		
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Likelihood x Severity = Risk level 3 x 3 = 9 (medium)																																																	
Risk Level: ✓						Responsible Manager for arranging additional controls:																																											
Low Risk	Medium Risk ✓	High Risk	Very High Risk	(Insert Name / Title)		Signature:																																											

Risk Assessment Form – Airborne Pathogens

Risk Level Acceptable: ✓		Date additional controls to be in place:			
Yes ✓ <i>(If medium risk indicate any additional controls desirable)</i>	No <i>(Indicate additional controls required)</i>	No additional controls identified.			
Final Risk Level: ✓		Low	Medium	High	Very High

Requirement to Add to Risk Register? ✓	Y	N	Requirement to share Risk Assessment? ✓	Y	N	Services / Depts. shared with:	
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Assessed by / Job Title:	Date:	Review Date:
Mike Leach Clinical Director Alistair Hart Consultant Haematology Alistair Leanord Consultant Microbiologist Myra Campbell Interim General Manager Regional Services Alan Gallacher, Head of Compliance Tom Steele Director Estates and Facilities Kirsty Strannigan Head of Health and Safety	22 nd June 2021	June 2022

Risk Assessment Form – Airborne Pathogens

Appendix 1



Ward 4C Room Validation Reports.zip



Particle Counts Ward 4C.zip



QEUH - Ward 4C -
January 2020.pdf

Risk Assessment Form – Airborne Pathogens

Activity being assessed:		Hazards identified: ✓					
The risk associated with exposure to airborne pathogens from the ventilation system, for immune compromised patients		Violence and aggression		Blood and body fluids		Radiation	
		Lone working		Machinery/equipment		Fire / Sources of ignition	
		Sharps		Hazardous substances		Ergonomic	
		Slips, trips, falls		Electricity		Work methodology	
		Manual Handling		Weather		Environment	X
Department:	Haemato- Oncology	Additional information: Ward 4C at the Queen Elizabeth University Hospital is a 10 single room unit caring for Haematooncology patients. A number of disease types are managed here but those most at risk of airborne fungal infections are patients with acute myeloid and lymphoblastic leukaemias. These patients typically endure long periods of neutropenia following intensive chemotherapy. Many of these patients are given anti-fungal prophylaxis medication which is highly effective. The other groups of patients treated for lymphoma, chronic leukaemias myeloma and autologous stem cell transplant are at low risk for fungal infection. Patients managed with allogeneic stem cell transplantation are not treated on ward 4C but are treated in the adjacent transplant unit, ward 4B. Patients undergoing treatment for acute leukaemia are normally confined to their room and only leave for essential imaging or diagnostic procedures. These patients are also high risk for bacterial infection, the source of which is normally the patient's own skin, lung and gut commensal flora during periods of severe neutropenia. We regularly monitor these patients for features suggestive of fungal infection; namely fevers refractory to broad spectrum antibiotics, new pulmonary infiltrates, skin lesions, serological testing and relevant cultures from blood, indwelling lines, sputum, tissue or body fluids. We have not noted any change in the background low incidence of these infections compared to those identified historically					
Location:	Ward 4C QEUH						
Person(s) exposed:		Patients with weakened immune systems					
Control measures currently in place:						Specific risk assessments or guidance to be referred to:	
1. NICE guidelines (2016) recommending the use of single rooms for accommodating high-risk patients. All accommodation in Ward 4C is in single rooms. 2. Anti-fungal prophylactic medicines : The use of anti-fungal prophylaxis is strongly recommended in patients being treated for acute leukaemia. Several classes of drugs are used for prophylaxis but the azoles, particularly posaconazole,						NICE Guidelines 2016 IDSA ESCMID Infection Rates reports	

Risk Assessment Form – Airborne Pathogens

are the most commonly used. Posaconazole has been shown in multi-centre, randomised controlled trials to be highly effective, in one trial published in the NEJM showing a reduction in overall mortality in addition to fungal related mortality. Furthermore, there is prospective, observational, single centre, real-life data showing significant clinical benefit. In addition there is a good understanding of how posaconazole works at the cellular level that explains its efficacy as a prophylactic agent. All international guidelines including IDSA and ESCMID recommend anti-fungal prophylaxis in high-risk patients.

3. Regular routine surveillance for possible fungal infection as noted above.

4. Management of patients in single rooms with movement outside this environment only for essential imaging or diagnostic/therapeutic procedures. Limited access by visitors.

5. We propose regular air sampling monitoring for fungal species and other airborne pathogens for all single rooms in ward 4C.

6. Adults Ward 4C is located on the 4th floor of the Queen Elizabeth University Hospital and is supplied by 3 Air Handling Units located on level 12 plant room 124, these AH-units also serve adjacent ward levels 5,6 &7 for the C core and have thermal wheel recovery incorporated within them at source. The original filtration and pressure set up from building hand over for ward 4C was as follows :

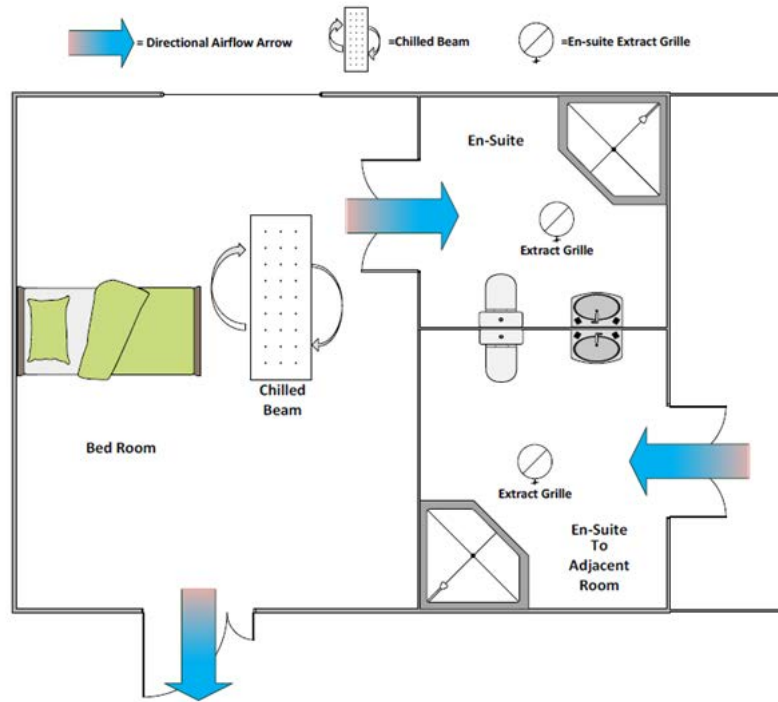
General ward - G4 rated primary filtration and F7 Secondary filtration at source with an ambient (0pa) pressure cascade from room to corridor and a non-official derogated ACH Rate from SHTM03-01.

Subsequent improvement modifications include :

1. Oct/Nov 2018 plant re calibration and ventilation system re balance to change ward 4C Room Differential pressures to corridor to be nominally positive (+ve)
2. Jan 2019 Installation of F9 secondary filtration to improve the source air quality delivered to these departments.
3. Deployment of mobile city M HEPPA air scrubbers to assist in reducing the existing particulate within the Air.
4. CVG (Ceiling Ventilation Grilles x10) removed and replaced with a standard ceiling tile to reduce the risk of particulate moving from the corridor ceiling void into the corridor transfer area and rooms.

Now post survey it is confirmed that the current performance within ward 4C is reflective of :

Risk Assessment Form – Airborne Pathogens



- 1) Room ACRs = 3AC/HR
- 2) EN-suite ACRs = 6AC/HR
- 3) Room Differential pressures to corridor to be nominally positive (+ve)
- 4) EN-suite toilet to be -ve to the room.

Risk Assessment Form – Airborne Pathogens

Evaluation of Risk:						Additional Control Measures Required:																																										
<table border="1"> <thead> <tr> <th>Likelihood</th> <th colspan="5">Severity</th> </tr> <tr> <th></th> <th>Negligible 1</th> <th>Minor 2</th> <th>Moderate 3</th> <th>Major 4</th> <th>Extreme 5</th> </tr> </thead> <tbody> <tr> <td>Almost Certain 5</td> <td>Medium</td> <td>High</td> <td>High</td> <td>V High</td> <td>V High</td> </tr> <tr> <td>Likely 4</td> <td>Medium</td> <td>Medium</td> <td>High</td> <td>High</td> <td>V High</td> </tr> <tr> <td>Possible 3</td> <td>Low</td> <td>Medium</td> <td>Medium</td> <td>High</td> <td>High</td> </tr> <tr> <td>Unlikely 2</td> <td>Low</td> <td>Medium</td> <td>Medium</td> <td>Medium</td> <td>High</td> </tr> <tr> <td>Rare 1</td> <td>Low</td> <td>Low</td> <td>Low</td> <td>Medium</td> <td>Medium</td> </tr> </tbody> </table>						Likelihood	Severity						Negligible 1	Minor 2	Moderate 3	Major 4	Extreme 5	Almost Certain 5	Medium	High	High	V High	V High	Likely 4	Medium	Medium	High	High	V High	Possible 3	Low	Medium	Medium	High	High	Unlikely 2	Low	Medium	Medium	Medium	High	Rare 1	Low	Low	Low	Medium	Medium	Beyond those listed above no further control measures are required. As the risk score is medium, Clinical and Estates management will progress with developing a scheme of works to further enhance the environment to reduce the risk level further.
Likelihood	Severity																																															
	Negligible 1	Minor 2	Moderate 3	Major 4	Extreme 5																																											
Almost Certain 5	Medium	High	High	V High	V High																																											
Likely 4	Medium	Medium	High	High	V High																																											
Possible 3	Low	Medium	Medium	High	High																																											
Unlikely 2	Low	Medium	Medium	Medium	High																																											
Rare 1	Low	Low	Low	Medium	Medium																																											
Likelihood Rare - Can't believe this event would happen – will only happen in exceptional circumstances. Unlikely - Not expected to happen, but definite potential exists Possible - May occur occasionally, has happened before on occasions Likely - Strong possibility that this could occur Almost Certain - This is expected to occur frequently / in most circumstances		Severity Negligible – minor injury first aid not required Minor – minor injury or illness first aid required Moderate – agency reportable, significant injury/illness medical treatment or counselling required Major – major injury or long term incapacity/disability Extreme – death or permanent incapacity																																														
Likelihood x Severity = Risk level 3 x 2 = 6 (medium)																																																
Risk Level: ✓						Responsible Manager for arranging additional controls:																																										

Risk Assessment Form – Airborne Pathogens

Low Risk	Medium Risk ✓	High Risk	Very High Risk	(Insert Name / Title)	Signature:
Risk Level Acceptable: ✓				Date additional controls to be in place:	
Yes ✓ <i>(If medium risk indicate any additional controls desirable)</i>		No <i>(Indicate additional controls required)</i>		Target within 2020	
Final Risk Level: ✓				Low	Medium
				High	Very High

Requirement to Add to Risk Register? ✓	Y	N	Requirement to share Risk Assessment? ✓	Y	N	Services / Depts. shared with:
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Assessed by / Job Title:	Date:	Review Date:
Mike Leach Clinical Director Alistair Hart Consultant Haematology Prof Brian Jones Head of Microbiology Melanie McColgan General Manager Regional Services Myra Campbell Clinical Services Manager Darryl James Conner AP Ventilation Tom Steele Director Estates and Facilities John Green Interim Health and Safety Lead	28 th February 2020	January 2021

Risk Assessment Form – Airborne Pathogens

Appendix 1

Queen Elizabeth University Hospital Wards 4C, 5C, 6C & 7C

Ventilation Proposal

Graham Construction Ltd

Job No: 1031731
Doc Ref: QEUH-CDL-XX-XX-RP-Z-90201
Revision: —
Revision Date: 20 May 2022

Project title	Queen Elizabeth University Hospital Wards 4C, 5C, 6C & 7C	Job Number
Report title	Ventilation Proposal	1031731

Document Revision History

Revision Ref	Issue Date	Purpose of issue / description of revision
—	20 May 2022	Initial issue

Document Validation (latest issue)

 Invalid signature

X Mahmoud Layas

Principal author

Signed by: Layas, Mahmoud

X

Checked by

 Invalid signature

X Tony Centola

Verified by

Signed by: Centola, Tony

Executive Summary

Cundall were appointed by Graham Construction Ltd to assess whether the existing Air Handling Units (AHUs) AHU 04 & AHU 05 located within plant room 124 has any additional capacity to allow the volume of air delivered to the single patient rooms within wards 4C, 5C, 6C and 7C at Queen Elizabeth University Hospital (QEUH) located at 1345 Govan Rd, Glasgow G51 4TF to be increased to allow an air change rate to 6 air changes per hour (ACH) or higher.

This feasibility report will review the existing plant and highlight the associated works required to existing services as well as listing any additional equipment needed to achieve increased ventilation rates.

At the time of writing, we approached Barkell, the manufacturer of the AHUs installed at the QEUH to seek assistance with the three scenarios posed by the end client, NHSGG&C. Barkell originally engaged with us to review modifications and alterations, However, they broke off communications due to ongoing Legal Proceedings between them (Barkell) and their Client, Mercury Engineering.

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1.0

Introduction

1.0 Introduction

1.1 Purpose of analysis

The purpose of this report is to determine the viability for increasing the ventilation rates within the single bedrooms on wards 4C, 5C, 6C and 7C to 6 ach. These wards are located on levels 4 to 7.

This report will only address the impact of increasing the ventilation rates to the single bedroom within these wards. The ventilation rates for all other rooms served by the same system will not be considered and will remain the same.

Ward 4C has 25 No. single bedrooms and floors wards 5C, 6C and 7C have 28 No. single bedrooms on each.

The analysis will also assess the impact this will have on the existing installation and recommended modifications required to facilitate the increase in ventilation rates.

This report will investigate each of the following scenarios as posed by NHSGG&C:

- Utilising existing ductwork, fans and AHU carcasses, can we increase air volume supply to all floors to achieve the required 6 ach.
- Utilising existing ductwork, AHU carcasses and altering the pulleys on the existing fans, can we increase air volume supply to all floors to achieve the required 6 ach.
- Utilising existing ductwork, AHU carcasses and changing the existing fan arrangement to EC fans (perhaps a fan wall), can we increase air volume supply to all floors to achieve the required 6 ach.
- In all of the scenarios above, can we increase the air volume supply to just one floor to 6 ach.

2.0

System description

2.0 System description

2.1 System description

Wards 4C, 5C, 6C and 7C ventilation is currently served by AHU 04 & AHU 05 located on level 12 plantroom 124. The ventilation ducts from the AHUs drop down the mechanical riser to serve floors 4 to 7. Ducts then distribute from the riser through the ceiling voids to serve the wards.

Conditioned air is then supplied to the single bedrooms via a Swegon Parasol ceiling mounted heating / cooling terminal unit. This unit tempers the supply air via heating and cooling coils to achieve the rooms winter and summer design conditions.

Air is extracted from the en-suite, through a door mounted grill and then via a valve type terminal, before being ducted back through the ceiling voids to the mechanical services riser before returning to AHUs 04 & 05 located on level 12.

AHUs 04 & 05 only serve wards 4C, 5C, 6C & 7C with AHU 04 serving the lower portion of the wards and AHU 05 serving the upper portion.

It was noticed that the extract system serving the single bedrooms on the wards also serves the toilets within the general areas.

Extract air volumes are higher than supply volumes meaning that the single bed wards are under negative pressure in relation to corridors.

3.0

Assessment

3.0 Assessment

3.1 Existing room air change rates

The following supply and extract air volumes were calculated based on H&V commissioning data sheets.

3.1.1 Level 4 - Ward 4C

Room No.	Description	Area	Floor to ceiling	Volume	AHU	Terminal ref	Grille ref	Existing air volumes		
								Supply	Extract	ACR
		m ²	m	m ³				l/s	l/s	ac/h
RENW-130	Single Bed	17.36	2.7	46.872	AHU 04	CB/W1/L1	-	40.5		3.1
RENW-128	Ensuite	5.14	2.7	13.878	AHU 04	-	4-509/TG-006		46.2	12.0
RENW-131	Single Bed	18.87	2.7	50.949	AHU 04	CB/W1/L2	-	40		2.8
RENW-1??	Ensuite	5.31	2.7	14.337	AHU 04	-	4-509/TG-007		46.2	11.6
RENW-134	Single Bed	17.78	2.7	48.006	AHU 04	CB/W1/L2	-	40.3		3.0
RENW-133	Ensuite	5.31	2.7	14.337	AHU 04	-	4-509/TG-003		45.1	11.3
RENW-135	Single Bed	17.75	2.7	47.925	AHU 04	CB/W1/L2	-	40		3.0
RENW-136	Ensuite	5.32	2.7	14.364	AHU 04	-	4-509/TG-002		45.1	11.3
RENW-138	Single Bed	17.25	2.7	46.575	AHU 04	CB/W1/L2	-	40.6		3.1
RENW-137	Ensuite	5.32	2.7	14.364	AHU 04	-	4-510/TG-010		45.1	11.3
RENW-140	Single Bed	16.92	2.7	45.684	AHU 04	CB/W1/L2	-	40.6		3.2
RENW-141	Ensuite	5.32	2.7	14.364	AHU 04	-	4-510/TG-012		45.1	11.3
RENW-143	Single Bed	17.62	2.7	47.574	AHU 04	CB/W1/L2	-	40.3		3.0
RENW-14?	Ensuite	5.31	2.7	14.337	AHU 04	-	4-510/TG-011		45.1	11.3
RENW-14?	Single Bed	17.65	2.7	47.655	AHU 04	CB/W1/L2	-	40.6		3.1
RENW-145	Ensuite	5.32	2.7	14.364	AHU 04	-	4-510/TG-013		45.1	11.3
RENW-147	Single Bed	16.97	2.7	45.819	AHU 04	CB/W1/L2	-	40		3.1
RENW-146	Ensuite	5.31	2.7	14.337	AHU 04	-	4-510/TG-014		45.1	11.3
RENW-1??	Single Bed	17.15	2.7	46.305	AHU 04	CB/W1/L2	-	40.3		3.1
RENW-1??	Ensuite	5.32	2.7	14.364	AHU 04	-	4-510/TG-015		45.1	11.3
RENW-152	Single Bed	17.52	2.7	47.304	AHU 04	CB/W1/L2	-	40		3.0
RENW-151	Ensuite	5.31	2.7	14.337	AHU 04	-	4-510/TG-016		46.2	11.6
RENW-154	Single Bed	18.17	2.7	49.059	AHU 04	CB/W1/L2	-	40		2.9
RENW-153	Ensuite	7.9	2.7	21.33	AHU 04	-	4-510/TG-017		45.1	7.6
Sub total								483	545	

Room No.	Description	Area	Floor to ceiling	Volume	AHU	Terminal ref	Grille ref	Existing air volumes		
								Supply	Extract	ACR
		m ²	m	m ³				l/s	l/s	ac/h
RENW-155	Single Bed	18.5	2.7	49.95	AHU 05	CB/W1/L2	-	41.6		3.0
RENW-156	Ensuite	7.67	2.7	20.709	AHU 05	-	4-510/TG-001		45.2	7.9
RENW-15?	Single Bed	17.36	2.7	46.872	AHU 05	CB/W1/L2	-	40.6		3.1
RENW-158	Ensuite	5.28	2.7	14.256	AHU 05	-	4-510/TG-003		45.2	11.4
RENW-15?	Single Bed	17.02	2.7	45.954	AHU 05	CB/W1/L2	-	40.6		3.2
RENW-159	Ensuite	5.32	2.7	14.364	AHU 05	-	4-510/TG-002		45.2	11.3
RENW-162	Single Bed	17.17	2.7	46.359	AHU 05	CB/W1/L2	-	41.3		3.2
RENW-1??	Ensuite	5.35	2.7	14.445	AHU 05	-	4-510/TG-004		45.2	11.3
RENW-165	Single Bed	17.69	2.7	47.763	AHU 05	CB/W1/L2	-	40.3		3.0
RENW-164	Ensuite	5.31	2.7	14.337	AHU 05	-	4-510/TG-005		45.2	11.3
RENW-16?	Single Bed	17.41	2.7	47.007	AHU 05	CB/W1/L2	-	41.6		3.2
RENW-167	Ensuite	5.32	2.7	14.364	AHU 05	-	4-510/TG-007		45.2	11.3
RENW-16?	Single Bed	17.15	2.7	46.305	AHU 05	CB/W1/L2	-	40		3.1
RENW-168	Ensuite	5.31	2.7	14.337	AHU 05	-	4-510/TG-006		46.33	11.6
RENW-1??	Single Bed	16.85	2.7	45.495	AHU 05	CB/W1/L2	-	40.6		3.2
RENW-1??	Ensuite	5.3	2.7	14.31	AHU 05	-	4-510/TG-008		45.2	11.4
RENW-1??	Single Bed	17.75	2.7	47.925	AHU 05	CB/W1/L2	-	41.3		3.1
RENW-1??	Ensuite	5.31	2.7	14.337	AHU 05	-	4-511/TG-005		45.2	11.3
RENW-1??	Single Bed	17.16	2.7	46.332	AHU 05	CB/W1/L1	-	40.5		3.1
RENW-1??	Ensuite	5.15	2.7	13.905	AHU 05	-	4-511/TG-004		45.2	11.7
RENW-1??	Single Bed	17.17	2.7	46.359	AHU 05	CB/W1/L1	-	40.1		3.1
RENW-1??	Ensuite	5.12	2.7	13.824	AHU 05	-	4-511/TG-003		47.46	12.4
RENW-1??	Single Bed	16.99	2.7	45.873	AHU 05	CB/W1/L1	-	40.1		3.1
RENW-1??	Ensuite	5.14	2.7	13.878	AHU 05	-	4-511/TG-002		45.2	11.7
RENW-1??	Single Bed	16.88	2.7	45.576	AHU 05	CB/W1/L1	-	40.1		3.2
RENW-1??	Ensuite	5.16	2.7	13.932	AHU 05	-	4-511/TG-001		45.2	11.7
Sub total								529	591	

3.1.2 Level 5 to 7 – Typical Ward

Room No.	Description	Area	Floor to ceiling	Volume	AHU	Terminal ref	Grille ref	Existing air volumes		
								Supply	Extract	ACR
		m ²	m	m ³				l/s	l/s	ac/h
GENWC-0??	Single Bed	19.95	2.7	53.865	AHU 04	CB/W1/L1	-	40.1		2.7
GENWC-002	Ensuite	5.16	2.7	13.932	AHU 04	-	5-509/TG-007		45.1	11.7
GENWC-004	Single Bed	16.75	2.7	45.225	AHU 04	CB/W1/L1	-	40.1		3.2
GENWC-???	Ensuite	5.15	2.7	13.905	AHU 04	-	5-509/TG-006		45.1	11.7
GENWC-???	Single Bed	16.63	2.7	44.901	AHU 04	CB/W1/L1	-	40.1		3.2
GENWC-???	Ensuite	5.17	2.7	13.959	AHU 04	-	5-509/TG-004		45.1	11.6
GENWC-???	Single Bed	17.28	2.7	46.656	AHU 04	CB/W1/L1	-	40.1		3.1
GENWC-???	Ensuite	5.16	2.7	13.932	AHU 04	-	5-509/TG-005		45.1	11.7
GENWC-010	Single Bed	18.78	2.7	50.706	AHU 04	CB/W1/L1	-	40.1		2.8
GENWC-???	Ensuite	5.31	2.7	14.337	AHU 04	-	5-509/TG-003		45.1	11.3
GENWC-013	Single Bed	17.8	2.7	48.06	AHU 04	CB/W1/L1	-	40.1		3.0
GENWC-012	Ensuite	5.31	2.7	14.337	AHU 04	-	5-509/TG-002		45.1	11.3
GENWC-014	Single Bed	17.67	2.7	47.709	AHU 04	CB/W1/L1	-	40.5		3.1
GENWC-015	Ensuite	5.31	2.7	14.337	AHU 04	-	5-509/TG-001		45.1	11.3
GENWC-017	Single Bed	17.26	2.7	46.602	AHU 04	CB/W1/L1	-	41.2		3.2
GENWC-016	Ensuite	5.32	2.7	14.364	AHU 04	-	5-510/TG-011		45.1	11.3
GENWC-019	Single Bed	16.94	2.7	45.738	AHU 04	CB/W1/L1	-	40.5		3.2
GENWC-020	Ensuite	5.31	2.7	14.337	AHU 04	-	5-510/TG-013		45.1	11.3
GENWC-022	Single Bed	17.63	2.7	47.601	AHU 04	CB/W1/L1	-	40.8		3.1
GENWC-???	Ensuite	5.32	2.7	14.364	AHU 04	-	5-510/TG-012		45.1	11.3
GENWC-023	Single Bed	17.65	2.7	47.655	AHU 04	CB/W1/L1	-	40.5		3.1
GENWC-024	Ensuite	5.31	2.7	14.337	AHU 04	-	5-510/TG-015		45.1	11.3
GENWC-026	Single Bed	17.08	2.7	46.116	AHU 04	CB/W1/L1	-	40.5		3.2
GENWC-???	Ensuite	5.32	2.7	14.364	AHU 04	-	5-510/TG-016		45.2	11.3
GENWC-028	Single Bed	17.15	2.7	46.305	AHU 04	CB/W1/L1	-	40.5		3.1
GENWC-029	Ensuite	5.32	2.7	14.364	AHU 04	-	5-510/TG-017		45.2	11.3
GENWC-031	Single Bed	17.49	2.7	47.223	AHU 04	CB/W1/L1	-	40.1		3.1
GENWC-???	Ensuite	5.31	2.7	14.337	AHU 04	-	5-510/TG-018		45.2	11.3
Sub total								565	632	

Room No.	Description	Area	Floor to ceiling	Volume	AHU	Terminal ref	Grille ref	Existing air volumes		
								Supply	Extract	ACR
		m ²	m	m ³				l/s	l/s	ac/h
GENWC-033	Single Bed	19.59	2.7	52.893	AHU 05	CB/W1/L1	-	40.1		2.7
GENWC-034	Ensuite	8.28	2.7	22.356	AHU 05	-	5-510/TG-001		45.2	7.3
GENWC-035	Single Bed	17.16	2.7	46.332	AHU 05	CB/W1/L3	-	40		3.1
GENWC-???	Ensuite	5.31	2.7	14.337	AHU 05	-	5-510/TG-003		46.33	11.6
GENWC-038	Single Bed	17.18	2.7	46.386	AHU 05	CB/W1/L3	-	40		3.1
GENWC-???	Ensuite	5.31	2.7	14.337	AHU 05	-	5-510/TG-002		45.2	11.3
GENWC-040	Single Bed	17.18	2.7	46.386	AHU 05	CB/W1/L3	-	40		3.1
GENWC-???	Ensuite	5.31	2.7	14.337	AHU 05	-	5-510/TG-004		45.2	11.3
GENWC-???	Single Bed	17.67	2.7	47.709	AHU 05	CB/W1/L3	-	40.3		3.0
GENWC-???	Ensuite	5.31	2.7	14.337	AHU 05	-	5-510/TG-005		48.59	12.2
GENWC-???	Single Bed	17.4	2.7	46.98	AHU 05	CB/W1/L3*	-	40		3.1
GENWC-045	Ensuite	5.31	2.7	14.337	AHU 05	-	5-510/TG-007		45.2	11.3
GENWC-???	Single Bed	17.15	2.7	46.305	AHU 05	CB/W1/L3	-	40		3.1
GENWC-???	Ensuite	5.31	2.7	14.337	AHU 05	-	5-510/TG-006		46.33	11.6
GENWC-049	Single Bed	16.86	2.7	45.522	AHU 05	CB/W1/L3	-	40		3.2
GENWC-050	Ensuite	5.32	2.7	14.364	AHU 05	-	5-510/TG-008		45.2	11.3
GENWC-052	Single Bed	17.72	2.7	47.844	AHU 05	CB/W1/L3	-	40		3.0
GENWC-051	Ensuite	5.31	2.7	14.337	AHU 05	-	5-511/TG-007		45.2	11.3
GENWC-053	Single Bed	19.41	2.7	52.407	AHU 05	CB/W1/L3	-	40.3		2.8
GENWC-056	Ensuite	5.61	2.7	15.147	AHU 05	-	5-511/TG-006		45.2	10.7
GENWC-057	Single Bed	16.69	2.7	45.063	AHU 05	CB/W1/L3	-	40		3.2
GENWC-058	Ensuite	5.15	2.7	13.905	AHU 05	-	5-511/TG-004		45.2	11.7
GENWC-060	Single Bed	17.09	2.7	46.143	AHU 05	CB/W1/L3	-	40		3.1
GENWC-059	Ensuite	5.12	2.7	13.824	AHU 05	-	5-511/TG-005		45.2	11.8
GENWC-062	Single Bed	17.08	2.7	46.116	AHU 05	CB/W1/L3	-	40		3.1
GENWC-063	Ensuite	5.15	2.7	13.905	AHU 05	-	5-511/TG-002		45.2	11.7
GENWC-???	Single Bed	16.91	2.7	45.657	AHU 05	CB/W1/L3	-	40		3.2
GENWC-064	Ensuite	5.15	2.7	13.905	AHU 05	-	5-511/TG-003		46.33	12.0
Sub total								561	640	

Note: the maximum fresh air supply to the existing Swegon Parasol ceiling terminals is limited to 40 l/s.

The tables above illustrate the existing ventilation air change rate for the single bedrooms to be between 2.7 to 3.2 ach.

3.2 Proposed air volumes

The following supply and extract air volumes were calculated to achieve the required 6 ach. Note, we have assumed balanced air volumes for the purposes of the report. If the single bed wards are to be under negative pressure this will increase the extract volumes.

3.2.1 Level 4 - Ward 4C

Room No.	Description	Area	Floor to ceiling	Volume	AHU	Terminal ref	Grille ref	Existing air volumes		
								Supply	Extract	ACR
		m ²	m	m ³				l/s	l/s	ac/h
RENEW-130	Single Bed	17.36	2.7	46.872	AHU 04	CB/W1/L1	-	78	-	6
RENEW-128	En-suite	5.14	2.7	13.878	AHU 04	-	4-509/TG-006	-	78	20.3
RENEW-131	Single Bed	18.87	2.7	50.949	AHU 04	CB/W1/L2	-	85	-	6
RENEW-1??	En-suite	5.31	2.7	14.337	AHU 04	-	4-509/TG-007	-	85	21.3
RENEW-134	Single Bed	17.78	2.7	48.006	AHU 04	CB/W1/L2	-	80	-	6
RENEW-133	En-suite	5.31	2.7	14.337	AHU 04	-	4-509/TG-003	-	80	20.1
RENEW-135	Single Bed	17.75	2.7	47.925	AHU 04	CB/W1/L2	-	80	-	6
RENEW-136	En-suite	5.32	2.7	14.364	AHU 04	-	4-509/TG-002	-	80	20.0
RENEW-138	Single Bed	17.25	2.7	46.575	AHU 04	CB/W1/L2	-	78	-	6
RENEW-137	En-suite	5.32	2.7	14.364	AHU 04	-	4-510/TG-010	-	78	19.5
RENEW-140	Single Bed	16.92	2.7	45.684	AHU 04	CB/W1/L2	-	76	-	6
RENEW-141	En-suite	5.32	2.7	14.364	AHU 04	-	4-510/TG-012	-	76	19.1
RENEW-143	Single Bed	17.62	2.7	47.574	AHU 04	CB/W1/L2	-	79	-	6
RENEW-14?	En-suite	5.31	2.7	14.337	AHU 04	-	4-510/TG-011	-	79	19.9
RENEW-14?	Single Bed	17.65	2.7	47.655	AHU 04	CB/W1/L2	-	79	-	6
RENEW-145	En-suite	5.32	2.7	14.364	AHU 04	-	4-510/TG-013	-	79	19.9
RENEW-147	Single Bed	16.97	2.7	45.819	AHU 04	CB/W1/L2	-	76	-	6
RENEW-146	En-suite	5.31	2.7	14.337	AHU 04	-	4-510/TG-014	-	76	19.2
RENEW-1??	Single Bed	17.15	2.7	46.305	AHU 04	CB/W1/L2	-	77	-	6
RENEW-1??	En-suite	5.32	2.7	14.364	AHU 04	-	4-510/TG-015	-	77	19.3
RENEW-152	Single Bed	17.52	2.7	47.304	AHU 04	CB/W1/L2	-	79	-	6
RENEW-151	En-suite	5.31	2.7	14.337	AHU 04	-	4-510/TG-016	-	79	19.8
RENEW-154	Single Bed	18.17	2.7	49.059	AHU 04	CB/W1/L2	-	82	-	6
RENEW-153	En-suite	7.9	2.7	21.33	AHU 04	-	4-510/TG-017	-	82	13.8
Sub total								950	950	

Room No.	Description	Area	Floor to ceiling	Volume	AHU	Terminal ref	Grille ref	Existing air volumes		
								Supply	Extract	ACR
		m ²	m	m ³				l/s	l/s	ac/h
RENW-155	Single Bed	18.5	2.7	49.95	AHU 05	CB/W1/L2	-	83	-	6
RENW-156	En-suite	7.67	2.7	20.709	AHU 05	-	4-510/TG-001	-	83	14.5
RENW-15?	Single Bed	17.36	2.7	46.872	AHU 05	CB/W1/L2	-	78	-	6
RENW-158	En-suite	5.28	2.7	14.256	AHU 05	-	4-510/TG-003	-	78	19.7
RENW-15?	Single Bed	17.02	2.7	45.954	AHU 05	CB/W1/L2	-	77	-	6
RENW-159	En-suite	5.32	2.7	14.364	AHU 05	-	4-510/TG-002	-	77	19.2
RENW-162	Single Bed	17.17	2.7	46.359	AHU 05	CB/W1/L2	-	77	-	6
RENW-1??	En-suite	5.35	2.7	14.445	AHU 05	-	4-510/TG-004	-	77	19.3
RENW-165	Single Bed	17.69	2.7	47.763	AHU 05	CB/W1/L2	-	80	-	6
RENW-164	En-suite	5.31	2.7	14.337	AHU 05	-	4-510/TG-005	-	80	20.0
RENW-16?	Single Bed	17.41	2.7	47.007	AHU 05	CB/W1/L2	-	78	-	6
RENW-167	En-suite	5.32	2.7	14.364	AHU 05	-	4-510/TG-007	-	78	19.6
RENW-16?	Single Bed	17.15	2.7	46.305	AHU 05	CB/W1/L2	-	77	-	6
RENW-168	En-suite	5.31	2.7	14.337	AHU 05	-	4-510/TG-006	-	77	19.4
RENW-1??	Single Bed	16.85	2.7	45.495	AHU 05	CB/W1/L2	-	76	-	6
RENW-1??	En-suite	5.3	2.7	14.31	AHU 05	-	4-510/TG-008	-	76	19.1
RENW-1??	Single Bed	17.75	2.7	47.925	AHU 05	CB/W1/L2	-	80	-	6
RENW-1??	En-suite	5.31	2.7	14.337	AHU 05	-	4-511/TG-005	-	80	20.1
RENW-1??	Single Bed	17.16	2.7	46.332	AHU 05	CB/W1/L1	-	77	-	6
RENW-1??	En-suite	5.15	2.7	13.905	AHU 05	-	4-511/TG-004	-	77	20.0
RENW-1??	Single Bed	17.17	2.7	46.359	AHU 05	CB/W1/L1	-	77	-	6
RENW-1??	En-suite	5.12	2.7	13.824	AHU 05	-	4-511/TG-003	-	77	20.1
RENW-1??	Single Bed	16.99	2.7	45.873	AHU 05	CB/W1/L1	-	76	-	6
RENW-1??	En-suite	5.14	2.7	13.878	AHU 05	-	4-511/TG-002	-	76	19.8
RENW-1??	Single Bed	16.88	2.7	45.576	AHU 05	CB/W1/L1	-	76	-	6
RENW-1??	En-suite	5.16	2.7	13.932	AHU 05	-	4-511/TG-001	-	76	19.6
Sub total								1013	1013	

Level 5 to 7 – Typical Ward

Room No.	Description	Area	Floor to ceiling	Volume	AHU	Terminal ref	Grille ref	Existing air volumes		
								Supply	Extract	ACR
		m ²	m	m ³				l/s	l/s	ac/h
GENWC-0??	Single Bed	19.95	2.7	53.865	AHU 04	CB/W1/L1	-	90	-	6
GENWC-002	En-suite	5.16	2.7	13.932	AHU 04	-	5-509/TG-007	-	90	23.2
GENWC-004	Single Bed	16.75	2.7	45.225	AHU 04	CB/W1/L1	-	75	-	6
GENWC-???	En-suite	5.15	2.7	13.905	AHU 04	-	5-509/TG-006	-	75	19.5
GENWC-???	Single Bed	16.63	2.7	44.901	AHU 04	CB/W1/L1	-	75	-	6
GENWC-???	En-suite	5.17	2.7	13.959	AHU 04	-	5-509/TG-004	-	75	19.3
GENWC-???	Single Bed	17.28	2.7	46.656	AHU 04	CB/W1/L1	-	78	-	6
GENWC-???	En-suite	5.16	2.7	13.932	AHU 04	-	5-509/TG-005	-	78	20.1
GENWC-010	Single Bed	18.78	2.7	50.706	AHU 04	CB/W1/L1	-	85	-	6
GENWC-???	En-suite	5.31	2.7	14.337	AHU 04	-	5-509/TG-003	-	85	21.2
GENWC-013	Single Bed	17.8	2.7	48.06	AHU 04	CB/W1/L1	-	80	-	6
GENWC-012	En-suite	5.31	2.7	14.337	AHU 04	-	5-509/TG-002	-	80	20.1
GENWC-014	Single Bed	17.67	2.7	47.709	AHU 04	CB/W1/L1	-	80	-	6
GENWC-015	En-suite	5.31	2.7	14.337	AHU 04	-	5-509/TG-001	-	80	20.0
GENWC-017	Single Bed	17.26	2.7	46.602	AHU 04	CB/W1/L1	-	78	-	6
GENWC-016	En-suite	5.32	2.7	14.364	AHU 04	-	5-510/TG-011	-	78	19.5
GENWC-019	Single Bed	16.94	2.7	45.738	AHU 04	CB/W1/L1	-	76	-	6
GENWC-020	En-suite	5.31	2.7	14.337	AHU 04	-	5-510/TG-013	-	76	19.1
GENWC-022	Single Bed	17.63	2.7	47.601	AHU 04	CB/W1/L1	-	79	-	6
GENWC-???	En-suite	5.32	2.7	14.364	AHU 04	-	5-510/TG-012	-	79	19.9
GENWC-023	Single Bed	17.65	2.7	47.655	AHU 04	CB/W1/L1	-	79	-	6
GENWC-024	En-suite	5.31	2.7	14.337	AHU 04	-	5-510/TG-015	-	79	19.9
GENWC-026	Single Bed	17.08	2.7	46.116	AHU 04	CB/W1/L1	-	77	-	6
GENWC-???	En-suite	5.32	2.7	14.364	AHU 04	-	5-510/TG-016	-	77	19.3
GENWC-028	Single Bed	17.15	2.7	46.305	AHU 04	CB/W1/L1	-	77	-	6
GENWC-029	En-suite	5.32	2.7	14.364	AHU 04	-	5-510/TG-017	-	77	19.3
GENWC-031	Single Bed	17.49	2.7	47.223	AHU 04	CB/W1/L1	-	79	-	6
GENWC-???	En-suite	5.31	2.7	14.337	AHU 04	-	5-510/TG-018	-	79	19.8
Sub total								1107	1107	

Room No.	Description	Area	Floor to ceiling	Volume	AHU	Terminal ref	Grille ref	Existing air volumes		
								Supply	Extract	ACR
		m ²	m	m ³				l/s	l/s	ac/h
GENWC-033	Single Bed	19.59	2.7	52.893	AHU 05	CB/W1/L1	-	88	-	6
GENWC-034	En-suite	8.28	2.7	22.356	AHU 05	-	5-510/TG-001	-	88	14.2
GENWC-035	Single Bed	17.16	2.7	46.332	AHU 05	CB/W1/L3	-	77	-	6
GENWC-???	En-suite	5.31	2.7	14.337	AHU 05	-	5-510/TG-003	-	77	19.4
GENWC-038	Single Bed	17.18	2.7	46.386	AHU 05	CB/W1/L3	-	77	-	6
GENWC-???	En-suite	5.31	2.7	14.337	AHU 05	-	5-510/TG-002	-	77	19.4
GENWC-040	Single Bed	17.18	2.7	46.386	AHU 05	CB/W1/L3	-	77	-	6
GENWC-???	En-suite	5.31	2.7	14.337	AHU 05	-	5-510/TG-004	-	77	19.4
GENWC-???	Single Bed	17.67	2.7	47.709	AHU 05	CB/W1/L3	-	80	-	6
GENWC-???	En-suite	5.31	2.7	14.337	AHU 05	-	5-510/TG-005	-	80	20.0
GENWC-???	Single Bed	17.4	2.7	46.98	AHU 05	CB/W1/L3*	-	78	-	6
GENWC-045	En-suite	5.31	2.7	14.337	AHU 05	-	5-510/TG-007	-	78	19.7
GENWC-???	Single Bed	17.15	2.7	46.305	AHU 05	CB/W1/L3	-	77	-	6
GENWC-???	En-suite	5.31	2.7	14.337	AHU 05	-	5-510/TG-006	-	77	19.4
GENWC-049	Single Bed	16.86	2.7	45.522	AHU 05	CB/W1/L3	-	76	-	6
GENWC-050	En-suite	5.32	2.7	14.364	AHU 05	-	5-510/TG-008	-	76	19.0
GENWC-052	Single Bed	17.72	2.7	47.844	AHU 05	CB/W1/L3	-	80	-	6
GENWC-051	En-suite	5.31	2.7	14.337	AHU 05	-	5-511/TG-007	-	80	20.0
GENWC-053	Single Bed	19.41	2.7	52.407	AHU 05	CB/W1/L3	-	87	-	6
GENWC-056	En-suite	5.61	2.7	15.147	AHU 05	-	5-511/TG-006	-	87	20.8
GENWC-057	Single Bed	16.69	2.7	45.063	AHU 05	CB/W1/L3	-	75	-	6
GENWC-058	En-suite	5.15	2.7	13.905	AHU 05	-	5-511/TG-004	-	75	19.4
GENWC-060	Single Bed	17.09	2.7	46.143	AHU 05	CB/W1/L3	-	77	-	6
GENWC-059	En-suite	5.12	2.7	13.824	AHU 05	-	5-511/TG-005	-	77	20.0
GENWC-062	Single Bed	17.08	2.7	46.116	AHU 05	CB/W1/L3	-	77	-	6
GENWC-063	En-suite	5.15	2.7	13.905	AHU 05	-	5-511/TG-002	-	77	19.9
GENWC-???	Single Bed	16.91	2.7	45.657	AHU 05	CB/W1/L3	-	76	-	6
GENWC-064	En-suite	5.15	2.7	13.905	AHU 05	-	5-511/TG-003	-	76	19.7
Sub total								1103	1103	

4.0

Impact on the existing installation

4.0 Impact on the existing installation

4.1 Air Handling Units

From the information provided, the manufacturers technical detail for the existing AHUs are as follow:

AHU ref:	AHU 04	AHU ref:	AHU 05
Manufacturer:	BARKELL Ltd	Manufacturer:	BARKELL Ltd
Fan model:	TZAF400FFR	Fan model:	TZAF400FFR
Design supply air flow (100%):	2.56 m ³ /s	Design supply air flow (100%):	2.36 m ³ /s
Design supply air flow (125%):	3.2 m ³ /s	Design supply air flow (125%):	2.95 m ³ /s
Total static pressure:	928 Pa	Total static pressure:	852 Pa
Fan model:	TZAF450FFR	Fan model:	TZAF500FFR
Design extract air flow (100%):	2.61 m ³ /s	Design extract air flow (100%):	3.06 m ³ /s
Design extract air flow (125%):	3.26 m ³ /s	Design extract air flow (125%):	3.83 m ³ /s
Total static pressure:	657 Pa	Total static pressure:	676 Pa

Table 4.1 – Existing AHUs information

Note:

- The technical information provided states that the existing AHUs are designed to operate at 125% duty.
- AHUs are manufactured to DW143 Class B leakage standard.

The H&V commissioning sheets identifies the following:

AHU ref:	Supply		Extract	
	Design (m ³ /s)	Actual (m ³ /s)	Design (m ³ /s)	Actual (m ³ /s)
AHU 04	2.56	2.788	2.608	2.75
AHU 05	2.36	2.502	3.064	3.193

Table 4.2 – AHU 04 Existing, required and shortfall supply and extract rates serving single bedrooms per floor

The table below shows the required AHU duties in order to achieve the required 6 ach to all the single bedrooms within all 4 floors:

AHU 04

Floor	Existing		Required		Shortfall	
	Supply	Extract	Supply	Extract	Supply	Extract
	l/s	l/s	l/s	l/s	l/s	l/s
4th	483	545	914	914	431	370
5th	565	632	1066	1066	501	435
6th	569	649	1063	1063	494	414
7th	562	648	1065	1065	503	417
Total	2180	2473	4109	4109	1929	1636

Table 4.3 – AHU 04 Existing, required and shortfall supply and extract rates serving single bedrooms per floor

AHU 05

Floor	Existing		Required		Shortfall	
	Supply	Extract	Supply	Extract	Supply	Extract
	l/s	l/s	l/s	l/s	l/s	l/s
4th	529	591	975	975	447	384
5th	561	640	1062	1062	501	422
6th	569	649	1066	1066	497	417
7th	565	652	1061	1061	496	409
Total	2223	2531	4165	4165	1941	1634

Table 4.4 – AHU 05 Existing, required and shortfall supply and extract rates serving single bedrooms per floor

Note: The total volumes shown above are the sum of the ventilation rates required for the single rooms only and do not include other rooms served by the same system e.g. Day Trolleys rooms, non ensuite WCs etc.

The AHU manufacturer confirmed that the existing AHUs cannot provide the required air volumes to achieve single bedroom 6 ach. The limiting factors are the existing fans, motors and cooling and heating coils. The manufacturer confirmed that by replacing the existing belt driven fans with a more efficient solution such as an EC plenum direct drive fan array (fan motors will be located in the airstream) and replacing the existing cooling and heating coil section on the supply AHU with a taller section and larger coils section, the existing AHU duties can be increased.

We were awaiting confirmation from the AHU manufacturer on what additional air volume these changes will achieve. This would have determined the number of floors this option could serve.

4.1.1 Supply and extract duct

4.1.1.1 Riser:

The following table illustrates the impact of increasing the ventilation rates on the riser ductwork:

AHU	System	Floor	Duct size	Existing		Proposed	
				Flowrate	Velocity	Flowrate	Velocity
			(mm x mm)	(m ³ /s)	(m/s)	(m ³ /s)	(m/s)
AHU 04	Extract	4	550 x 300	0.660	4.0	1.065	6.5
AHU 04	Extract	5	600 x 500	1.317	4.4	2.197	7.3
AHU 04	Extract	6	750 x 600	1.989	4.4	3.324	7.4
AHU 04	Extract	7	1000 x 600	2.660	4.4	4.453	7.4
AHU 04	Extract	12	1000 x 600	2.660	4.4	4.453	7.4
AHU 04	Supply	4	500 x 400	0.683	3.4	1.150	5.8
AHU 04	Supply	5	600 x 500	1.328	4.4	2.337	7.8
AHU 04	Supply	6	900 x 500	1.978	4.4	3.522	7.8
AHU 04	Supply	7	1000 x 600	2.620	4.4	4.708	7.8
AHU 04	Supply	12	1000 x 600	2.620	4.4	4.708	7.8
AHU 05	Extract	4	550 x 350	0.723	3.8	1.145	5.9
AHU 05	Extract	5	675 x 550	1.530	4.1	2.415	6.5
AHU 05	Extract	6	850 x 650	2.341	4.2	3.684	6.7
AHU 05	Extract	7	1150 x 650	3.156	4.2	4.949	6.6
AHU 05	Extract	12	1150 x 650	3.156	4.2	4.949	6.6
AHU 05	Supply	4	500 x 350	0.697	4.0	1.181	6.7
AHU 05	Supply	5	600 x 500	1.258	4.2	2.284	7.6
AHU 05	Supply	6	700 x 600	1.826	4.3	3.390	8.1
AHU 05	Supply	7	900 x 600	2.392	4.4	4.493	8.3
AHU 05	Supply	12	900 x 600	2.392	4.4	4.493	8.3

Table 4.1.1.1 – Air velocities within the existing riser

CIBSE guide B table 3.4 recommends the maximum air velocity within risers for rectangular duct in critical areas should be limited to 5 m/s and 7.5m/s in normal areas.

Table 1.5.2.1 shows by increasing the air volumes within the existing riser ducts to the required volumes to achieve the 6 ach would increase the air velocity within the ducts to above the CIBSE guidance.

Due to spatial constraints within the riser, there is minimal scope to increase the size of the ducts within the riser particularly from levels 12 through to 7. If the trust deems the increase in air velocities within the riser ducts acceptable, the existing riser ducts may be retained. The riser ducts may be acoustically treated if required.

4.1.1.2 Supply and extract duct

Level 5 AHU 04 and AHU 05 Supply and extract duct

Level 5

AHU 04 - Supply - Branch 1

Ref	AHU	System	Floor	Duct size	Existing		Proposed	
					Flowrate	Velocity	Flowrate	Velocity
				(mm x mm) / Ømm	(m³/s)	(m/s)	(m³/s)	(m/s)
1	AHU 04	Supply	5	160 Ø	0.040	2.0	0.090	4.5
2	AHU 04	Supply	5	200 Ø	0.080	2.6	0.165	5.3
3	AHU 04	Supply	5	250 x 200	0.120	2.4	0.240	4.8
4	AHU 04	Supply	5	250 x 200	0.160	3.2	0.318	6.4
5	AHU 04	Supply	5	350 x 200	0.201	2.9	0.402	5.7
6	AHU 04	Supply	5	350 x 200	0.241	3.4	0.482	6.9
7	AHU 04	Supply	5	400 x 200	0.281	3.5	0.562	7.0
8	AHU 04	Supply	5	450 x 200	0.322	3.6	0.640	7.1
9	AHU 04	Supply	5	500 x 200	0.363	3.6	0.716	7.2
10	AHU 04	Supply	5	500 x 200	0.404	4.0	0.795	8.0

Table 4.1.1.2 – Air velocities within the existing distribution ducts

Level 5

AHU 04 - Supply - Branch 2

Ref	AHU	System	Floor	Duct size	Existing		Proposed	
					Flowrate	Velocity	Flowrate	Velocity
				(mm x mm) / Ømm	(m³/s)	(m/s)	(m³/s)	(m/s)
1	AHU 04	Supply	5	160 Ø	0.040	2.0	0.040	2.0
2	AHU 04	Supply	5	200 Ø	0.080	2.5	0.080	2.5
3	AHU 04	Supply	5	250 x 200	0.121	2.4	0.159	3.2
4	AHU 04	Supply	5	300 x 200	0.161	2.7	0.236	3.9
5	AHU 04	Supply	5	300 x 200	0.202	3.4	0.313	5.2
6	AHU 04	Supply	5	400 x 200	0.242	3.0	0.392	4.9

Table 4.1.1.3 – Air velocities within the existing distribution ducts

Level 5

AHU 05 - Supply - Branch 1

Ref	AHU	System	Floor	Duct size	Existing		Proposed	
					Flowrate	Velocity	Flowrate	Velocity
				(mm x mm) / Ømm	(m³/s)	(m/s)	(m³/s)	(m/s)
1	AHU 05	Supply	5	160 Ø	0.040	2.0	0.088	4.4
2	AHU 05	Supply	5	200 Ø	0.080	2.5	0.165	5.3
3	AHU 05	Supply	5	250 x 200	0.120	2.4	0.243	4.9
4	AHU 05	Supply	5	250 x 200	0.160	3.2	0.320	6.4
5	AHU 05	Supply	5	300 x 200	0.200	3.3	0.400	6.7
6	AHU 05	Supply	5	350 x 200	0.240	3.4	0.478	6.8

Table 4.1.1.4 – Air velocities within the existing distribution ducts

Level 5

AHU 05 - Supply - Branch 2

Ref	AHU	System	Floor	Duct size	Existing		Proposed	
					Flowrate	Velocity	Flowrate	Velocity
				(mm x mm) / Ømm	(m³/s)	(m/s)	(m³/s)	(m/s)
1	AHU 05	Supply	5	160 Ø	0.040	2.0	0.076	3.8
2	AHU 05	Supply	5	200 Ø	0.080	2.5	0.153	4.9
3	AHU 05	Supply	5	250 x 200	0.120	2.4	0.230	4.6
4	AHU 05	Supply	5	250 x 200	0.160	3.2	0.305	6.1
5	AHU 05	Supply	5	300 x 200	0.200	3.3	0.392	6.5
6	AHU 05	Supply	5	350 x 200	0.240	3.4	0.472	6.7
7	AHU 05	Supply	5	400 x 200	0.280	3.5	0.548	6.9
8	AHU 05	Supply	5	450 x 200	0.320	3.6	0.625	6.9
9	AHU 05	Supply	5	350 x 250	0.320	3.7	0.625	7.1

Table 4.1.1.5 – Air velocities within the existing distribution ducts

Level 5

AHU 04 - Extract - Branch 1

Ref	AHU	System	Floor	Duct size	Existing		Proposed	
					Flowrate	Velocity	Flowrate	Velocity
				(mm x mm) / Ømm	(m³/s)	(m/s)	(m³/s)	(m/s)
1	AHU 04	Extract	5	160 Ø	0.045	2.2	0.090	4.5
2	AHU 04	Extract	5	200 Ø	0.090	2.9	0.165	5.3
3	AHU 04	Extract	5	250 Ø	0.135	2.8	0.240	4.9
4	AHU 04	Extract	5	300 x 250	0.180	2.4	0.318	4.2
5	AHU 04	Extract	5	300 x 250	0.226	3.0	0.402	5.4
6	AHU 04	Extract	5	350 x 250	0.271	3.1	0.482	5.5
7	AHU 04	Extract	5	400 x 250	0.316	3.2	0.562	5.6
8	AHU 04	Extract	5	450 x 250	0.361	3.2	0.640	5.7
9	AHU 04	Extract	5	500 x 250	0.406	3.2	0.716	5.7
10	AHU 04	Extract	5	550 x 250	0.451	3.3	0.795	5.8
11	AHU 04	Extract	5	550 x 250	0.496	3.6	0.875	6.4
12	AHU 04	Extract	5	550 x 250	0.587	4.3	1.029	7.5
13	AHU 04	Extract	5	550 x 250	0.632	4.6	1.107	8.1
14	AHU 04	Extract	5	550 x 250	0.654	4.8	1.129	8.2

Table 4.1.1.6 – Air velocities within the existing distribution ducts

Level 5

AHU 05 - Extract - Branch 1

Ref	AHU	System	Floor	Duct size	Existing		Proposed	
					Flowrate	Velocity	Flowrate	Velocity
				(mm x mm) / Ømm	(m³/s)	(m/s)	(m³/s)	(m/s)
1	AHU 05	Extract	5	160 Ø	0.045	2.2	0.088	4.4
2	AHU 05	Extract	5	200 Ø	0.092	2.9	0.165	5.3
3	AHU 05	Extract	5	250 Ø	0.137	2.8	0.243	4.9
4	AHU 05	Extract	5	250 Ø	0.182	3.7	0.320	6.5
5	AHU 05	Extract	5	250 x 250	0.231	3.7	0.400	6.4

Table 4.1.1.7 – Air velocities within the existing distribution ducts

Level 5

AHU 05 - Extract - Branch 2

Ref	AHU	System	Floor	Duct size	Existing		Proposed	
					Flowrate	Velocity	Flowrate	Velocity
				(mm x mm) / Ømm	(m³/s)	(m/s)	(m³/s)	(m/s)
1	AHU 05	Extract	5	160 Ø	0.038	1.9	0.038	1.9
2	AHU 05	Extract	5	200 Ø	0.084	2.7	0.117	3.7
3	AHU 05	Extract	5	200 Ø	0.130	4.1	0.194	6.2
4	AHU 05	Extract	5	350 x 200	0.175	2.5	0.270	3.9
5	AHU 05	Extract	5	350 x 200	0.220	3.1	0.350	5.0
6	AHU 05	Extract	5	400 x 200	0.266	3.3	0.437	5.5
7	AHU 05	Extract	5	350 x 250	0.311	3.6	0.512	5.9
8	AHU 05	Extract	5	400 x 250	0.356	3.6	0.589	5.9
9	AHU 05	Extract	5	450 x 250	0.401	3.6	0.666	5.9
10	AHU 05	Extract	5	500 x 250	0.447	3.6	0.742	5.9
11	AHU 05	Extract	5	600 x 250	0.678	4.5	1.142	7.6

Table 4.1.1.8 – Air velocities within the existing distribution ducts

CIBSE guide B table 3.4 recommends the maximum duct air velocity within ceilings for rectangular duct in critical areas should be limited to 3 m/s and 5 m/s in normal areas. Furthermore, for circular ducts 5 m/s in critical areas and 7 m/s in normal areas.

Table 1.5.2.1 shows by increasing the air volumes within the existing riser ducts to the required volumes to achieve the 6 ach would increase the air velocity within the ducts to above the CIBSE guidance.

4.1.1.3 Supply terminals

Fresh air is currently delivered to the single bedrooms via a flush ceiling mounted Swegon – Parasol unit, these units provide fresh air as well as heating and cooling. The H&V commissioning sheets shows the air supplied to each unit is around 40 l/s. The literature available online suggests the maximum fresh air permitted through these units is 49 l/s.

This small increase will not achieve the required 6 ach. Furthermore, increasing the air volume through these units will have a significant impact on the noise generated by the unit as well as a significant increase in the system pressure.

4.1.1.4 Extract Terminals

Air is extracted from the adjacent ensuite through door mounted transfer grilles and then via a ceiling mounted circular extract valve terminals. We do not anticipate that changing the air volumes will have a significant impact on the noise levels generated by these terminals.

However, it may be necessary to increase the size of the door mounted transfer grilles, although this will need to be assessed when the exact transfer grille type and size are known.

5.0

Scenarios

5.0 Scenarios

5.1 Review of scenarios

From the desktop study, the AHUs were designed to achieve the duties set out by the original designers. Even though it may be possible to replace specific elements from within the AHU to increase its performance, this will have further implication on the overall AHU. The impact of any changes will affect the following aspects:

1. AHU Specific Fan Power (SFP); This measures the AHU's fan energy efficiency and is a building regulation requirement that should be met.
2. Air leakage due to over pressurisation of the unit and distribution system; The AHU carcasses, intake, discharge and distribution ducts are sizes in line with the parameters set out by the designers. By retaining the existing system and increasing the air volume, the system pressure will increase, which may impact the system performance and potentially result in not achieving the required air volumes.
3. Performance of the heating and cooling coils; The coils are sized to achieve a specific thermal transfer at a specific air velocity, by increasing the air volume withing the existing AHU, the air velocity through the coils will increase resulting in insufficient thermal transfer. This will have a big impact on the entire systems especially on the Swegon ceiling mounted units resulting in condensation. This will also increase the risk of moisture carry over within the air stream from the cooling coils due to the higher velocity.
4. Noise levels; increasing air velocity through the ducts will result in higher noise levels through out the system. This will impact the room current noise levels.
5. Intake and exhaust louver sizing; The existing louvers are sized to cope with the current air volumes, increasing the air volume will result in higher static pressure and noise levels
6. System static pressure, increasing air volume through the distribution system will result in higher system static pressure. This will impact the fan performance and system air leakage.
7. Shorter economic life expectancy for the unit, by essentially over running the AHU, the expected economic life expectancy will be reduced due to additional ware and tear, this will also result in greater maintenance requirement and higher energy/running costs.

Impact on the existing supply and extract ducts, The existing distribution system is sized on the current ventilation rates, the existing system is inadequately sized to facilitate the increased air volume, it should be noted that as the rooms are currently designed to be negatively pressurised, the existing extract ducts are generally larger that the supply duct resulting in lower air velocities.

Increasing the air volume through the distribution system will increase the air velocity within the ducts above the industry guidance stated within CIBSE Guide B. This will result in higher noise levels, the supply and extract terminals and increased air leakage. It should also be noted that the existing Swegon ceiling mounted induction units within the bedroom as limited to 49 l/s, the required air volume needed to achieve the 6 ach is more that the unit allowance making it inadequate for this purpose.

Duct location	Duct type	Maximum air velocity / m·s ⁻¹ for stated room type		
		Critical	Normal	Non-critical
Riser or above plasterboard ceiling	Rectangular	5	7.5	10
	Circular	7	10	15
Above suspended ceiling	Rectangular	3	5	6
	Circular	5	7	10

Scenario 1:

Utilising existing ductwork, fans and AHU carcasses, can we increase air volume supply to all floors to achieve the required 6 ach.

Figure 5.1 shows that the fans have been selected to operate in the lower range of the fan curve, this does give some scope to increase the air volume within the system. However, even though the fan may provide the required volumes, the noise level increase resulting from the increase in duty will require additional treatment consisting of acoustically lining the existing ducts and replacing the existing duct mounted attenuators located within the plantroom.

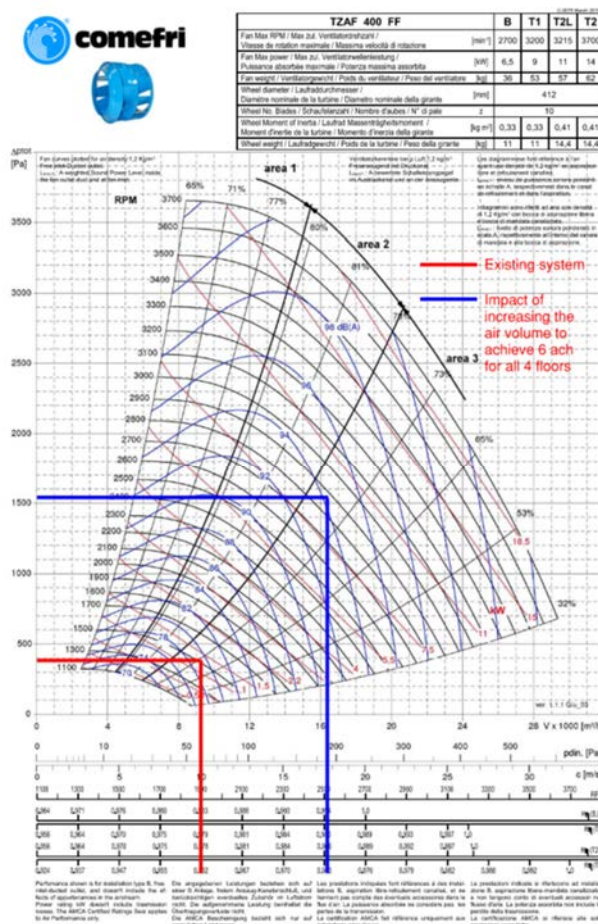


Figure 5.1 – AHU 04 supply existing and increased air volume plotted on Comefri TZAF 400 FF fan curve.

Increasing the AHU's duty will impact the energy consumption, Fan SFP and carbon rating of the unit.

The fact that the fans may achieve the volumes is not the only limiting factor. From the study, it was established that coils within the AHU are not capable of facilitating the required air volume needed to achieve the 6 ach for all floors. Furthermore, the existing distribution ductwork within the risers and ceiling voids are not sized for the required air volume. This will result in excessive air velocities within the ductwork. The impact of the increased velocities within the riser may be acceptable subject to confirmation from the trust. However, The increased velocities within the distribution ducts will need to be addressed. This will require new dew ductwork from the riser to the rooms running parallel to the existing distribution system or replacing the existing distribution system with a new distribution system sized to facilitate the required air volumes.

We were advised by AHU manufacturer that the limiting factors on these AHUs are the sizes of the coils as well as the physical sizes on the AHU. Increasing the air flowrate through the unit by changing the fans, pullies or any other method would have a detrimental effect on the efficiencies of the coils resulting in incomplete thermal transfer between the coils and the air, increased risk of moisture droplets carried over within the air stream due to increased velocities, this is particularly critical within this system due to the fact this will increase the risk of condensation within the rooms.

New supplementary supply diffusers will need to be installed in all single bedroom to provide the additional fresh air as the current fresh air rates supplied to the rooms via the Swegon Parasol ceiling terminals can't be increased.

New door transfer grills will need to be installed on the doors between the room and en-suites.

Also, Confirmation is required from the AHU manufacturer if the existing components within the AHU such as bearings will need to be upgraded to facilitate the increase in air volume.

Taking all of the above into consideration, we consider this scenario to be not feasible.

Scenario 2:

Utilising existing ductwork, AHU carcasses and altering the pulleys on the existing fans, can we increase air volume supply to all floors to achieve the required 6 ach.

This scenario is also not feasible for the same reason stated in Scenario 1.

Scenario 3:

Utilising existing ductwork, AHU carcasses and changing the existing fan arrangement to EC fans (perhaps a fan wall), can we increase air volume supply to all floors to achieve the required 6 ach.

Even though replacing the fans will result in a higher air volume, the limiting factor within the AHU are the size of the existing units and coils.

By replacing the existing belt driven fans with a more efficient solution such as an EC plenum direct drive fan array (fan motors will be located in the airstream) and replacing the existing cooling and heating coil section on the supply AHU with a taller section and larger coils section. This will allow the existing fresh air supply volume to be increased. However, It is very unlikely that the full required air volume needed to achieve the 6 ach can be achieved. We are awaiting confirmation from the AHU manufacturer on what additional air volume these changes will have on the AHU supply. This will determine the number of floors this option can serve.

It should be noted that even though the required air volumes may be achieved, the existing distribution ductwork within the risers and ceiling void are not adequately sized for the new air volumes. Below are possible options to overcome this issue:

Option 3.1: Retain the existing AHU and upgrade the existing fan, motor, cooling and heating coils, retain the existing ductwork within the plant room and riser (velocity between 6.5 & 8.5) as there is minimal scope to increase the duct size in the riser due to space constraints. Retain the existing distribution ductwork within the floors serving the Swegon Parasol ceiling terminals and install a new duct branch from the riser and run parallel to the existing duct to serve new supplementary diffusers within each single bedroom. The existing extract duct system will need to be recommissioned resulting in higher extract velocities. New door transfer grilles will need to be installed between the rooms and en-suite to ensure adequate return air path.

Option 3.2: Take a new branch from the existing supply air plenum leaving the supply AHU. Air within the new branch will need to be conditioned via cooling and heating coils within the plant room to ensure thermal comfort prior to dropping to below (riser location yet to be identified). Retain the existing distribution ductwork within the plantroom, riser and floors serving the Swegon Parasol ceiling terminals and install a new duct work from the new supply duct within the riser and run parallel to the existing duct to serve new supplementary diffusers within each single bedroom. New door transfer grilles will need to be installed between the rooms and en-suite to ensure adequate return air path.

Option 3.3: Strip out existing ventilation system including AHU 04 & 05, retain the existing ductwork within the riser (velocity between 6.5 & 8.5) as there is minimal scope to increase the duct size in the riser due to space constraints, strip out the distribution ductwork and Swegon Parasol ceiling terminals within all floors. Install a new AHU sized to deliver the required air volume in same locations of the existing AHUs. Install new ductwork within the plantroom, distribution ductwork within the floors and new diffusers and grills within the rooms/en-suits. The room heating and cooling will be provided via the ventilation system with a supply air temperature of 14°C for summer conditions and either radiant panels in the rooms or heater batteries on branches serving multiple rooms to condition the air for winter conditions.

New door transfer grilles will need to be installed between the rooms and en-suite to ensure adequate return air path.

All the above option assumes that there is sufficient space within the corridor ceiling void to allow the installation of a new supply duct to serve the new supplementary supply diffusers.

Scenario 4:

From the Variable Speed Drivers (VSD)s information below provided by the trust, there is some scope to increase the duty of AHU 05 by adjusting the VSD. However, the increase would be limited to about 20-25% at best which will cover a single floor. This is on the basis that the existing AHU is designed to run at 125% of the original design duty.

This is not the case for AHU 04 as the VSD is currently operating close to its upper limit.

From the information provided by the trust, the existing VSD serving these AHU as currently set to the following parameters:

AHU 04:

Supply fan VSD: 50 Hz

Extract fan VSD: 60 Hz

AHU 05:

Supply fan VSD: 47 Hz

Extract fan VSD: 37 Hz

It should be noted that further consideration would need to be given to the impact this will have on the existing units SFP and the face velocity at the cooling coils. Also, this will reduce the allowance made for operating the AHU with a dirty filter. This will require the filters to be replaced at a higher frequency to ensure that the required air volumes are achieved.

Adjusting the VSD will result in the following increase:

AHU ref:	Existing		Proposed	
	Supply	Extract	Supply	Extract
	(m ³ /s)	(m ³ /s)	(m ³ /s)	(m ³ /s)
AHU 05	2.502	3.193	3.128	3.99

Table 5.2 – Proposed AHU air volume increase

This can facilitate either of these two options:

Option 4.1: increase all single bedroom ventilation rate on a single floor served by AHU 05 to 6 ach and maintain 3 floors at their existing ventilation rates.

The existing ductwork within the plantroom, riser and distribution within all floors will be retained, however, a new supply distribution duct will need to be installed on the selected floor running parallel to the existing duct to serve new supplementary diffusers within the single bedrooms.

New door transfer grills will need to be installed on the doors between the room and en-suites.

The existing extract system will need to be recommissioned to facilitate the higher ventilation rates. This will result in higher duct velocities as shown in tables 4.1.1.6 to 4.1.1.8

Option 4.2: Increase all single bedroom ventilation rate within all 4 wards (4C, 5C, 6C and 7C) from between 2.7 and 3.2 ach to between 3.5 and 4.2 ach.

This option will increase the fresh air supply to the single bedrooms from about 40 l/s to 52 l/s. This increase will push the supply flowrate over the maximum amount of fresh air permitted through the existing Swegon Parasol ceiling terminals. Therefore, new supplementary diffusers will need to be installed in each single bedroom to supply the additional 12 l/s. These diffusers will be served by the existing duct serving the Swegon Parasol ceiling terminals.

New door transfer grills will need to be installed on the doors between the room and en-suites.

The existing extract system will need to be recommissioned to facilitate the higher ventilation rates. This will result in higher duct velocities.

We understand that the trust has been advised that the Chilled Water (CHW) pipework serving the existing Swegon Parasol ceiling terminals need to be replaced due to corrosion. Therefore, there will be a level of disruption from the plate heat exchanges and throughout the floors. This period could be utilised to carry out the changes to the existing ventilation system as required.

AHU 04 fan, motor and VSD will need to be upgraded to enable any increase in its existing duty. This upgrade would enable the implementation of option 4.1 and 4.2.

6.0

Summary of findings

6.0 Summary of findings

6.1 Summary of findings

The ventilation air change rates for the single bedrooms within wards 4C, 5C, 6C and 7C were found to be between 2.7 and 3.2 ach, this is lower than the SHTM 03-01 Table A1 – Design conditions for miscellaneous room recommendation of 6 ach.

The single bedrooms and associated en-suite are commissioned to operate under a negative pressure in relation to the adjacent circulation space.

The supply and extract distribution ducts within the risers and ceiling voids are inadequately sized to facilitate the required air volumes needed to achieve the single bedrooms 6 ach.

The maximum fresh air permitted through the Swegon Parasol ceiling terminals is significantly lower than what is required to achieve the required 6 ach within the single bedrooms.

We do not anticipate that changing the air volumes will have a significant impact on the noise levels generated by the extract valve terminals.

The existing AHU fans, motors, cooling and heating coils are deemed inadequate to facilitate the required ventilation rate increase. The sizes of LTHW and chilled water pipework serving the exist AHUs will need to be reviewed.

The optimum solution would be the complete replacement of the existing AHU as this will ensure the required duty is achieved as well as a significant annual energy savings from the increased heat recovery efficiency and EC fan technology in a state-of-the-art AHU.

A further advantage of replacing the existing AHU is that if adequately sized, the single bedrooms heating and cooling requirement can be provided via the ventilation system. The existing Swegon Parasol ceiling terminals will no longer be required.

QUEEN ELIZABETH UNIVERSITY HOSPITAL – HAEMATO-ONCOLOGY WARD, LEVEL 4

BRIEFING NOTE ON DESIGN OF UNIT

1.0 BOARD'S REQUIREMENTS

The requirements are set out in the following documents;

- Clinical output specification for Haemato-oncology
- SHPN 054 Facilities for Cancer Centres
- SHTM 03-01 Ventilation for Healthcare Premises

In summary, the above documents collectively set the following design parameters; a sealed room, HEPA filtration, single rooms to have positive pressure from rest of hospital and an enhanced air change rate.

Compensation event No.051 was issued on 2nd October 2013 and instructed that an additional number of rooms, that were then in the Renal Ward, should be built to the same specification as those in the Haemato-oncology Ward. There was no detail within the change control form, from the service, to suggest that these rooms should be anything more than HEPA filtered and built to same standard as the 10 planned Haemato-oncology rooms.

2.0 DESIGN DEVELOPMENT

Designs for the department were developed based on a single room with en-suite, the model used elsewhere in the hospital, in other words individual lobbied rooms were not a user requirement. Designs were developed during the Phase 2 design development process in 2010 by the NHS user team, NHS Project Team, Brookfield Multiplex(BM) and their design team. It is not clear as yet where design assumptions were made that did not include all elements of the Board's specification noted above; and this is the subject of a review being undertaken by the BM design team.

What is clear, a design was concluded for the ward that did not meet all the requirements/recommendations and this progressed through to construction on site.

3.0 WHAT HAS BEEN BUILT

The rooms as constructed meet a range of the Board's design requirements, sealed external window, no chilled beam, HEPA filtration, positive pressured room, air system supplying 6 air changes per hour. The key design issue that appears to be affecting the operation of the air system and the high particle count is that the ceiling is not sealed. This is probably not allowing the air handling plant to reach its desired room pressure due to leakage into the ceiling void, and particles may transfer from this void into the room via loose fitting tiles or through the doorway when open due to drop in room pressure.

4.0 COMMISSIONING

The ventilation system serving the ward has been commissioned in accordance with CIBSE Commissioning Code A and the design air flow rate (based on 6ac/h). Thereafter sample room pressures were checked to confirm a positive differential pressure between the bedrooms and the corridor (generally 3-4Pa). The differential pressure was also checked between the ward exits and the cores / corridors again to ensure positive pressure (generally 1.5-2.5Pa). HEPA Filters were installed within all the bedrooms and visually checked to ensure seals were sound.

The Supervisor's (Capita) scope of work does not include design, build, commissioning and validation. The overall role of the Supervisor is to witness or carry out tests and inspections. The Supervisor also notifies Defects but may not accept a defect. The Supervisor is required to ensure that the works are provided to the standard and performance required in the works information. The works information for this ward was the Construction Issue drawings and specification which, as we now know, had shortcomings.

5.0 OPTIONS FOR SOLUTION

5.1 Testing Existing Installation

The Brookfield Multiplex team will undertake testing over the next 7 days, and will carry out a validation test (Air flow and static differential pressure test) on the rooms as they currently sit.

They intend to test 3 of the rooms with regards what can be achieved by sealing the rooms.

- Room 1 - seal the perimeter,
- Room 2 - seal the perimeter and the tiles
- Room 3 - we have ordered an alternative ceiling grid system which will confirm delivery of shortly. This is a manufactured self-sealing system (commonly found in theaters and CAT III rooms)
- All Rooms - adjust AHU performance to ensure optimal output
- All Rooms - install IP44 diffusers to light fittings

A further test will be taken at this point to understand the benefits of carrying this out (air flow and static differential pressure test).

We would require the Board to carry out a deep/clinical clean of the three rooms to allow a particle count to be taken at this time and we would like this to be undertaken by the Board's Infection Control team.

The purpose of the feasibility study is to establish the optimal position we can achieve with the currently installed services. Should test results meet the Board's requirements this would lead to minimal disruption and necessity of works (reducing the time the ward is rendered unavailable). At this time, should we achieve acceptable outputs we would present a formal submission to the NHS for agreement/approval, and this will need to include all design criteria on which the finished works would be measured by. Should all parties agree this will close the issue.

5.2 Alter Existing Installation

In carrying out the testing regime proposed above we will have a joint understanding of the capacity currently available with the installed system. The tests we are proposing are carried out (both by BMCE and the NHS) will provide information that will allow consideration to be given to the actual clinical performance of the rooms tested. Should an acceptable performance level be achieved we would carry out the following:

- Empty the rooms of all Board equipment to an agreed storage area.
- Remove the existing ceilings and services.
- Clean ductwork

- Install the new style sealed ceiling and replace the services as required dependent on test results.
- Decoration and making good to be carried out, builders clean and inspections.
- Replace HEPA filters and carry out challenge (DOP) testing
- Final deep/clinical clean and air particle count (By the Board)

This less invasive solution could be carried out in the region of 6 weeks construction time and has an overall duration of between 8 to 10 weeks depending on sign off and procurement.

5.3 What else will Brookfield Multiplex be doing - Full Change Option

We will over the next 2 weeks carry out a feasibility study on increasing the performance of the ward beyond what the currently installed services/building fabric can provide.

During this period we will consider alterations that would be required, including design review of :-

- Duct size
- Plant capability, Air Handling Units, heater batteries and Fans
- Room pressure monitoring
- Spatial constraints for duct work alterations and maintenance requirements in sealed rooms
- Access Maintenance
- Fabric/Lighting/seals

Subsequent to approval/agreement, to minimise the programme, we will progress to a full design while also progressing the procurement of materials on longer lead in times. We understand items to be on a 4 to 6 week lead in period and will express these for best delivery dates. This will take a further 3 weeks including the time for the Board to sign off design.

We would anticipate that to this point 5 weeks will be required.

To achieve a 10 air changes per hour, we anticipate a full strip out of the existing mechanical ventilation system and upgrade of the air handling units which we would be unlikely to install and complete in less than 5 or 6 months from design to completion and tested.

5.4 Why has this happened?

Brookfield Multiplex is reviewing the information set out in the employers requirements associated with the Ward and what specification the design was developed to.

9th July 2015.

SBAR – Ward 6A environment
26/8/19, Microbiology dept QEUH

Situation	Ward 2A in Paediatric haemato-oncology was moved to Ward 6A QEUH in September 2018. This was initially planned to be a short term decant assessed via an options appraisal to enable water control measures to be implemented on 2A. During that time HPS commissioned a review of the ventilation strategy for ward 2A. An external report concluded that the ventilation strategy for 2A was abnormal, placing patients at risk of infection, therefore the decant had to be extended to enable extensive ventilation remedial actions. Given that there were no further cases that met the water incident case definition between September and April, a repeat options appraisal was not undertaken when it became apparent that the decant was to last much longer than at first anticipated. A PAG was held on 3rd June 2019 to discuss 4 cases of Gram negative bacteraemias. An IMT followed on 19th June due to a further environmental bacteraemia, this time a <i>Mycobacterium</i> species which was subsequently found to be related to the water supply utilising whole genome sequencing. The hypothesis for <i>M. chelonae</i> acquisition was exposure to unfiltered water outside 6A, possibly operating theatres. The IMT process is still ongoing and to date there have been 11 confirmed and one possible case of Gram negative bacteraemias since 13th April.
Background	Surveillance of all bacteraemias was put in place when the ward was decanted to 6A. From September to April bacteraemia rates were very low and any Gram negatives were coliforms, i.e. expected species of bacteria and usually endogenous gut flora. From April 2019, bacteraemias secondary to environmental organisms have occurred, some of these meet the case definition from the previous incidents from 2A e.g. <i>Stenotrophomonas maltophilia</i>, <i>Enterobacter cloacae</i>. Others are from rare organisms not part of that incident but of a soil/water type of bacterial species. Examples include <i>Chryseomonas</i> sp, <i>Elizabethkingia miricola</i>, <i>Pantoea septica</i>.
Assessment	Current environmental risks on ward 6A 1. Air changes – essential for dilution and removal of pathogens generated within the room environment e.g.

	from toilet plume, respiratory generated infectious aerosols, and water generated aerosols from taps and drains containing pathogens as well as flora shed from skin such as <i>Staphylococcus aureus</i>. Current Air Changes per Hour is less than 3. SHTM guidance is 10 for neutropenic rooms i.e. less than a third of fresh air turnover required to meet standards 2. Chilled beam technology is in place in each bedroom at the point of supply Chilled beam technology should NOT be used in the neutropenic setting. Infection risks associated with chilled beams : 1. Build up of dust which typically harbours skin organisms, fungi and <i>Acinetobacter sp.</i> This is due to recirculation of air, with no clean to dirty pathway and with essentially the beam functioning as a filter that is not changeable which collects up dust and fibres from the room air. These are requiring 6 weekly cleaning schedule, however they are not designed to be thoroughly cleaned in situ and will require removal under HAISCRIBE conditions to achieve. 2. Water source from a) Condensation b) Leaks from the hot and cold circulating water (known contaminated cold water) c) Dripping water from both can become contaminated with the dust organisms The SHTM guidance states that condensation should not be allowed to occur when these systems are in place. However condensation events have been recorded on numerous occasions throughout the hospital including on 2A and 6A. This allows multiplication and growth of bacteria and fungi, particularly when dripping through collected dirt on the unit. Leaking connections have also occurred which allows water borne organisms from a complex water system to ingress into the room. This poses a risk of <i>Legionella</i> as well as <i>Pseudomonas</i> and other water borne organisms. Water has been seen to pool in the frame of the unit thus causing a significant potential for fungal overgrowth. This chilled beam water system has not been subject to the water quality management system through the water governance structures of the organisation. <i>Pseudomonas aeruginosa</i> and <i>P. oleovorans</i> and unidentified environmental organisms have been grown
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	from the water supply, and from the surface swabs <i>Stenotrophomonas sp</i>, <i>Pantoea sp</i>, <i>Acinetobacter sp</i>, <i>Exophiala</i>, <i>Pseudomonas olerovans</i>, and fungal species. 3. Pressure cascade: recommended pressure of 10 pascals positive pressure to corridor in SHTM, currently there is a nominal 2 pascal positive pressure which is insufficient to ensure robust air movement out of the room, allowing external contaminants to ingress into the rooms from the building void and corridor. Furthermore air sampling studies have shown ingress from risers of heavily unfiltered contaminated air. 4. HEPA filtration: SHTM recommends HEPA filtration of all air supplied to the neutropenic rooms. Currently on 6A there is no HEPA filtration on the supply air. Portable HEPAs are in place in an effort to reduce airborne contamination, but this is not ensuring that HEPA filtered air only is breathed by patients. Contaminated air continues to enter the room and we are reliant on portable HEPA to clean the air 5. Air sampling in the bathrooms has detected pathogenic fungi such as <i>Aspergillus</i> and <i>Mucoraceous</i> mould. Previous issues with mould in the bathrooms was identified and rectified due to weak joins between the shower floor and the wall, however the risk remains as the weak join remains as per original spec – it is only a matter of time before the join is coming apart again. A long term solution to remove the join altogether has not been supplied to date. There is potential for HEPA filters to be placed in the bathroom ceilings, however again, this is a cleaning method for air rather than a HEPA supply. 6. Toilets – toilet plume is a risk as no toilet seat in place. These are currently being rolled out 7. Exposure to unfiltered water ; while all bathroom and bedroom outlets have had point of use filters applied , it has not been possible to place these in the DSR where water is sourced for domestic cleaning . 8. Ceiling: solid ceilings are required to both assist with positive pressure achievement and protection from ingress of water from services in ceiling; however ceilings are tiled and therefore inappropriate for this setting. 9. Play areas; there is no play area and communal toys are
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	situated in the corridor, thus presenting a risk of cross transmission 10. Door entry – no double door or pressure cascade therefore external hospital air ingresses to the unit readily 11. Kitchen hand wash sink is a non compliant size and no POU filters. 12. Prep room – stainless steel sink, not useable due to tap misalignment and therefore clinical hand hygiene sink is being used for prep room functions
Recommendations	1. The decant from 2A was for a short term only and given ongoing environmental risks and recent environmental bacteraemias, a reassessment of the options appraisal is urgently acquired. 2. 6A should be considered to have significant unacceptable levels of infection risk for the immune compromised patients due to the built environment. 3. External peer review from colleagues in Great Ormond Street

In alphabetical order;

Dr Alison Balfour
Dr Ash Deshpande
Dr Teresa Inkster
Dr Kam Khalsa
Dr Nitish Khanna
Dr Christine Peters
Dr Kalyopi Valyraki
Dr Pauline Wright

References

1. Nishiura H. Early detection of nosocomial outbreaks caused by rare pathogens : A case study employing score prediction value. Osong Public Health Res Perspect 2012;3:121-127

2. Urrea M , Rives S, Cruz O, Navarro A, Garcia JJ, Estella J. Nosocomial infections among paediatric haematology/oncology patients: results of a prospective incidence study. *Am J Infect Control* 2003;**32**:205-208
3. Arega B, Wolde-Amanuel Y, Adane K, Belay E, Abubeker, Asrat A. Rare bacterial isolates causing bloodstream infections in Ethiopian patients with cancer. *Infectious Agents and Cancer* 2017;**12**:40
4. Simon A, Ammann RA, Bode U, Fleischack G, Wenchel HM et al. Healthcare associated infections in paediatric cancer patients : results of a prospective surveillance study from university hospitals in Germany and Switzerland. *BMC Infectious Diseases* 2008;**8**:70
5. UK Department of Health. HTM 03-01. Specialised ventilation for healthcare premises. Part A Design and Validation . 2007
6. Health Facilities Scotland. SHTM 03-01. Specialised ventilation for healthcare premises. Part A, Design and Validation 2014
7. CDC. Guidelines for environmental infection control in healthcare facilities 2003
8. CDC . Guideline for isolation precautions : preventing transmission of infectious agents in the healthcare setting. 2007
9. CDC. Guidelines for preventing opportunistic infections among haematopoietic stem cell transplant recipients. Recommendations of CDC, the Infectious Disease Society of America and the American Society of Blood and Bone Marrow Transplantation. 2000
10. Yokoe D, Casper C, Dubberke E, Lee G, Munoz P et al. Infection prevention and control in healthcare facilities in which haematopoietic cell transplant recipients are treated. *Bone Marrow Transplantation* 2009;**44**:495-507
11. Sherertz RJ, Belani A, Kramer BS , Elfenbein GJ, Weiner RS et al. Impact of air filtration on nosocomial aspergillus infections. Unique risk of bone marrow transplant recipients. *Am J Med* 1987;**83**:709-718
12. Withington S, Chambers ST, Beard ME, Inder A, Allen JR. Invasive aspergillosis in severely neutropenic patients over 18 years: impact of intranasal Amphotericin B and HEPA filtration. *Journal of Hospital Infection* 1998;**38**:11-18
13. Hahn T, Cummings KM, Michalek AM, Lipman BJ, Segal BH, McCarthy PL. Efficacy of high efficiency particulate air filtration in preventing aspergillosis in immunocompromised patients with haematologic malignancies. *Infect Control Hosp Epidemiol* 2002;**23**:525-531
14. Noksins GA, Peterson LR. Engineering infection control through facility design. *Emerg infect Dis* 2001;**7**:354-357
15. Rhame FS, Streifel AJ, Kersey JH Jr, McGlave PB. Extrinsic risk factors for pneumonia in the patient at high risk of infection. *American Journal of Medicine* 1984;**76**:42-52
16. Humphreys H. Positive pressure isolation and the prevention of invasive aspergillosis. What is the evidence? *Journal of Hospital Infection* 2004;**56** :93-100

17. Thio CL, Smith D, Merz WG, Streifel A. Refinements of environmental assessment during an outbreak investigation of invasive aspergillosis in a leukaemia and bone marrow transplant unit. *Infection Control and Hospital Epidemiology*. 2000;**21**:18-23
18. Gray JW, Ludman LJ. The protected environment for high-risk haematology patients: as safe as we think? *J Hosp Infect* 2016; 92(3): 295.
19. Cervia JS, Barber F, Armellino D, Klocke J, Bayer RL. Point of use water filtration reduces hospital acquired infection in bone marrow transplant recipients. *Transplant Infectious Diseases* 2010;**12**:238-241
20. Garvey MI, Bradley CW, Holden E. Waterborne *Pseudomonas aeruginosa* transmission in a haematology unit. *American Journal of Infection Control* . 2018;**46**:383-386
21. Litvinov N, da Silva MT, van der Herjden IM, Graca MG, Marques de Oliveria L et al. An outbreak of invasive fusariosis in a children's cancer hospital. *Clinical microbiology Infection* . 2015**21**;268 e1-7
22. Dziubian E, Franks J, So M, Peacock G, Blaney D. *Elizabethkingia* in children; a comprehensive review of symptomatic cases reported from 1944 to 2017

QUEEN ELIZABETH UNIVERSITY HOSPITAL**WARD 6A PRESSURE PROFILE****QEUH Adults – Ward 6a - Pressure Profile**

Client:	NHS Greater Glasgow & Clyde	Client Contact:	James Guthrie
Hospital:	Queen Elizabeth University Hospital	Site Address:	1345 Govan Road, Glasgow G51 4TF
Area:	Ward 6A	AHU:	122AHU04 S&E 122AHU05 S&E
Theatre Condition:	N/A	Report No:	0056706
Date of Test:	12 TH September 2019	Date of Last Test:	3 rd December 2018
Test Engineer & Report Preparation:	Daniel Kane	Signature:	
CSSL Review:	Ian McKenzie	Signature:	
Client Reviewed by:	James Guthrie	Client Signature:	

Correctair Solutions (Scotland) Limited
Unit RO7 Trident House 175
Renfrew Road,
Paisley.
PA3 4EF

QUEEN ELIZABETH UNIVERSITY HOSPITAL

WARD 6A PRESSURE PROFILE

Table of Contents

1. Scope of Works
2. Executive Summary
3. Pressure Profile Ward 6A Room to Corridor
4. Test Equipment Used & Calibration Certificate

QUEEN ELIZABETH UNIVERSITY HOSPITAL

WARD 6A PRESSURE PROFILE

Section 1 – Scope of Works

Record room pressures from bedroom to corridor. Recorded for information only.

QUEEN ELIZABETH UNIVERSITY HOSPITAL

WARD 6A PRESSURE PROFILE

Section 2 – Executive Summary – Ward 6A

Room differential pressures have dropped since previous visit from setup since November 2018. To help improve the room pressures we could assist by several adjustments;

1. Check replace AHU pre and or secondary filters and fan/motor drive belts.
2. *Reduce toilet extract to maintain higher pressures within the rooms by maintaining SHTM03-01 (single room occupancy) compliance by ensuring a minimum of 3 air change rates are maintained.
3. Fit door dropdown seals on the bedroom doors to help maintain room pressure.
4. Replace/fit door seals to help reduce construction door leakage.

*NB: An isolation room WC should be 10 air changes per hour, although these rooms are designed to be single occupancy standard rooms. A clinical decision would be required on this adjustment.

Corridor to external corridor pressures

Pressure cascade from ward 6A to corridor facing ward 6D is +4.6Pa.

Pressure cascade from ward 6A to corridor facing ward 6B is +6.0Pa.

QUEEN ELIZABETH UNIVERSITY HOSPITAL

WARD 6A PRESSURE PROFILE

Section 3 - Pressure Profile Ward 6A Room to Corridor

WARD +6A (Positive Pressure Ward)

Room/Bed Nos.:	Pre Fan alteration (BMS Control)	Room To Corridor Pressure (Pa)	Room/Bed Nos.:	Pre Fan alteration (BMS Control)	Room To Corridor Pressure (Pa)
1	--	+0.6	15	--	+0.5
2	--	0	16	--	+0.4
3	--	0	17	--	+0.6
4	--	0	18	--	+0.4
5	--	0	19	--	+0.5
6	--	+0.4	20	--	+0.5
7	--	+0.5	21	--	0
8	--	+0.4	22	--	+0.6
9	--	+0.7	23	--	+0.7
10	--	0	24	--	+0.4
11	--	0	25	--	0
12	--	+0.6	26	--	0
13	--	0	27	--	+0.4
14	--	+0.7	NA	--	--

Comments: None

The adjustments made to these bedrooms was to achieve a +ve pressure from rooms to corridor. This was previously achieved. Please see executive summary for corrective actions and recommendations.

QUEEN ELIZABETH UNIVERSITY HOSPITAL

WARD 6A PRESSURE PROFILE

Section 4 - Test Equipment Used & Calibration Certificate

Type of Equipment	Serial No	Cal Due Date
Micro-manometer	8651	June 2020



DP MEASUREMENT

Unit 11, Top Angel, Buckingham Industrial Park, Buckingham. MK18 1TH
Tel/Fax: 01280 817122 e-mail: dpm@ttseries.com www.ttseries.com

CALIBRATION CERTIFICATE

CUSTOMER DETAILS:

Customer: Correctair Solutions Ltd

Customer Serial Number: N/A

CONDITION ON RECEIPT: New

1 Required repair:

2 In spec:

3 If yes to 2 adjustment:

4 If no to 2 adjustment:

INSTRUMENT DETAILS:

Model: TT570 S

Serial Number: 8651

CALIBRATION DETAILS:

Date Of Calibration: 12/06/19

Due Date: 12/06/20

Certificate Number: 45518

TEST ROOM CONDITIONS:

Temperature: 22°C ± 2°C

Manufacturers Specification

Readings less than 100 counts ± 2 counts

Readings greater than 100 counts ± 1% of reading ± 1 count

Manufacturer: DP Measurement

	0	40	80	160	400	800	kPa	kPa	kPa
TEST RESULTS:	0	40	80	160	400	800	1.60	3.00	6.00
Calibration Points Pa:	0	40	80	160	399	800	1.60	3.00	6.00
Indicated Readings:	0	-0.50%	-0.37%	0.00%	-0.25%	0.00%	0.00%	0.00%	0.00%
Percentage Error:									

	0	-40	-80	-160	-400	-800	kPa	kPa	kPa
TEST RESULTS:	0	-40	-80	-160	-400	-800	-1.60	-3.00	-6.00
Calibration Points Pa:	0	-40	-80	-160	-400	-800	-1.60	-3.00	-6.00
Indicated Readings:	0	0.25%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Percentage Error:									

	0	5.0	8.2	11.5	15.0	16.3	25.8	36.5	50.0
Calibration Points m/sec:	0	5.0	8.2	11.5	15.0	16.3	25.8	36.5	50.0
Indicated Readings:	0	5.0	8.2	11.5	15.0	16.3	25.8	36.5	50.0
Percentage Error:	0	0.0	0.0	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%

Notes:

Equipment: The instrument detailed above has been calibrated against equipment serial number 0047368 which in turn has been calibrated against instruments and equipment that are traceable to National Standards. (UKAS Calibration Laboratory N° 0157). The above results are obtained on the date of calibration. The percentage error quoted refers to the measured values only, with no account being taken of the instruments ability to maintain its calibration.

Velocity Range: Is calibrated for the ellipsoidal nose (NPL Type) Pitot Static Tubes used at air density 1.20kg/m³. Air stream temperature set at 16°C and barometric pressure set at 1000 mbar on the instrument.

Calibrated by Hussein Khimji

Page 1 of 1

Version 2
07.06.2017

Associated Instrument Repairs Ltd. Trading as DP Measurement.
Company Reg. No: 3485904 VAT No: 685 868 755
Registered Office: Ebenezer House, Poole Road, Bournemouth, Dorset. BH2 5QJ.

The Following document is a Request for Information (RFI) response received by the Scottish Hospital Inquiry from NHS GGC

RFI (Request for Information) 10

Ward 6A of the QEUH: In respect of all perceived problems, defects and issues with the ventilation system within Ward 6A of the QEUH, following building handover in January 2015 to present date.

This response is presented as a chronology, identifying documents to answer to the various sections of 4.1 to 4.7 against each of the work programmes that may in a wide interpretation be considered as “remedial and/or refurbishment works”. We have included works that were undertaken to create improvement in the ventilation however this does not necessarily mean that they were undertaken in respect of a perceived problem, defect or issue.

The response below must be read in conjunction with the documents previously provided which, together with the chronology below, form the full response to RFI 10, Section 4. The responses to RFI 1 6 submitted 10.11.2021, RFI 3.4 submitted on 01.04.2022, RFI 4 submitted 04.04.2022, and much of the response to RFI 7 provide background and detail to the decisions taken to proceed with works; information previously provided has in general not been duplicated in the response below.

Filename	Descriptive comment
	On 26 September 2018 some patients from RHC Ward 2A/B were moved into QEUH Ward 6A and 4B. At the Ward 2A, RHC Incident Management Team on 28 September 2018 a request for portable hepa filtration units is noted. The subsequent meeting on 5 October 2018 of the same group recorded “<i>4 portable hepafilter units have been delivered to Ward 6A for patients stepping down from ward 4B BMT</i>”. This was anticipating that Ward 4B BMT paediatric patients might be stepped down from 4B to 6A. (refer to the Ward 2A, RHC IMT minutes provided in response to RFI 1 6)
	The response previously provided to RFI 1 6, included a “Water and Cryptococcus timeline” indicating that in November 2018 the Cryptococcus Incident commenced. Within Ward 6A, activities undertaken to improve the built environment in response to a hypothesis or considered opinion of that group are tracked in the notes of the Cryptococcus IMT. (refer to responses previously provided to RFI 1 6) Works related to the ventilation system / air quality included: • Deployment of mobile/portable city M HEPA Air Scrubbers • F7 filters on AHUs changed to F9

	• CVG (Ceiling Ventilation Grilles) removed and replaced with a standard ceiling tile • Chilled Beam Units - control adjustments, fitting replacements and cleaning • Installation of recirculation air scrubber fans
Cryptococcus minutes IMT 7.1.19.doc	7 January 2019: Cryptococcus Incident Management Team notes. Already submitted - Part of RFI 1, Qu 6.
Cryptococcus minutes IMT 16.1.19.doc	16 January 2019: Cryptococcus Incident Management Team. Already submitted - Part of RFI 1, Qu 6.
Cryptococcus minutes IMT 17.1.19 am meeting.doc	17 January 2019 (am meeting): Cryptococcus Incident Management Team Already submitted - Part of RFI 1, Qu 6.
Cryptococcus minutes IMT 17.1.19 pm meeting.doc	17th January 2019 (pm meeting): Cryptococcus Incident Management Team Already submitted - Part of RFI 1, Qu 6. <i>"18 mobile/portable HEPA filter air units arrived and will be moved up to ward 6A once facilities have completed a volumetric calculation for the corridor to determine how many are required."</i> <i>"Facilities will look into filters for the air ducts that can stop Cryptococcus from entering the air supply."</i>
Cryptococcus minutes IMT 18.1.19.doc	Cryptococcus Incident Management Team notes from meeting held on 18th January 2019 . Already submitted - Part of RFI 1, Qu 6.
ATO102_03206503 Fwd ExternaltoGGCOFFICIAL RE Call to Peter Hoffman.msg	18 January 2019: Summary of communication with Peter Hoffman about F7 filter use and testing. Communication forwarded by Director of Estates and Facilities to Estates Management colleagues.
ATO101_02556534 QEUH Ward 6A Flooring Issues.msg	19 January 2019: Confirmation that 3 (of the 20) HEPA filter air units arrived this morning and placed in Ward 6A, Rooms 20, 21 and 23 (units placed in both the bedroom and the en-suite).

Cryptococcus minutes IMT 21.1.19.doc	21 January 2019: Cryptococcus Incident Management Team Already submitted - Part of RFI 1, Qu 6.
Cryptococcus minutes IMT 22.1.19.doc	22 January 2019: Cryptococcus Incident Management Team Already submitted - Part of RFI 1, Qu 6. <i>"Jenn Rodgers has requested for more HEPA filters for ward 6A, but awaiting delivery of more. "</i>
Cryptococcus minutes IMT 25.1.19.doc	25th January 2019: Cryptococcus Incident Management Team Already submitted - Part of RFI 1, Qu 6. <i>"Dr. Inkster confirmed that when Ward 6A re-opens there should be a HEPA filter in every patient room with an additional 7 HEPA filters within the corridor."</i>
Cryptococcus minutes IMT 28.1.19.doc	28 January 2019: Cryptococcus Incident Management Team Already submitted - Part of RFI 1, Qu 6.
Cryptococcus minutes IMT 30.1.19.doc	30 January 2019: Cryptococcus Incident Management Team Already submitted - Part of RFI 1, Qu 6. <i>There are currently 26 HEPA filters throughout Ward 6A. Currently awaiting delivery 13 new units and have requested 30 more units which are currently being built. Myra Campbell said Ward 6A could have some of the HEPA filters currently in her ward. Myra will identify the HEPA filters that can be used, but will check with Dr Inkster before any are removed.</i>
ATO101_02558443 RE Crypto IMT.msg	1 February 2019: Email communication update on IMT actions. Advising that Estates Manager is working on calculation / review process to determine what current F7 filter can be replaced with a F8 or possibly a F9 filter. Checks taking place against commissioning figures for the capacity of the AHU fan and motor to ensure sufficient air flow can be achieved.
	F9 filters have a higher 'average efficiency' than F7 filters. When filters were changed filter frames were sealed at the same time preventing air bypass.

Cryptococcus minutes IMT 4.2.19.doc	4 February 2019: Cryptococcus Incident Management Team notes of meeting Already submitted - Part of RFI 1, Qu 6. <i>“Delivery of 13 HEPA filters happened on Friday 1st February. They were taken to Ward 6A to cover every patient room and corridors.”</i> <i>“As soon as facilities get confirmation data that filters can be fitted into air ducts then they will target the air ducts which pose the highest risk first.”</i>
Cryptococcus minutes IMT 8.2.19.doc	8 February 2019: Cryptococcus Incident Management Team notes of meeting Already submitted - Part of RFI 1, Qu 6. <i>“HEPA filters are to stay within each patient room and ward corridors until solution for ward 2A/2B is obtained.”</i>
ATO102_03303562.xlsx	1 March 2019: Estates (internal) Action Plan indicating that F7 filters on AHUs (serving Ward 6A) have been changed to F9 filters.
	From April 2019: CVG (Ceiling Ventilation Grilles) were removed and replaced with a standard ceiling tile. Wards are fitted with Ceiling Vent Grilles (CVG's) which are open vents between the ceiling and the ward corridors. Among the purposes of these grilles are allowing for venting and detection of gas services leaks above the ceiling where there are mechanical joints. Removing the CVGs reduces the risk of particulates moving from the corridor ceiling void into the corridor transfer area and rooms in Ward 6A. The notes of the Cryptococcus IMT Expert Advisory Sub-Group previously provided in response to RFI 7-2, 2.17 provide the narrative on the background and the progress towards a decision to remove the CVG's and replace with a standard ceiling tile. The date when this was achieved is not recorded, however confirmation that was done is captured in the “Report from the Cryptococcus IMT Expert Advisory Sub-Group Unredacted FINAL 2022-04-05.pdf” also submitted in response to RFI 7-2, 2.17.

2019-04-10 7. Notes of Cryptococcus IMT Expert 100419 final.doc	10 April 2019: Cryptococcus IMT Expert Advisory Sub-Group. Already submitted - Part of RFI 7, Qu 2.17.
2019-05-09 9. Notes of Cryptococcus IMT Expert 090519 final.doc	9 May 2019: Cryptococcus IMT Expert Advisory Sub-Group. Already submitted - Part of RFI 7, Qu 2.17.
Leakage from chilled beams Ward 6A.pdf	3 June 2019: SBAR "Leakage from chilled beams Ward 6A.pdf" Already submitted - Part of RFI 7, Qu 2.24
	The chilled beam units used throughout the QEUH and RHC use Chilled Water or Low Temperature Hot Water to control the air temperature provided to the rooms. The air to the chilled beams is provided by the ductwork from the Air Handling Units in the plantrooms. Intermittent "leaks" from the chilled beams have been attributed to thermal movement in the push type fixings of the pipework. In June/July 2019 the replacement of push fit connections with compression fittings in Ward 6A was commenced. On 29 June 2019, across the hospital, there were reports of multiple "leaks". The cause of these was determined as condensation related to the high relative humidity in the ambient air. The chiller control strategy was adjusted to resolve. Quality checks on works to "clean" the chilled beam grilles identified they were not sufficiently cleaned and an alternate methodology was then implemented. This new methodology was implemented in the cleaning of the Ward 6A chilled beam grilles in August 2019. Refer the SHI to the Gram Negative Bacteraemia IMT minutes which provide the record of decision making and progress reporting. "HSE Ventilation IN Progress Tracker v12.pdf" date April 2022 records that "Chilled beam push fit connections changed to compression".

2019-06-21 12. Notes of Cryptococcus IMT Expert 210619 final.doc	21 June 2019: Cryptococcus IMT Expert Advisory Sub-Group. Already submitted - Part of RFI 7, Qu 2.17.
2019-07-26 14. Notes of Cryptococcus IMT Expert 260719 final.doc	26 July 2019: Cryptococcus IMT Expert Advisory Sub-Group. Already submitted - Part of RFI 7, Qu 2.17.
IMT Ward 6A Gram Negative Blood Cultures 01 08 19.doc	1 August 2019: Gram Negative Blood Cultures Incident Management Team Already submitted - Part of RFI 7, Qu 2.18.
ATO102_01591433 Re HIIAT RED QEUH.msg	Email summary of discussion from clinical meeting held on 2 August 2019 noting HEPA filters to be <i>“sourced and placed in bathrooms”</i> .
2019-08-09 15. Notes of Cryptococcus IMT Expert 090819 final.doc	9 August 2019: Cryptococcus IMT Expert Advisory Sub-Group. Already submitted - Part of RFI 7, Qu 2.17.
VCS-002 Vent grille cleaning HIGH RISK WARD.pdf	SOP for exchange / cleaning of chilled beams
2019-09-16 19. Notes of Cryptococcus IMT Expert 160919 final.doc	16 September 2019: Cryptococcus IMT Expert Advisory Sub-Group. Already submitted - Part of RFI 7, Qu 2.17. <i>“the Ventilation Group are happy to remove the CVGs as the risk of leakage or dilution required is minimal. This has not been formally signed off by HFS but they are happy if the Authorised Engineer has approved this. It was agreed that Darryl ask the Authorised Engineer to send him the re-endorsement again to close off this action”</i>
ATO102_01600174.pdf	8 August 2019: Action Plan, prepared by Estates, detailing Ward 6A ongoing compliance works, including the installation of HEPA filtration units in en-suites. Action Plan circulated as part of meeting papers for Gram Negative IMT scheduled for 14 August 2019.

IMT Ward 6A Gram Negative Blood Cultures 08 08 19.doc	8 August 2019: Gram Negative Blood Cultures Incident Management Team Already submitted - Part of RFI 7, Qu 2.18. The 'Risk Management/Control Measures' section notes that estates have <i>"drawn up an action plan which will focus on the chilled beams within Ward 6A and how estates issues/services are managed within this area"</i>
	From August 2019: Installation of recirculation air scrubber fans in ceiling space of en-suite room Recirculation air scrubber fans (Camfil Camcleaner 400 concealed fan units) were installed in the ceiling space of patient en-suite rooms within Ward 6A. The unit consists of a F7 pre-filter and a secondary H13 HEPA filter. A trial commenced within Room 6 prior to roll out of the units within all remaining patient en-suites.
IMT Ward 6A Gram Negative Blood Cultures 14 08 19.doc	14 August 2019: Incident Management Team notes. Already submitted - Part of RFI 1, Qu 6. <i>"A sample of a HEPA filtration unit which can be deployed within patient en-suites above the ceiling tiles has been sourced. Tom Steele will send the data sheet to Dr Inkster before any decision is made. If the HEPA units can be deployed then air testing will be carried out before and after deployment."</i>
ATO102_00831568.pdf	20 August 2019: Action Plan, prepared by Estates, detailing Ward 6A ongoing compliance works, dated 20th August 2019 (Update to previous version dated 8th August 2019). Action Plan circulated to IMT membership on 20th August 2019.
2019-08-23 17. Notes of Cryptococcus IMT Expert 230819 final.doc	23 August 2019: Cryptococcus IMT Expert Advisory Sub-Group. Already submitted - Part of RFI 7, Qu 2.17.
IMT Ward 6A Gram Negative Blood Cultures 23 08 19.doc	23 August 2019: Gram Negative Blood Cultures Incident Management Team notes. This document will be submitted as part of RFI11, Qu 1 response. <i>"HEPA filtration units are to fitted to the every patient en-suite."</i>

ATO102_01600962 FW Vent SOPs.msg	23 August 2019: Email forwarding the SOP for exchange / cleaning of chilled beams as discussed at the Gram Negative Bacteraemia Incident Management Team meeting on 23 rd August 2019
VCS-002 Vent grille cleaning HIGH RISK WARD.pdf	SOP for exchange / cleaning of chilled beams
IMT Action List Ward 6A.doc	Action List from Incident Management Team notes from meeting held on 23 August 2019 . Confirms that trial unit had been installed in room 6.
QEUH – Single Ocupncy Bedroom Ward 6A Bedroom 6 with en-suite recirculation scrubber fan.pdf	23 August 2019: Correctair Solutions Ltd, Critical ventilation annual verification and inspection, Adults Ward 6A – Room 6 Annual inspection was completed following the installation of a Camfil Recirculation Unit (schematic of unit shown in Section 8 of the verification report).
ATO102_01630676 Ward 6A IMT Update 230819.msg	23 August 2019: Communication from Microbiology Technical Services Manager of air sampling requirements to be carried out in Room 6.
GQEE2008107 Quote_Trial_Hepa Installation.pdf; GQEE2008107 PO_Trial_Hepa Installation.pdf; GQEE2008107 Invoice_Trial_Hepa Installation.pdf	August 2019: Morris and Spottiswood install a HEPA filter unit within Ward 6A, Room 6. Quote, Purchase Order Number and Invoice provided.
ATO102_01591260 Re SBAR 6A.msg; ATO102_01600143.doc	29 August 2019: SBAR – Ward 6A environment authored by QEUH Microbiology Department, dated 26 August 2019, sent to Chair of Incident Management Team. Point 5 of the ‘Assessment’ describes the outcome of air sampling in bathrooms and notes the <i>“potential for HEPA filters to be placed in the bathroom ceilings, however again, this is a cleaning method for air rather than a HEPA supply”</i> .
QEUH 6A Room Particle Counts 300819.pdf	30 August 2019: Particle counts completed within Ward 6A (including room 6) taken on 30 August 2019.

GQEE1960773-000-001 Quote_20 Hepa Concealed Units.pdf;	September 2019: Quote, Purchase Order Number for Camfil Ltd to supply 20 Aircleaner 400 concealed units (lead time noted to be 6-7 weeks).
GQEE1960773-000-001 PO_20 Hepa Concealed Units.pdf	<i>Note: the quote is dated 25th August 2019; the Purchase Order Number was raised on 3rd September 2019; the final signature on the Waiver of Tender is dated 9th September 2019.</i>
ATO102_03303562.xlsx	2 September 2019: Estates (internal) Action Plan indicating “Change flexible push fit connectors.” completed
IMT Ward 6A Gram Negative Blood Cultures 06.09.19.doc	6 September 2019: Gram Negative Blood Cultures Incident Management Team notes Already submitted - Part of RFI 1, Qu 6. <i>“It was decided the ward will reopen when the remedial actions have been carried out regarding sampling and results, HEPA filters fitted, timeline created and the peer review carried out.”</i>
Ward 6A Room to Corridor pressure 12 Sept 2019.pdf	12 September 2019: Date of test in Correctair Solutions (Scotland) Limited Report - Ward 6A Pressure Profile. This report contained recommendations to improve the room differential pressures.
IMT Ward 6A Gram Negative Blood Cultures 13.09.19.doc	13 September 2019: Gram Negative Blood Cultures Incident Management Team Already submitted - Part of RFI 1, Qu 6. <i>“results from air sampling from room 6 in 6a (HEPA filter in shower room) should be available Tuesday/Wednesday next week”.</i>
IMT Ward 6A Gram Negative Blood Cultures 18 09 19.doc	18 September 2019: Gram Negative Blood Cultures Incident Management Team Already submitted - Part of RFI 1, Qu 6. <i>“the IMT confirmed that all work within the ward is complete apart from the installation of the en-suite HEPA filters which we are currently awaiting delivery”.</i>
GQEE2008106 PO.pdf; GQEE2008106 Quote.pdf;	October 2019: Quote, Purchase Order Number and Invoice for MMM Joinery to supply drop seals for Ward 6A. <i>Note: the quote is dated 10th October 2019; the Purchase Order Number was raised on 24th October 2019; the Invoice is dated 28th October 2019.</i>

GQEE2008106 Invoice.pdf	
HAI SCRIBE RHC WARD 6A Heppa Filter Installation Multiple rooms.doc	19th October 2019: SHFN 30: HAI-Scribe: Risk Assessment to install 20 No H13-400 in-line HEPA filters above the ceilings in 20 No en-suites toilets in Ward 6A. Page 14 notes the operation of works includes the elements performed by Contractors.
26 documents – QEUH – Single Occupancy Bedroom Ward 6A Bedrooms (numbers range from 1 to 5 and 7 to 27) with en-suite recirculation scrubber fan.pdf	29th October 2019 to 24th November 2019: Correctair Solutions Ltd, Critical ventilation annual verification and inspection, Adults Ward 6A – Rooms 1 to 5, and 7 to 27.
FINAL IMT Ward 6A Gram Negative Blood Cultures 05 11 19.doc	5 November 2019: Gram Negative Bacteraemia Incident Management Team notes. Already submitted - Part of RFI 1, Qu 6. <i>“twelve rooms have had their HEPA filters fitted into their en-suites with the rest being completed by the next week”.</i>
ATO102_03192061 FW Emailing Revised Programme Heppa Filter Installation Ward 6A.msg	5th November 2019: HEPA filter installation programme forwarded on from Morris and Spottiswood. Excel document details what rooms were completed on what date and look ahead programme to completion.
HPS Review of NHSGG&C paediatric haemato-oncology data (October 2019).pdf	Summary Report: Review of NHSGG&C paediatric haemato-oncology data (October 2019) A Management Information publication for Scotland Publication date: November 2019 .
Ward 6A reopening bundle action plan 081119 1.2.docx	8th November 2019: Bundle for re-opening of Ward 6A to high risk haematology oncology patients. Table outline work elements that have been completed, or require to be completed ahead of reopening the ward.
IMT Ward 6A Gram Negative Blood Cultures 11 11 19.pdf	11 November 2019: Gram Negative Bacteraemia Incident Management Team notes. Already submitted - Part of RFI 7, Qu 2.18. <i>“A Ward 6A re-opening bundle has been created following a meeting with management and clinicians. An action plan highlighting elements that require to be in place before the ward is reopened, from a managerial point of view, has been created and will be taken forward. “</i>

IMT Ward 6A Gram Negative Blood Cultures 14 11 19.pdf	14 November 2019: Gram Negative Bacteraemia Incident Management Team notes. Already submitted - Part of RFI 7, Qu 2.18. <i>HPS report received showed the data does not support the ongoing restrictions to admissions and therefore it supports IMT recommendation for lifting restrictions for admissions to the ward.</i>
ExternaltoGGCReopening of ward 6A to new admissions.msg	18 November 2019: Email from Scottish Government To NHSGGC Chief Executive noting actions to be confirmed as complete to allow ward re-opening.
ATO101_04452177.pdf	21 November 2019: Letter to Parents/Carers, signed by Chief Executive, advising of the reasons to accept a recommendation to re-open Ward 6A.
GQEE2061698 PO_Hepa Installation.pdf; GQEE2061698 Invoice_Hepa Installation.pdf	November 2019: Purchase Order Number and Invoice from Morris and Spottiswood for installation of HEPA filter units within Ward 6A up to and including 24 th November 2019. <i>Note: the Purchase Order Number was raised on 24th December 2019; the Invoice is dated 31st December 2019.</i>
GQEE2045877 Quote_12 Hepa Concealed Units.pdf; GQEE2045877 PO_12 Hepa Concealed Units.pdf	December 2019: Quote and Purchase Order Number for Camfil Ltd to supply 12 Aircleaner 400 concealed units. <i>Note: the quote is dated 18th November 2019; the Purchase Order Number was raised on 4th December 2019.</i>
Report from the Cryptococcus IMT Expert Advisory Sub-Group Unredacted FINAL 2022-04-05.pdf	5 April 2022: In the section 'Action taken by NHSGGC to mitigate this potential risk', the bullet notes that Ceiling Vent Grilles were removed and replaced with a standard ceiling tile to reduce the risk of particulates moving from the corridor ceiling void into the corridor transfer area and rooms in Ward 4B, 4C and 6A. Already submitted - Part of RFI 7, Qu 2.17.

6/19/2019

RE: Respiratory ward ventil... - INKSTER, Teresa (NHS GREATER GLASGOW & CLYDE)

RE: Respiratory ward ventilation

Powrie, Ian <Ian.Powrie@nhs.uk>

Thu 26/05/2016 13:34

To: Inkster Teresa (NHS GREATER GLASGOW & CLYDE) <teresa.inkster@nhs.uk>; Frew Shiona (NHS GREATER GLASGOW & CLYDE) <Shiona.Frew@nhs.uk>;
 Loudon David (NHS GREATER GLASGOW & CLYDE) <David.Loudon@nhs.uk>; Harkness Anne (NHS GREATER GLASGOW & CLYDE) <Anne.Harkness@nhs.uk>; Walsh Thomas (NHS
 GREATER GLASGOW & CLYDE) <Tom.Walsh@nhs.uk>

4 attachments

Extract from M and E Clarification Log docx; Signed off vent drawing - ZBP-ZH-XX-PL-524-058.pdf; 20160518 Ward Ventilation Strategy - Issue 3.pdf; Ward Ventilation Design strategy_Dec 09-SP2
 (4).docx

Hi Teresa,

I can confirm that a typical single room with en-suite is supplied with air at a rate of 40 l/s (equating to 3.19 ACH) and an extract derived via the en-suite at 45 l/s. The move away from the requirement in SHTM 03-01 for 6 ACH was agreed by the Board prior to formal contract award, the justification for the proposed variation to that specified and its acceptance is provided in the following attached documents:

1. Ward ventilation design strategy Dec 2009-SP2
2. Extract from M&E clarification log
3. Signed off vent drawing ZBP-ZH-XX-PL-524-058

As can be seen from the clarification log, the board accepted this proposal with the caveat "Negative pressure to be created in the design solution." achievement of the -ve pressure design has been validated by Brookfield's design team in the attached report ref: 20160518 ward-ventilation strategy - issue 3.

If you require any further information or support on this matter please let me know.

Regards

Ian

<https://email.nhs.net/owa/#viewmodel=ReadMessageItem&ItemID=AAMkADA0YzZhNDg5LWFiYjllNDIzYy1hODk1LWU5NmFiYjU2NmU5OQBGAUAAAAUcOA4QT CZQKn82bGXlLhBwD6quDU4MKTYEHR6vE4VIAAKnm...> 1/3

6/19/2019

RE: Respiratory ward ventil... - INKSTER, Teresa (NHS GREATER GLASGOW & CLYDE)

I. Powrie

Sector Estates Manager (South & Clyde)
Queen Elizabeth University Hospital Campus,
1345 Govan Rd,
Glasgow,
G51 4TF,
[REDACTED]

From: Inkster Teresa (NHS GREATER GLASGOW & CLYDE) [mailto:teresa.inkster@nhs.uk] [REDACTED]

Sent: 25 May 2016 13:42

To: Powrie, Ian; Frew, Shiona

Cc: Loudon, David; Harkness, Anne; Walsh, Tom

Subject: Respiratory ward ventilation

Dear both,

Despite numerous requests for information I have not received anything in writing confirming the ventilation spec of the rooms in level 7 Respiratory at QEUH .

I have been told verbally that these rooms have 3 ACH and are at neutral pressure - is this accurate and can I be sent confirmation of this?

I appreciate there is nothing that can be done to remedy this. However, I need to do an infection control risk assessment and put risk mitigating measures in place on the unit .

It would be useful if I could have the same information for the other high risk areas in the hospital : These are; respiratory outpatient clinics , ward 5C , level 4 renal transplant.

Do we know whether the same decision to reduce air changes was made for RHC?

Kind Regards

Teresa

Dr Teresa Inkster

Lead Infection Control Doctor NHSGGC

Training Programme Director Medical Microbiology

Dept of Microbiology

Queen Elizabeth University Hospital

Glasgow
[REDACTED]

<https://email.nhs.net/owa/#viewmodel=ReadMessageItem&ItemID=AAMkADA0YzZhNDg5LWFiYjllNDIzYy1hODk1LWU5NmFiYjU2NmU5OQBGAAAAAucOA4QTCZQKn82bGXklhBwD8qjU4MKTYEHR6vE4V1AAKnm...> 2/3

A48946859

Extract from M&E clarification Log (Final Agreed for Contract)

Ventilation:

Board Comment: Ward Air change to be 6AC/HR, currently shown as 2.5AC/HR which is not in compliance with SHTM 03-01.

Status: Agreed

Brookfield Comments: Brookfield proposal as outlined within the bid submission is to incorporate chilled beams as a low energy solution to control the environment which do not rely on large volumes of treated air or variable natural ventilation. All accommodation is single bedrooms and therefore the need for dilution of airborne microbiological contamination should be reduced (rooms could also be at slightly negative pressure to corridor). Providing 6 air changes is energy intensive and not necessary.

Agreed Position: The proposal is accepted on the basis of 40 litres per second per single room (8 litres per second per second) for one patient and four others. Joint review to be carried out between the Board and Brookfield of the energy model to determine any impact on the energy target/BREEAM rating. Brookfield, however, remain responsible for achievement of the energy target/BREEAM, with £250,000 added to the contract sum in this regard. Negative pressure to be created in the design solution.

NSGH WARD VENTILATION DESIGN STRATEGY

Board Requirement

The design requirements for the NSGH states that the summertime temperature limit is 'not to exceed 26°C'.

This exceeds the guidance provided within the draft SHTM 03-01 on the design of ventilation in healthcare premises, limiting the summertime temperature to 'not exceed 28°C for more than 50 hours per year'.

Natural Ventilation

The SHTM allows for the natural ventilation of areas including general wards. In clause 2.3 it states that 'as the motivating influences of natural ventilation are variable, it is almost impossible to maintain consistent flow rates and ensure that minimum ventilation rates will be achieved at all times. This variability is normally acceptable for general wards'.

Through the use of thermal modeling during the bid stage the use of natural ventilation using openable windows was investigated and results showed that the Board's requirement for temperature control could not be achieved. Furthermore, adding additional background cooled mechanical ventilation, at a quantity to balance the ensuite extract rate, still did not achieve the requirement. Other concerns with natural ventilation included patient comfort due to uncontrolled wind driven ventilation and air quality, particularly in winter when windows would be closed.

Therefore, the sole use of mechanical ventilation was explored, again using thermal modeling.

Mechanical Ventilation

The recommended air change rate for single rooms in SHTM 03-01 Appendix 1 Table A1 for single rooms is 6 air changes per hour (ac/h).

Modelling was carried out based on this recommendation, but it was found that the requirement of 26°C could not be met. To try to achieve this, the ventilation rate was further increased, but became excessive and likely to cause draughts to the occupants, poor temperature control and increased energy consumption.

Consideration was then given to a terminal cooling solution, using active chilled beams which provide cooling, heating and fresh air via the primary air supply system. The performance of chilled beams is related to their physical size and thus the amount of primary air supplied from the central air handling plant. The primary air volume will also

provide make up for the extract from the ensuite toilets to achieve a negative inflow of air into the bedroom from the corridor as required by SHTM 03-01 Appendix 1 Table A1.

Using active chilled beams delivers the temperature control requirement, provides individual room control and fresh air, albeit less than the recommendation of SHTM 03-01.

Chilled beams are also an energy efficient solution and save some 9kg/m^2 of CO_2 over that of an all air system delivering 6ac/h, equivalent to about 10% of the hospitals' total emissions.

Conclusion

If natural ventilation could be employed then the air change rates within the bedrooms would be variable dependant on window opening and external conditions, and is rarely likely to achieve 6ac/h.

The recommended air change rate of 6ac/h in the SHTM is considered to relate to the ability to achieve an acceptable internal environment, i.e 50 hours exceedence above 28°C . This could be achieved with 6ac/h of cooled air.

However, the Board's requirement for a reduced temperature makes this solution impractical and the use of chilled beams is the only viable solution, using a reduced quantity of primary air.

Whilst the air change rate is less than the SHTM, at a supply air volume of 30 litres per second it is in compliance with Scottish Building Regulations and also CIBSE codes, giving sufficient fresh air for a continuous occupation of three people at 10-12 litres per second each.

19/08/2020

Air changes QEUH - INKSTER, Teresa (NHS GREATER GLASGOW & CLYDE)

Air changes QEUH

Inkster Teresa (NHS GREATER GLASGOW & CLYDE)

Fri 27/05/2016 10:11

To: Peters Christine (NHS GREATER GLASGOW & CLYDE) <Christine.Peters@nhs.uk>; Pritchard Lynn (NHS GREATER GLASGOW & CLYDE) <Lynn.Pritchard@nhs.uk>; Joannidis Pamela (NHS GREATER GLASGOW & CLYDE) <Pamela.Joannidis@nhs.uk>;
Cc: McNamee Sandra (NHS GREATER GLASGOW & CLYDE) <Sandra.McNamee@nhs.uk>; Walsh Thomas (NHS GREATER GLASGOW & CLYDE) <Tom.Walsh@nhs.uk>

Hi all ,

I have had confirmation from Ian Powrie that the single rooms in QEUH have air changes of <3 which is half the recommended 6/hr. In addition the rooms are at neutral pressure and not negative as was intended to compensate for this drop in ACH .

I know Lynn/ Christine that you have put measures in place on the respiratory ward already but we now need to consider what we do for the rest of the hospital. Of particular concern is renal transplant as these rooms should have been designed at positive pressure. Can I suggest the four of us meet up to discuss. I am free from 3pm on Tuesday if that suits at QEUH.

Pamela - I am awaiting confirmation from Ian regarding RHC . I also need to find out the answer to your question Lynn about the retained site

Kind Regards
Teresa

Dr Teresa Inkster
Lead Infection Control Doctor NHSGGC
Training Programme Director Medical Microbiology
Dept of Microbiology
Queen Elizabeth University Hospital
Glasgow
Direct dial : [REDACTED]

A48946859

SBAR – Air changes , patient rooms , QEUH
Dr Teresa Inkster, June 2016

Situation	During an investigation into Mycobacterium abscessus cases in Cystic fibrosis patients at QEUH the ICT were alerted to reduced air changes in patient rooms.
Background	Recommended air changes for a single room on a ward are 6 air changes / hour as per HTM 03-01 (Specialised ventilation for healthcare premises). This would not normally have infection control sign off. A decision was made to reduce air changes to 3 ACH/hr in the renal dialysis unit for energy efficiency. This decision was then extrapolated to the rest of the hospital. Sufficient negative pressure of the rooms was not obtained to make this a safe option. Rooms are currently at a neutral pressure. There is therefore both reduced dilution of microbial contamination and escape of air out of the rooms into surrounding areas.
Assessment	Placement of patients with airborne infections in these rooms represents a risk of cross transmission to other patients and staff via the airborne route. High risk areas in the QEUH have been identified as; 1) Level 7 Respiratory wards 2) Outpatient respiratory clinics 1st floor clinic B rooms 77-85 3) Physio department – Room 16 , Ground floor 4) Renal transplant , level 4 5) ID unit , level 5 6) During winter months and respiratory virus season other wards will be high risk
Recommendations	1) Doors to rooms should remain closed 2) For aerosol generating procedures in in-patients 2 hours should be left before non- essential personnel enter the room and before a new patient is admitted. 3) For aerosol generating procedures 2 hours should be left between patients in the outpatient setting 4) Staff should continue to wear appropriate PPE 5) Renal transplant patients should where possible be nursed in ward 4C until 12 months post transplant. 6) ICT should be made aware of any renal transplant patients with PCP. 7) This information should be reviewed in conjunction with the HFS review of isolation rooms. Contingency planning may be required for patients with active pulmonary tuberculosis.

RE: SBAR Room air changes

Armstrong, Jennifer <Jennifer.Armstrong@nhs.uk>

Mon 20/06/2016 22:50

To: Inkster Teresa (NHS GREATER GLASGOW & CLYDE) <teresa.inkster@nhs.uk> Loudon David (NHS GREATER GLASGOW & CLYDE) <David.Loudon@nhs.uk> Harkness Anne (NHS GREATER GLASGOW & CLYDE) <Anne.Harkness@nhs.uk>

Cc: Dunn Patricia (NHS GREATER GLASGOW & CLYDE) <Patricia.Dunn@nhs.uk>

All

It seems to me that there are quite significant implications of this note; I would be keen that we get together to discuss this note and what we need to do about this; I have also alerted Robert Calderwood to this issue; Perhaps we need to set up an urgent meeting to discuss the implications and what we need to do about this asap.

I wonder if you would all be good enough to flex your diaries; In addition, I think David you were going to review how these decisions were reached and also what the thinking was behind the new room designs? I wonder if perhaps one of the project team and perhaps we need some clinical advice from specialists about the implications for patients. However in the first instance can we discuss this please

From: Inkster Teresa (NHS GREATER GLASGOW & CLYDE) [mailto:teresa.inkster@nhs.uk]

Sent: 20 June 2016 17:34

To: Armstrong, Jennifer; Loudon, David; Harkness, Anne

Subject: SBAR Room air changes

Dear all

I have all the info now in relation to the patient rooms with reduced air changes. I have produced the attached SBAR FYI. The ICNs will action recommendations 1-6.

Kind Regards

Teresa

Dr Teresa Inkster

Lead Infection Control Doctor NHSGGC

Training Programme Director Medical Microbiology

Dept of Microbiology

pressure checks QEUH

INKSTER, Teresa (NHS GREATER GLASGOW & CLYDE)

Fri 09/11/2018 09:27

To: STEELE, Tom (NHS GREATER GLASGOW & CLYDE) <tom.steele@[REDACTED]> Wilson, Andy <Andy.Wilson@[REDACTED]>

Cc: John.Hood@[REDACTED] <John.Hood@[REDACTED]> HOOD, John (NHS GREATER GLASGOW & CLYDE) <johnhood@[REDACTED]>

Tom - further to our phone conversation details of the pressures we checked yesterday are below. We used two methods - a micro anemometer and a smoke test

As per SHTM 03-01 a single rooms spec is 6 ach/hr and a pressure of 0 to negative. My understanding is that to offset the reduction in air changes with chilled beam technology the rooms were to be at a definite negative pressure. In most areas this is not an issue but is problematic for immunosuppressed patients particularly haemato-oncology.

You will note the pressures recorded below. Ward 4C is housing haematology patients and the rooms should be positive. The readings we have confirm that they are but they are not as positive as they should be. This requires more thought.

What I am more concerned about is the readings from 5C/D as these indicate we have rooms at neutral positive pressure. These wards are where we have ID patients including non resistant TB cases. As this is an airborne infection these patients must be in a negative pressure environment. We have PPVL rooms on the critical care floor in the process of being upgraded to negative pressure. These will be used for multi drug resistant TB cases and any query MERs -Coronavirus but there are still several patients with non resistant TB who will need to be nursed in 5C/D. The risk here is not to the patient but to staff and members of the public as the contaminated air is coming out of the room.

As we discussed it would be useful to have a review of these areas. I have had a conversation with Andy re these results and will catch up with you later today

Kind regards
Teresa

Ward 4C

Room 72 ; 0.7-1.0 Positive

Room 73 ; 1.1, Positive

Room 74 0.3 , Positive

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A48946859

5/17/2019

pressure checks QEUH - INKSTER, Teresa (NHS GREATER GLASGOW & CLYDE)

Page 1504

Room 75 0.3-0.5 Positive

Ward 5C

Room 60 0.0 to -0.2 Neutral to slightly negative

Room 61 - 0.0 Neutral

Room 66 - 0.0 Neutral

Ward 5D

Room 29 0 to 0.1 Positive

Room 30 0 to 0.1 Positive

Room 32 0.1 Positive

Dr Teresa Inkster

Lead Infection Control Doctor NHSGGC

Training Programme Director Medical Microbiology

Dept of Microbiology

Queen Elizabeth University Hospital

Glasgow

Direct dial : [REDACTED]

6/14/2019

RE: Ventilation wards 5C and 5D - INKSTER, Teresa (NHS GREATER GLASGOW & CLYDE)

RE: Ventilation wards 5C and 5D

Fleming, Kenneth <Kenneth.Fleming@nhs.uk>

Mon 03/12/2018 14:17

To: INKSTER, Teresa (NHS GREATER GLASGOW & CLYDE) <teresa.inkster@nhs.uk>

Cc: Peters Seija (NHS GREATER GLASGOW & CLYDE) <Erica.Peters@nhs.uk>; Wilson, Andy <Andy.Wilson@nhs.uk>; STEELE, Tom (NHS GREATER GLASGOW & CLYDE) <tom.steele@nhs.uk>; Walsh Thomas (NHS GREATER GLASGOW & CLYDE) <Tom.Walsh@nhs.uk>; RAEBURN, Cameron (NATIONAL SERVICES SCOTLAND) <cameron.raeburn@nhs.uk>; Gardner, Morag <Morag.Gardner@nhs.uk>

Hi Teresa

Thanks for the email. Cameron Raeburn has set up a meeting to take place on Thursday with regards to the recent HSE issues that have been highlighted and resulted in an Improvement Notice, as you are aware.

I will ask Cameron to take into account the information that you have provided with regards to ventilation. I have also copied Morag Gardner who is directly involved with both the HSE requirements and the meeting that will be taking place on Thursday.

I will be on leave over the next 2 weeks and so I will ask Cameron to liaise with you after the meeting on Thursday.

Regards

Kenneth

Kenneth Fleming
Head of Health and Safety
NHS Greater Glasgow and Clyde
West Glasgow ACH (Yorkhill)
[Redacted]

<https://email.nhs.net/owa/#viewmodel=ReadMessageItem&ItemID=AAMkADAOYzZhNDg5LWFYIjIINDIzYy1hODk1LWU5NmFIYU2NmU5OQBGAUAAAAUcOA4QTCZQKn82bGXKlHbYD8quDU4MKTYEHR6vE4VIAAKre...> 1/3

6/14/2019

RE: Ventilation wards 5C en... - INKSTER, Teresa (NHS GREATER GLASGOW & CLYDE)

HR Support and Advice Unit
Tel: 0141 278 2700 (Ext 12700)
Email: HR.Support@ggc.scot.nhs.uk

PS. I've signed up to [improving our email culture](#)

From: INKSTER, Teresa (NHS GREATER GLASGOW & CLYDE) [mailto:teresa.inkster@...]
Sent: 03 December 2018 14:03
To: Fleming, Kenneth
Cc: Peters, Erica; Wilson, Andy; STEELE, Tom (NHS GREATER GLASGOW & CLYDE); Walsh, Tom
Subject: [ExternaltoGGC]Ventilation wards 5C and 5D

Hi Kenneth,

I am writing to make you aware of an issue with ventilation in wards 5C/D in QEUH as there is a health and safety issue.

By means of a background, the ventilation in QEUH, with chilled beam technology, was designed to be 3 air changes per hour with rooms at a slightly negative pressure.

Investigation of ventilation in the now decanted 2A/B RHC revealed some matters of concern. I therefore requested other high risk areas on the site be assessed to see if these issues were replicated.

On checking pressures and air direction with my colleague Dr Hood we found there to be varying pressures in the rooms on 5C/D. Some were slightly negative but others were positive. It was not clear to us why there should be inconsistency between rooms on the same ward.

I have discussed with estates colleagues and my understanding is that these pressures have been verified by an external company and they are investigating how to rebalance the system. If this is not possible we will need to determine exactly what rooms are safe for each patient group.

5D is used for patients with TB therefore rooms at a positive pressure represent a risk. The risk is not to the patients in the room or staff entering the room wearing PPE but to others. This is because air is being pushed out of the room into the corridor and ward.

HIV patients, housed on 5C, are immunosuppressed and would benefit from rooms at a slightly positive pressure.

My concern at the moment relates to the potential for staff/patients to have been exposed in 5D and I would welcome your input.

Kind regards

<https://email.nhs.net/owa/#viewmodel=ReadMessageItem&ItemID=AAMkADA0YzZhNDg5LWFiYjIiNDIzYy1hODk1LWU5NmFIYjU2NmU5OQBGAAAAAucQA4QTCZQk182bGxKLH8wD6guDU4MKTYEHR6vE4VIAAKr...> 2/3

Ventilation

Wilson, Andy <Andy.Wilson@nhs.uk>

Wed 05/12/2018 13:23

To: INKSTER, Teresa (NHS GREATER GLASGOW & CLYDE) <teresa.inkster@nhs.uk>

Cc: Steele, Tom <Tom.Steele@nhs.uk>

Hi Teresa,

We are progressing with the work discussed to review, and improve where necessary, the pressure regimes across a number of wards; 4C, 5C, 5D, 7A & 7D.

As discussed today, following the changes made to the operating parameters for the plant across all of these wards, we have already confirmed that we have been able to achieve the 1Pa negative pressure in the room vs corridor for ward 5C and our next area of focus for balancing work is ward 5D. I am awaiting confirmation from the contractor of what has been achieved in 5C.

As discussed today, you are not certain that a positive environment is correct for all patients in 7A & 7D and will need to get confirmation from clinical colleagues before proceeding so I have put on hold further work to these wards until confirmed.

For ward 4C, we will continue with work to provide as positive an environment as possible but it would be useful to know the minimum positive pressure you would like to see in the room so we know whether simple re-balancing may be sufficient or whether we should progress with consultant reviews of the system to identify what size / power of fan is required to achieve the desired pressure regime. Can you please confirm the minimum positive pressure that would be acceptable for 4C?

Thanks,
Andy

Andrew S. E. Wilson | CEng MIMechE
Sector Estates Manager (South)

Queen Elizabeth University Hospital
1345 Govan Road
Glasgow
G51 4TF

andy.wilson@nhs.uk

Inkster, Teresa

From: Steele, Tom
Sent: 13 December 2018 12:55
To: Inkster, Teresa
Cc: Walsh, Tom; Armstrong, Jennifer; Wilson, Andy
Subject: RE: Airborne pathogen infection control

Importance: High

Teresa, I will liaise with the site team and revert ASAP, I cannot comment on what was said in 2015 to clinicians, but can establish the current operating conditions.

Regards Tom

Tom Steele | Director of Estates and Facilities
| NHS Greater Glasgow and Clyde | JB Russell House | Gartnavel Royal Hospital | 1055 Great Western Road | Glasgow | G12 0XH


From: Inkster, Teresa
Sent: 13 December 2018 12:42
To: Steele, Tom <Tom.Steele@nhs.uk>
Cc: Walsh, Tom <Tom.Walsh@nhs.uk>
Subject: FW: Airborne pathogen infection control

Dear Tom

I was copied into this email from ID clinicians yesterday. In order to provide assurances with respect to patient safety I need the following;

- Written documentation of the pressures in the rooms in wards 5C and 5D - I thought this had been undertaken by an external company but have been told that this was done in-house
- An understanding of the ductwork configuration and whether the same issues identified in wards 2A/B are present in these wards
- What rebalancing has already taken place
- Any further remedial works required.
- How we ensure that room pressures do not flip from negative to positive – this is very important in the context of airborne infection in that even slightly positive rooms will lead to egress of contaminated air

Ward 5C/D is where we house infectious disease patients where we could expect to see patients with airborne infections including TB, Chickenpox and Measles

Kind regards
 Teresa

From: Bell, David
Sent: 12 December 2018 14:30
To: Harkness, Anne; Davidson, Scott; Perry, Colin (NHSmail); Gay, Fiona
Cc: Inkster, Teresa; Peters, Erica
Subject: Airborne pathogen infection control

Dear Scott, Anne, Fiona and Colin;

Last week we were informed that estates are investigating the ventilation systems in the Infectious Diseases wards, 5C and 5D. In 2015 the Infectious Diseases team moved to the QEUG in 2015 we were reassured that there would be

2 negative pressure rooms on 1st floor that we would have access to. These turned out to be positive pressure ventilated lobby rooms which are not deemed safe enough to manage high consequence airborne infections.

Once this was realised an interim measure was put in place after meetings with estates, infection control, management and following discussion with our clinical colleagues in GRI and Lanarkshire. It was decided that pulmonary tuberculosis could be managed on 5D with appropriate PPE. Immunosuppressed patients, largely those with HIV, would be geographically separated from those with TB and managed on 5C. Those with a high risk of MDR TB or with an established diagnosis of MDR TB would have to have their care transferred to one of the 2 negative pressure rooms on the GRI site. Any patient with proven MERS CoV would need to be transferred to Monklands negative pressure rooms. This was supposed to be a temporary arrangement while an engineering solution was found to convert the 1st floor rooms to negative pressure.

We understand that the engineering solution for the negative pressure rooms on 1st floor has been problematic and we understand the work has currently been suspended. We have also heard that the basic expected air exchange in the standard 5th floor rooms is not the expected 3 exchanges per hour but that there is a mixture of positive and negative ventilation in different rooms.

There is an immediate patient safety concern as those with airborne infection may be currently housed in a positive pressure room, thus spreading pathogens into the corridor and potentially other rooms. Those susceptible patients e.g. with HIV, on various immunotherapies, neutropenics etc may be housed in negative pressure rooms thus sucking pathogens into their rooms from the corridor. Given GG and C has the highest burden of tuberculosis in Scotland and that we provide the only inpatient infection service for the area, including HIV inpatient care there is a real concern about the ability to safely provide this service at present on the QEUH site.

We are requesting urgent reassurances from estates, endorsed by the Infection Control Lead that patient safety is not currently being compromised due to the ventilation system in the inpatient areas in QEUH.

Kind regards,

David Bell and Erica Peters

On Behalf of the Infectious Diseases Consultants

6/14/2019

Fw: Airborne pathogen infec... - INKSTER, Teresa (NHS GREATER GLASGOW & CLYDE)

From: Harkness, Anne
Sent: 20 December 2018 09:49
To: Bell, David; Davidson, Scott; Perry, Colin (NHSmail); Gay, Fiona
Subject: RE: Airborne pathogen infection control

Further update

They have ascertained why those rooms are failing (the dampers are closed) – so each room will need to be empty for an hour or so to allow estates access

Then we are confident they too will be negative pressure

Anne

From: Bell, David
Sent: 20 December 2018 09:31
To: Harkness, Anne; Davidson, Scott; Perry, Colin (NHSmail); Gay, Fiona
Subject: RE: Airborne pathogen infection control

Thanks Anne
 I will forward this to the ID team
 David

From: Harkness, Anne
Sent: 19 December 2018 20:20
To: Bell, David; Davidson, Scott; Perry, Colin (NHSmail); Gay, Fiona
Subject: RE: Airborne pathogen infection control

Just to confirm our conversation earlier today following a meeting with estates and the lead ICD

Adjustments to the ventilation in 5C have been made such that all rooms are now negative pressure
 Similar work has been undertaken on 5D and the report was due today (I will chase it in the am)
 Currently all rooms except rooms 56 and 54 are negative . Rooms 55 and 53 could not be tested but I suspect may be the same
 So until we hear otherwise sputum positive TB patients should not use those 4 rooms

<https://email.nhs.net/viewmodel=ReadMessageItem&ItemID=AAMkADA0YzZhNDg5LWFYlINDLzYyIhODk1LWU5NmFYjU2NmU5OQBGAAAAAucOA4QTQZQKs82bGXkLhBvD6qDuDU4MKTYEHR6vE4VIAAJ61...> 4/5

6/14/2019

Fw: Airborne pathogen Infection - INKSTER, Teresa (NHS GREATER GLASGOW & CLYDE)

For clarity the commitment given pre move was that the ID team would have access to two rooms which offered the same level of isolation as those in the Brownlee and although guidance has changed – the rooms met the required building note at the time. They continue to do so and the PPVL rooms with Hepa can continue to be used while we pursue the conclusion of the work to provide negative pressure in MHDU / ICU

Anne

From: Bell, David
Sent: 12 December 2018 14:30
To: Harkness, Anne; Davidson, Scott; Perry, Collin (NHSmail); Gay, Fiona
Cc: Inkster, Teresa; Peters, Erica
Subject: Airborne pathogen Infection control

Dear Scott, Anne, Fiona and Colin,

Last week we were informed that estates are investigating the ventilation systems in the Infectious Diseases wards, 5C and 5D. Before the Infectious Diseases team moved to the QEUI in 2015 we were reassured that there would be 2 negative pressure rooms on 1st floor that we would have access to. These turned out to be positive pressure ventilated lobby rooms which are not deemed safe enough to manage high consequence airborne infections.

Once this was realised an interim measure was put in place after meetings with estates, infection control, management and following discussion with our clinical colleagues in GRI and Lanarkshire. It was decided that pulmonary tuberculosis could be managed on 5D with appropriate PPE. Immunosuppressed patients, largely those with HIV, would be geographically separated from those with TB and managed on 5C. Those with a high risk of MDR TB or with an established diagnosis of MDR TB would have to have their care transferred to one of the 2 negative pressure rooms on the GRI site. Any patient with proven MERS CoV would need to be transferred to Monklands negative pressure rooms. This was supposed to be a temporary arrangement while an engineering solution was found to convert the 1st floor rooms to negative pressure.

We understand that the engineering solution for the negative pressure rooms on 1st floor has been problematic and we understand the work has currently been suspended. We have also heard that the basic expected air exchange in the standard 5th floor rooms is not the expected 3 exchanges per hour but that there is a mixture of positive and negative ventilation in different rooms.

There is an immediate patient safety concern as those with airborne infection may be currently housed in a positive pressure room, thus spreading pathogens into the corridor and potentially other rooms. Those susceptible patients e.g. with HIV, on various immunotherapies, neutropenics etc may be housed in negative pressure rooms thus sucking pathogens into their rooms from the corridor. Given GG and C has the highest burden of tuberculosis in Scotland and that we provide the only inpatient infection service for the area, including HIV inpatient care there is a real concern about the ability to safely provide this service at present on the QEUI site.

We are requesting urgent reassurances from estates, endorsed by the Infection Control Lead that patient safety is not currently being compromised due to the ventilation system in the inpatient areas in QEUI.

<https://email.nhs.uk/viewmodel=ReadMessageItem&itemID=AAMKADADyZzhNDgSLWFIYjIiNDIzYy1hODk1LUU5NmFiYU2NmU5OQBGAIAAAAcOA4QTCZQK82bGXkLhBwD5qUDU4MKTYEHR6vE4VIAAJ61...> 6/6

5/17/2019

RE: Ward 5D & 7D rebalance - INKSTER, Teresa (NHS GREATER GLASGOW & CLYDE)

Page 1512

To: Purdon, Colin

Subject: [ExternaltoGGC]Re: Ward 5D & 7D rebalance

Hi Colin, yes I was in on the 23rd and rechecked all the rooms that were noted on the original report as dampers closed (MFSD) the rooms were from -ve to -2.5Pa - favourable results, I checked all floors and a selection of rooms and the pressures were the same as the initial report, I completed the report on site but my laptop email stopped working! Hopefully the above detail is okay until I can transfer the report.

Thanks, Ian.

Best regards,

Ian.

Ian McKenzie

H&V Commissioning Services Ltd.

M: [REDACTED]

On 27 Dec 2018, at 12:31, Purdon, Colin <Colin.Purdon@[REDACTED]> wrote:

Hi Ian,

Did you manage to draft the report on 5D and 7D after we reset the closed fire dampers?

Are all the rooms reading as negative now?

Regards

Colin

Colin Purdon | BSc (Hons)

Interim Sector Estates Manager (South)



Estates Dept

Queen Elizabeth University Hospital Campus,

Laboratory Medicine and Facilities Management Bldg.

1345 Govan Rd

Glasgow

G51 4TF



9/08/2020

air changes - INKSTER, Teresa (NHS GREATER GLASGOW & CLYDE)

air changes

INKSTER, Teresa (NHS GREATER GLASGOW & CLYDE)

Tue 28/01/2020 15:05

To: BAIN, Marion (NHS NATIONAL SERVICES SCOTLAND) <marion.bain@nhs.uk>

Cc: Peters Christine (NHS GREATER GLASGOW & CLYDE) <Christine.Peters@nhs.uk>

2 attachments

sbar ach.doc; Air _ Appendix _ Environmental Guidelines _ Guidelines Library _ Infection Control _ CDC (2).pdf;

Dear Marion,

Further to our discussion this morning I attach the original SBAR I wrote in 2016 regarding air change rates. You will note that level 5 is designated a high risk area.

I have also attached the relevant table from the CDC guidelines. You will note that for 6 hours the time required for removal 99.9% efficiency is just over 1 hour, hence why 2 hours is applied for air changes of 3. If there is scientific evidence being provided to the contrary it would be useful to see this, as I have always worked to the CDC environmental guidance

Kind regards
Teresa

Dr Teresa Inkster
Consultant Microbiologist, QEUH
National Training Programme Director Medical Microbiology
Dept of Microbiology
Queen Elizabeth University Hospital
Glasgow
Direct dial : [REDACTED]

A48946859

Airborne Contaminant Removal

Table B.1. Air changes/hour (ACH) and time required for airborne-contaminant removal by efficiency *

ACH § ¶	Time (mins.) required for removal 99% efficiency	Time (mins.) required for removal 99.9% efficiency
2	138	207
4	69	104
6+	46	69
8	35	52
10+	28	41
12+	23	35
15+	18	28
20	14	21
50	6	8



QEUH Adults – Ward 5C - Change Pressure Profile



Client:	NHS Greater Glasgow & Clyde	Client Contact:	Darryl Conner
Hospital:	Queen Elizabeth University Hospital	Site Address:	1345 Govan Road, Glasgow G51 4TF
Area:	Ward +4C & -5C	AHU:	124AHU04 S&E 124AHU05 S&E
Theatre Condition:	N/A	Report No:	A11977
Date of Test:	3 rd December 2018	Date of Last Test:	N/A
Test Engineer & Report Preparation:	Ian McKenzie	Signature:	
H&V Approval:	Ian Stewart	Signature:	
Client Reviewed by:		Signature:	

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A4





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- 1. Scope of Works
- 2. Ward 4C & 5C - Results
- 3. Executive Summary



Section 1 – Scope of Works

Increase 124AHU04 @ 60Hz (RC = 7.7amps) & 124AHU05 @ 56Hz (RC = 7.2amps) max FLC 8.1amps for both extract fans set to full capacity.

Record room pressures form corridor to bedroom pre and ward/floor post balance.

Scope to maximise bedrooms on ward 5C to negative pressure from corridor to bedroom and ward 4C to positive pressure. Target pressures greater than 1Pa.



Section 2 – Ward 4C & 5C Results

WARD -5C (Negative Pressure Ward)

Room/Bed Nos.:	Pre Fan alteration (BMS Control)	Post Fan Ward Balance	Room/Bed Nos.:	Pre Fan alteration (BMS Control)	Post Fan Ward Balance
57	0	-1.0	71	0	-1.3
58	0	-1.9	72	0	-1.0
59	0	-2.6	73	0	-1.3
60	0	-1.3	74	0	-1.0
61	0	-2.0	75	0	-1.9
62	0	-1.0	76	0	-ve
63	0	-1.5	77	0	-1.4
64	0	-2.5	78	0	-1.0
65	0	-3.5	79	0	-1.4
66	-ve	-1.4	80	0	-ve
67	0	-2.3	81	+ve	-ve
68	0	-1.4	82	+ve	-1.0
69	0	-1.7	83	0	-1.0
70	0	-2.0	84	0	-ve

Comments:

-ve = 0 - <1Pa (notionally negative)

+ve = 0- <1Pa (notionally positive)

Any pressure greater than 1Pa is detailed.



WARD +4C (Positive Pressure Ward)

Room/Bed Nos.:	Pre Fan alteration (BMS Control)	Post Fan Ward Balance	Room/Bed Nos.:	Pre Fan alteration (BMS Control)	Post Fan Ward Balance
1-4 Renal Day	+ve	+1.8	64	+ve	+0.8
51	+1.3	+1.6	65	0	+0.8
52	+1.3	+1.7	66	+ve	+1.2
53	+1.1	+1.5	67	+ve	+1.0
54	+1.3	+1.6	68	+ve	+1.1
55	+2.2	+1.8	69	+ve	+1.5
56	+1.6	+1.5	70	+ve	+1.4
57	+1.2	+2.2	71	+1.7	+3.3
58	+2.2	+1.6	72	+1.2	+2.6
59	+1.1	+1.6	73	+1.1	+3.1
60	+1.0	+1.5	74	+ve	+1.8
61	+2.0	+1.9	75	+ve	+1.6
62	+1.3	+1.6			
63	-ve	+0.8			

Comments:

-ve = 0 - <1Pa (notionally negative)

+ve = 0- <1Pa (notionally positive)

Any pressure greater than 1Pa is detailed.

Pressure varied as the corridor doors operated, these also differed if patients toilet doors were open/closed this impacts on door differential pressure to corridor.

Several variances slightly change the profile, the door finish also has an impact on the pressure control. The retro fit of door drop down seals would help with this control and stabilise pressures, as fitted on ward 4B.



3. Executive Summary

The fan inverters, as advised by Barkell the AHU manufacturer were set to operate at their max capacity on FLC (Full Load Current) In the case of the AHU serving the floors 5C 124AHU04 & 124AHU05 we set the inverter drives to a max (in hand operation) set point of 56Hz for 124AHU05 and 60Hz for 124AHU04.

The detail shown is with main fan adjustments only, we await a HAI-SCRIBE sign off before commencing with individual ward balancing. The HAI-SCRIBE will cover us for gaining access to VCDs (volume control dampers) located about ceiling tiles, these are located and have been identified on layout drawings to form part of the HAI-SCRIBE.

The VCDs are either in and mostly located in corridor locations, however some are located within occupied bedrooms above suspended ceiling grids.

The next, as discussed actions, would be to alter the main branch VCDs, controlling alterations proportionally to each floor to increase extract volumes within rooms/wards that are to control to a negative pressure and reduce extract volumes to increase rooms/wards where positive pressures are required.

Another action discussed was to attach door drop down seals (as fitted in ward 4B) except we have recommended adjustable seals, as this will aid with the room pressure control on an individual room by room basis, without requiring access to individual rooms and local VCDs.

The initial findings are encouraging and alterations of main branch dampers will support the desired end result.

Going forward I will update and expand on the attached, for transparency of our actions and adjustments. This will also help with the assessment of the next required ward pressure change.

Ian McKenzie
H&V Commissioning Services Ltd.



QEUH Adults – Ward 7D & 5D - Change Pressure Profile to Negative Wards



Client:	NHS Greater Glasgow & Clyde	Client Contact:	Darryl Conner
Hospital:	Queen Elizabeth University Hospital	Site Address:	1345 Govan Road, Glasgow G51 4TF
Area:	Ward -5D & -7D	AHU:	123AHU04 Extract 123AHU05 Extract
Theatre Condition:	N/A	Report No:	A12104
Date of Test:	23 rd December 2018	Date of Last Test:	N/A
Test Engineer & Report Preparation:	Ian McKenzie	Signature:	
H&V Approval:	Ian Stewart	Signature:	
Client Reviewed by:		Signature:	

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1. Scope of Works
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Section 1 – Scope of Works

Increase 123AHU04 @ 56.5Hz (RC = 7.8amps) & 123AHU05 @ 51Hz (RC = 8.0amps) max FLC 8.1amps for both extract fans set to full capacity.

Record room pressures form corridor to bedroom pre and ward/floor post balance.

Scope to maximise bedrooms on ward 5D & 7D from a neutral pressure room to corridor to a negative pressure from corridor to bedroom. Target pressures greater than 1Pa.



Section 2 – Ward 5D & 7D Results

WARD -7D (Negative Pressure Corridor to Rooms)

Room/Bed Nos.:	Pre Fan alteration (BMS Control)	Post Fan Ward Balance	Room/Bed Nos.:	Pre Fan alteration (BMS Control)	Post Fan Ward Balance
29	+2.3	-ve	43	+0.8	-0.4
30	0	-1.1	44	+1.3	-1.0
31	+1	-2.8	45	+ve	-1.3
32	+1.3	-1.0	46	+2.7	-1.1
33	+1.0	-1.1	47	+1.6	-1.0
34	+0.7	-0.8	48	+1.3	-1.7
35	+0.9	-ve	49	+1.0	-1.0
36	+0.9	-ve	50	+0.7	-1.2
37	-ve	-ve	51	+0.8	-1.0
38	-ve	-1.4	52	+0.8	-1.9
39	-1.0	-1.0	53	+0.8	-1.2
40	-0.7	-1.4	54	+0.8	-1.4
41	-0.5	-1.0	55	+ve	-ve
42	-1.6	-1.8	56	+0.7	-1.1

Comments:

-ve = 0 - <1Pa (notionally negative)

+ve = 0- <1Pa (notionally positive)

Any pressure greater than 1Pa is detailed.

Room pressures vary due to toilet doors being open/closed fabric seal of room and door seal to frame and distance from frame to floor. Most bedrooms doors open during survey and these were closed one door at a time to record pressures. This will also have a varying factor to recording room pressures.



WARD -5D (Negative Pressure Corridor to Rooms)

Room/Bed Nos.:	Pre Fan alteration (BMS Control)	Post Fan Ward Balance	Room/Bed Nos.:	Pre Fan alteration (BMS Control)	Post Fan Ward Balance
29	-ve	-0.4	43	-ve	-1.1
30	-ve	-0.4	44	-ve	-1.3
31	-ve	-0.7	45	-ve	-1.0
32	0	-0.4	46	0	-1.0
33	0	-0.3	47	-ve	-1.4
34	0	-0.5	48	-ve	-1.8
35	+ve	-1.0	49	-ve	-2.4
36	-ve	-1.0	50	-ve	-1.3
37	0	-0.7	51	-ve	-1.5
38	+ve	-0.7	52	-1.2	-2.7
39	0	-0.8	53	+ve	-1.2
40	-ve	-1.1	54	+1.1	-2.1
41	+ve	-1.3	55	+1.7	-1.1
42	0	-0.6	56	+0.6	-1.8

Comments:

-ve = 0 - <1Pa (notionally negative)

+ve = 0- <1Pa (notionally positive)

Any pressure greater than 1Pa is detailed.

Pressure varied as the corridor doors operated, these also differed if patients toilet doors were open/closed this impacts on door differential pressure to corridor.

Several variances slightly change the profile, the door finish also has an impact on the pressure control. The retro fit of door drop down seals would help with this control and stabilise pressures, as fitted on ward 4B.



3. Executive Summary

The fan inverters, as advised by Barkell the AHU manufacturer were set to operate at their max capacity on FLC (Full Load Current) In the case of the AHU serving the floors 7D 123AHU04 & 123AHU05 we set the inverter drives to a max (in hand operation) set point of 51Hz for 123AHU05 and 56.5Hz for 123AHU04.

Another action discussed was to attach door drop down seals (as fitted in ward 4B) except we have recommended adjustable seals, as this will aid with the room pressure control on an individual room by room basis, without requiring access to individual rooms and local VCDs.

We did open a MFSD (Motorised Fire/Smoke Damper) in the toilet next to the mechanical riser that we found closed serving 123AHU04 Extract east side of Tower D 6th Floor

Ian McKenzie
H&V Commissioning Services Ltd.

Minutes QEUH – Isolation Rooms

Project: QEHB & RHC

Date & Time: Tuesday 31st May 2016 at 2:00pm

Venue: Meeting Room 5, New FM & Lab Medicine Building, QEUH

Invitees:

Ian Powrie (IP)	NHSGGC Sector Estates Manager
Douglas Ross (DRo)	Currie & Brown
David Wilson (DW)	Brookfield Multiplex
John McEwan (JMcE)	Hulley Sfm
Stewart McKechnie (SM)	TUV-SUD
Dave Ramsay (DRa)	Capita

Apologies: **David Loudon (DL)** NHSGGC Director of Facilities and Capital Planning

Purpose Of Meeting: Due to recent formal concerns raised by ID Physicians & ICD colleagues at QEUH, NHSGGC wish to seek confirmation from Health Facilities Scotland (HFS) on certain matters relevant to SHPN 04 Supplement 1. These are contained in Questions 1 and 2 of "HFS Isolation Room Status" document with Question 1 having been submitted to HFS. In advance of Question 2 submission, DL requested Supervisor to comment on Question 2 which highlights variations to SHPN 04 Supplement 1. The Team therefore requires to be unified in support of the submission and supporting information. Question 2 forms Part 1 of the agenda. IP and JMcE met on site on 25th May 2016 to view Isolation Rooms and Supervisor's (JMcE) Notes from that inspection forms Parts 2 and 3 of the agenda which includes relevant design and technical matters pertaining to the proposed submission.

Item	Minute	Action
1.0	PROPOSED SUBMISSION PACK TO HFS	
1.1	HFS Isolation Room Status In this document NHSGGC has prepared 2 Questions to be raised with HFS for confirmation. IP confirmed that the following Question 1 has now been forwarded to HFS. IP advised that HFS at this stage does not require detailed information of what has been provided in the Isolation Rooms at QEUH, but the likelihood is that HFS will be aware of Isolation Room layout. <i>Question 1:</i> <i>Is the ventilation design criteria set out in SHPN 04 supplement 1: Isolation Facilities in Acute Settings As detailed in Table 1: Isolation Suite – Ventilation Parameters and Sheet 2: New build single room with en-suite facilities and bed-access lobby (isolation suite), suitable for safe nursing of patients with the one of the following conditions?</i> 1. Multi Drug Resistant TB (MDRTB)? 2. MERS? 3. H1N1? In advance of NHSGGC issuing the following Question 2 to HFS, the Team requires to be unified in support of the submission of Question 2 and the supporting information for the main variations from SHPN 04 supplement 1. <i>Question 2:</i> <i>If the above design criterion is suitable for safe nursing of patients with any one of these conditions please advise if the following design variant is equally suitable?</i> <i>See attached schematic ref: ZBP-XX-XX-SC-524-871, along with a set of commissioning documents for a representative Critical Care Ward (CCW), isolation room ventilation arrangement within the QEUH.</i> <i>The following variations should be noted:</i> 1. The main extract is located in the isolation room. 2. The alarm system to the nurse's base was deleted, including: • Room Lobby pressure gauge alarm. • The extract air flow switch; alarm to the nurses' base. • The supply air flow switch; alarm to the nurses' base. 3. The transfer grille between the isolation room and the en-suite was deleted. Discussion centred on the design development process for the isolation room layout and ventilation design. DW explained that the original ventilation schematic design Drawing No ZBP-XX-XX-SC-524-707 dated 2010 for the Isolation Room Suite showed the extract located only in the En-Suite ceiling. In 2012 the ventilation schematic design submitted by Brookfield (Dwg No ZBP-XX-XX-SC-524-871) showed extract located in both the Isolation Room ceiling and the En-Suite ceiling. SM pointed out that there would have been several iterations of the drawing schematic during that period indicating that there presumably would have been discussions among the parties and reasons for developing the design. DW agreed that Brookfield would research into the process of the design development of the schematic design for the ventilation of the isolation Room Suites (Refer Action 4.1). Brookfield to track the Design Development of the Isolation Room Layouts to inform how the following were decided: - extract grille located within Isolation Room ceiling and En-Suite ceiling; no transfer grill on the En-Suite door; the location of the bed.	DW

2.0	IP/JMcE INITIAL REVIEW OF SOME ISOLATION ROOMS ON 25TH MAY 2016 AND MATTERS DISCUSSED	
2.1	CCW-163 Bed 50 would be used as an exemplar to understand installed standard v Compliance (Also taking into consideration any PMIs or Derogations). JMcE advised that Isolation Room Suite CCW-163 Bed 50 should be used as the exemplar for understanding the installed layout and ventilation design in comparison with SHPN 04 Supplement 1:- CCW-163 (Lobby); CCW-164 (En Suite); CCW-165 (Single Isolation).	Note
2.2	Provision of "all" available validation documentation provided under the construction contract for Bed 50- DW to collate all validation documentation for the Isolation Room Suite as Item 2.1.	DW
2.3	Provision of "all" available verification documentation provided under the FM contract for Bed 50 IP explained that Estates are currently verifying the Theatres and will shortly be commencing verification of the Isolation Rooms. IP confirmed that H&V Commissioning Services Ltd were doing verification. JMcE requested the standard pro- forma that is being used for verification so that he can review.	IP/JMcE
2.4	Confirmation on what design standards the rooms are built & validated to Discussions centred on the requirements of SHPN 04 supplement 1.	Note
3.0	SUPERVISOR (JMcE) INITIAL OBSERVATIONS (where access was gained) USING SHPN 04: SUPPLEMENT 1 AS REFERENCE	
3.1	Room pressure was sitting at 8pa. This was at the magnehelic and no true readings were taken to verify. Range should be between 10 and 12 pa. (Appendix 2 Acceptance Testing) DW confirmed that tests undertaken proved that a positive pressure of 10 Pascals between entry lobby and door had been achieved. JMcE requested confirmation of pressure readings taken between Isolation Room and Lobby and taken between Isolation Room and En-Suite. DW confirmed he would provide. DW to issue test results to Supervisor for review.	DW/JMcE
3.2	No Alarms installed to indicate to clinical team of potential ventilation issues or remote alarm at nurses stations. Also demonstrated by low pressures having no indication (4.22) SHPN 04 Supplement 1 Section 4.22 states: - "Audio and visual alarms must be located at the entrance to the lobby and bedroom to warn nursing and maintenance staff of potential unsafe conditions. Continuous monitoring should be provided with remote indication at nurses stations, interlinked to the Building Management System with time delay (adjustable by Estates personnel) to take account of running-up of standby motors or damper operations or other plant items that may take time to open or close." DRo explained that no alarms are provided to nurses' station as these were omitted by the Board in PMI 169 Nurse Call Interface which confirmed requirements of Nurse Base Panel and stated "monitoring bedroom pressure, not required". This was issued following a visit by Lead Nurse on the project and other project team members visiting example hospital in London. DW confirmed that pressure monitoring is linked to the BMS and alarms display on the main BMS control panel in accordance with the BMS specification.	Note
	PMI 169 states: - "Description The Board confirm their nurse call interface requirements for the Adult & Childrens Hospitals as per the attached document. Instruction Incorporate the attached interface requirement into your design development process for the nurse call system." Attached interface requirement states:- "NURSE CALL INTERFACE REQUIREMENTS Following static workshop and visit to Royal London Hospital we have agreed that we need the following items integrated with Static system: - Nurse call, Door access, Fire alarm, Medical gas alarm, PTS notification, Bedroom temperature notification, Control of 3rd party TV from patient handset i.e. static handset capable of operating as TV remote with infrared on static bedhead. We have discarded the following systems which they have used in RLH Bedroom pressure We have also discarded the following applications offered by Static systems as part of their presentations Patient information details, Patient "wandering" system, Voice communication for patient to staff calls"	
	It was discussed that the PMI concerns the Nurse Call interface requirements and does not appear to specifically instruct the deletion of the Audio and visual alarms.	Note
	Brookfield to track the Design Development process consequent to PMI 169 to inform on the deletion of alarms.	DW
	With DRo agreement DW to obtain a quotation for providing audio and visual alarms and forward to DRo.	DW/DRo
3.3	The pressure stabiliser was not operating correctly. With corridor door open top blade remained open. Bottom blade appears to have no status change when doors are either open or closed.(4.21) Brookfield to investigate and also forward pressure stabiliser testing and commissioning information to Supervisor.	DW

- | | | |
|-----|--|---------|
| 3.4 | <p>Door from lobby opens into room and in instance not closing properly leaving a greater leakage path and closing direction not as per exemplar within SHPN 04: Supplement 1. Sheet 2</p> <p>Brookfield to investigate and advise Supervisor. The inconsistency of lobby/room door handle provision was discussed with handles on some doors and pushplates on other doors.</p> | DW |
| 3.5 | <p>Extract grille located within room ceiling and toilet. All air should be extracted via the toilet with low level transfer grille within door (4.12)</p> <p>SHPN 04 Supplement 1 Section 4.12 states: - <i>An extract terminal should be fitted at high level in the ensuite room. An additional terminal may be fitted in certain circumstances at low level adjacent to the bedhead in the bedroom. The clinical requirement for this should be verified and such requirements would probably relate to highly infectious patients.</i> Refer Actions in 1.1 and 4.2.</p> | Note |
| 3.6 | <p>Bed location not as per exemplar within SHPN 04: Supplement 1. Sheet 2</p> <p>JMcE identified that the location of the bed was not in the position shown in SHPN 04: Supplement 1. Sheet 2. DRO advised that this would have been a clinical decision.</p> | Note |
| 3.7 | <p>Supply AHU (We used AHU 16 as example) is not identified with what room it serves and neither is the ductwork. (4.19 & SHTM03-01)</p> <p>DW advised that this matter is tracked as a Defect in FM First Summary Schedule and will be corrected.</p> | Ongoing |
| 3.8 | <p>Air Permeability (Leakage): We were advised this was carried out using the room volumes and not the envelope volumes. This will be checked on receipt of information noted within 2.2 above.</p> <p>Brookfield to issue Air Permeability results to JMcE for Supervisor review.</p> | DW/JMcE |
| 4.0 | <p>Agreed Actions</p> | |
| 4.1 | <p>As-Built and Commissioned Information Pack for Isolation Room Suite CCW-163 Bed 50</p> <p>With reference to Minute Item 2.1, Brookfield to pull together a pack of information for Isolation Room Suite CCW-163 Bed 50 comprising: - CCW -163 (Lobby); CCW-164 (En- Suite); CCW-165 (Single Isolation). This should comprise the as-built layouts and the ventilation strategy together with "all" available validation documentation.</p> | DW |
| 4.2 | <p>Specialist Ventilation Advice</p> <p>With NHSGGC consent JMcE offered to obtain an initial independent view on the extract grille located in the Isolation Room ceiling.</p> | DL/JMcE |
| 5.0 | <p>Next Meeting</p> <p>A follow-up meeting to track the actions TBA.</p> | ALL |

Julie Rothney

From: PETERS, Christine (NHS AYRSHIRE AND ARRAN) <christinepeters@nhs.uk>
Sent: 15 January 2020 12:09
To: BAIN, Marion (NHS NATIONAL SERVICES SCOTLAND)
Cc: INKSTER, Teresa (NHS GREATER GLASGOW & CLYDE)
Subject: Fw: [ExternaltoGGC]QEUH Patient Placement
Attachments: RE: Patient placementTo Subject Sent Size Categories ; RE: Patient placement

Hi Marion,

This email trail really illustrates the urgency of the need for a patient placement policy that is grounded on an evidence base of the rooms as well as clearly explained and embedded surrounding administrative processes and actions in event of failures. This is something Teresa and I have been pursuing since June 2015 and is still not satisfactorily sorted. My colleague Pauline Wright was so concerned about the situation she faced that she phoned me at 3 am on Monday morning even though I was not on call as she knew I would have some understanding of the issues. Unfortunately I was not able to give an answer other than a risk based approach to an unknown entity. Thankfully the case was not a MERS case, and joins a long list of cases which had they been "the real thing" would not have gone well.

kr

Christine

From: Peters, Christine <Christine.Peters@nhs.uk>
Sent: 15 January 2020 11:57
To: PETERS, Christine (NHS AYRSHIRE AND ARRAN)
Subject: FW: [ExternaltoGGC]QEUH Patient Placement

From: Peters, Christine
Sent: 15 January 2020 11:57
To: Inkster, Teresa (NHSmail) <teresa.inkster@nhs.uk>; WRIGHT, Pauline (NHS GREATER GLASGOW & CLYDE) <pauline.wright@nhs.uk>; Leanord, Alistair <Alistair.Leanord@nhs.uk>; Green, Rachel (NHSmail) <rachelgreen2@nhs.uk>
Cc: Ritchie, Neil <Neil.Ritchie@nhs.uk>; Peters, Erica <Erica.Peters@nhs.uk>; Khanna, Nitish <Nitish.Khanna@nhs.uk>; Deshpande Ashutosh (NHS NATIONAL WAITING TIMES BOARD) <ashutosh.deshpande@nhs.uk>; VALYRAKI, Kalliopi (NHS GREATER GLASGOW & CLYDE) <kalliopivalyaki@nhs.uk>; Khalsa Kamaljit (NHS NATIONAL WAITING TIMES BOARD) <kamaljit.khalsa@nhs.uk>; Balfour, Alison <Alison.Balfour@nhs.uk>
Subject: RE: [ExternaltoGGC]QEUH Patient Placement

Thanks Pauline, Teresa, Al

With regard to the RHC, the last information I have is regarding issues I raised in September following a chicken pox case. A table was circulated but did not reflect what I found in reality on the wards as per attached emails. We have not had any updates since then. The PPVL rooms remain with substantial design differences from published validated design with no evidence of equivalence that I am aware of – this pertains particularly to the lack of negative pressure of en-suite to room, and the location of the extracts in the bedroom, which is not in the SHTM published design, as well as reduced ACH in the ensuites.

It would be excellent to have a quality assured, document controlled patient placement policy with live updates if issues emerge (previously had dampers blocked, AHU failures, leaking rooms) completed for both Paediatric and Adult settings for

1. Infectious patients
2. Immunocompromised patients
3. Infectious immune compromised patients

I agree the WHO warnings are helpful in renewing the focus.

Kind regards

Christine

Consultant Microbiologist

From: INKSTER, Teresa (NHS GREATER GLASGOW & CLYDE) [mailto:teresa.inkster@nhs.uk]
Sent: 15 January 2020 11:39
To: WRIGHT, Pauline (NHS GREATER GLASGOW & CLYDE) <[redacted]@nhs.uk>; Leanord, Alistair <Alistair.Leanord@nhs.uk>; Green, Rachel (NHSmail) <rachelgreen@nhs.uk>
Cc: Ritchie, Neil <Neil.Ritchie@nhs.uk>; Peters, Erica <Erica.Peters@nhs.uk>; Khanna, Nitish <Nitish.Khanna@nhs.uk>; Peters, Christine <Christine.Peters@nhs.uk>; Deshpande Ashutosh (NHS NATIONAL WAITING TIMES BOARD) <ashutosh.deshpande@nhs.uk>; VALYRAKI, Kalliopi (NHS GREATER GLASGOW & CLYDE) <kalliopivalyrak@nhs.uk>; Khalsa Kamaljit (NHS NATIONAL WAITING TIMES BOARD) <kamaljit.khalsa@nhs.uk>; Balfour, Alison <Alison.Balfour@nhs.uk>
Subject: [ExternaltoGGC]Re: [ExternaltoGGC]QEUH Patient Placement
 Hi Pauline

The need for the patient placement policy was handed over by me when I resigned and we raised it several times in meetings with diagnostics senior management

I had a draft document in place but was unable to finalise due to the outstanding issues with the PPVL rooms delineated in the HFS report. There was an action for the facilities director at the end of August to take this aspect forward. These rooms were not built to specification in that they had modifications, and we have yet to establish what exactly they can be safely used for.

Perhaps in the meantime the IPCT could issue Comms on where the negative pressure rooms are within QEUH/RHC and confirmation that validation is satisfactory. Given the situation with a novel coronavirus and WHO instructing hospitals worldwide to prepare we need this information clarified urgently

There were 4 negative pressure rooms signed off by me in QEUH but that was some time ago and it would be important to check with estates that there have been no issues with these rooms including whether there have been any subsequent validation reports issued, requiring ICD sign off

Kr

Teresa

Dr Teresa Inkster
 Consultant Microbiologist, QEUH
 National Training Programme Director Medical Microbiology
 Dept of Microbiology
 Queen Elizabeth University Hospital
 Glasgow
 Direct dial : [redacted]

From: WRIGHT, Pauline (NHS GREATER GLASGOW & CLYDE)
Sent: 15 January 2020 10:12
To: Leanord Alistair (NHS GREATER GLASGOW & CLYDE); LEANORD, Alistair (NHS GREATER GLASGOW & CLYDE); GREEN, Rachel (NHS GREATER GLASGOW & CLYDE)
Cc: Ritchie, Neil; Peters Seija (NHS GREATER GLASGOW & CLYDE); Khanna Nitish (NHS GREATER GLASGOW & CLYDE); INKSTER, Teresa (NHS GREATER GLASGOW & CLYDE); Christine.Peters@nhs.uk; Deshpande Ashutosh (NHS NATIONAL WAITING TIMES BOARD); VALYRAKI, Kalliopi (NHS GREATER GLASGOW & CLYDE); Khalsa Kamaljit (NHS NATIONAL WAITING TIMES BOARD); alison.balfour@nhs.uk
Subject: Re: [ExternaltoGGC]QEUH Patient Placement

Hi Al,

Thanks for the response, and for Erica's input. The main issue is with negative pressure rooms in QEUH. I'm worried about relying on historical information / emails to make decisions about patient placement when there is nothing in writing. This happens not infrequently and we need the most up to date information to make the right decision.

My understanding is that the patient on Sunday night was in room 4 (SHDU1) rather than room 24, which Erica mentions in her email (cut and paste to the end of this email).

Teresa - can you comment?

Thanks

Pauline

Dr Pauline Wright

Consultant Microbiologist
Queen Elizabeth University Hospital

From: Leanord, Alistair <Alistair.Leanord@qeu.nhs.uk>

Sent: 14 January 2020 15:24

To: WRIGHT, Pauline (NHS GREATER GLASGOW & CLYDE); LEANORD, Alistair (NHS GREATER GLASGOW & CLYDE); GREEN, Rachel (NHS GREATER GLASGOW & CLYDE)

Cc: Ritchie, Neil

Subject: Re: [ExternaltoGGC]QEUH Patient Placement

Pauline

Thanks. This was raised at AICC today.

A draft document has identified the rooms in RHC and work is underway, and hopefully will be completed in short order.

Cheers

Al

Sent from my BlackBerry 10 smartphone on the EE network.

From: WRIGHT, Pauline (NHS GREATER GLASGOW & CLYDE)

Sent: Monday, 13 January 2020 04:43

To: Leanord, Alistair; LEANORD, Alistair (NHS GREATER GLASGOW & CLYDE); Green, Rachel (NHSmail)

Cc: Ritchie, Neil

Subject: [ExternaltoGGC]QEUH Patient Placement

As you know we have had several meetings relating to working as an ICD / giving IC advice out of hours as a Microbiologist at QEUH.

One of the issues we raised was the lack of an up to date patient placement policy based on validation data and we were assured that this would be made available as soon as possible. There was a recognition that this document would need to be dynamic, taking into account the ongoing work at this site.

I was called at 3am today by my ID colleague regarding appropriate patient placement for a patient under investigation for MERS coV.

Unfortunately the negative pressure rooms that I was aware of, rooms 43 and 44 were not available (one has an MDR TB case and the other a patient with complex respiratory problems who could not be moved). My decision was that the PPVL room that the patient was in (HDU1 room 3) was the next best thing and advised the staff nurse to keep the patient there. She informed me that HDU1 room 4 has now been converted to a negative pressure room and that the nurses are checking the pressures daily and they are sitting between -8 to -12.

I changed my advice on the basis of this information and advised the patient be placed in HDU1 room 4.

I am not an ICD but as a Microbiologist giving out of hours Infection Control advice I need to have the most up to date information to do this.

I am concerned about the potential risks to staff / patients by putting the patient in inappropriate accommodation. In addition, every time this happens, an unnecessary amount of nursing and medical time is spent trying to get this information instead of being able to give clear unambiguous advice and allow nurses and clinicians to get on with their jobs.

I might have missed an email communication about this and I apologise if that's the case but can you confirm to me if HDU1 room 4 is now a negative pressure room?

Can we have an up to date list of the current negative pressure rooms in QEUH and RHC?

Thanks for your help

regards

Pauline

Dr Pauline Wright

Consultant Microbiologist

Queen Elizabeth University Hospital

From: Peters, Erica

Sent: 14 January 2020 22:38

To: Leanord, Alistair
Cc: Wright, Pauline; Ritchie, Neil
Subject: FW: negative pressure rooms

Hi,

As discussed at the AICC today here is the email I had from TI last year. Clearly there are challenges using a room with no en suite if this is the 3rd room that was highlighted on Sunday night. I know that Teresa examined these reports carefully and as such I am confident in the 2 current rooms assuming appropriate checks via estates. I welcome the ventilation placement document that is coming-I presume I will see it before approval via the AICC? There were also rooms signed off in Childrens by the same company around the same time. I don't have any details of this and indeed no copies of the independent report but Teresa will have all of this.

Hope this helps.

KR

Erica

From: INKSTER, Teresa (NHS GREATER GLASGOW & CLYDE) [<mailto:teresa.inkster@nhs.uk>]

Sent: 17 June 2019 13:41

To: Peters, Erica

Cc: Pritchard, Lynn

Subject: [ExternaltoGGC]negative pressure rooms

Hi Erica

Just to let you know that I have signed off the validation reports for the 3 negative pressure rooms in critical care. The rooms are 43 and 44 and 24 . Note 24 has no en-suite. All meet the requirements for pressure, air changes and have hepa filtered extract.

On failure they will alarm centrally and at the nurses station. Daily records of pressures should be logged (Iain Thomson is aware of this)

The IPCT are working on a patient placement guide as there are now two different types of room in use , negative pressure and PPVL.

There will also be work done to assist with the interpretation of the pressure gauges with the addition of positive and negative pressure signage (at the moment it is red/green colour only)

Let me now if you have any queries

Kind regards

Teresa

Dr Teresa Inkster

Lead Infection Control Doctor NHSGGC

National Training Programme Director Medical Microbiology

Dept of Microbiology

Queen Elizabeth University Hospital

Glasgow

Direct dial : [REDACTED]

18th September 2020

**Action Plan in response to HSE Notification of
Contravention letter and IN KW/QEUH/DEC19/01 dated 17TH December 2019.
WARD 4C/HDU/ICU/PICU Ventilation**



Contravention Ref:	AREA	Verification date	Condition	Action Planned	Start Date	Finish date	Progress	R	A	G	
IN KW/QEUH/DE C19/01 COSHH reg 7 (1) (3) WARD 4C	<u>Hematology Oncology & Renal Patient Area;</u> Action - In order to dramatically improve the air quality within the ward 4C and to align with the newly established standard achieved within ward 6A the following will be carried out; • Agree Rooms where ICD can take Air Quality Samples so that a pre & post analysis of Air quality can be analysed; • Installation of En- suite Ceiling mounted HEPPA filters air scrubbers (the Air Cleaner Concealed is used to clean air by mechanically filtering through highly efficient filters); • Installation of door drop seals (to assist with room permability and contribute towards better AC rates and pressure control); • Replace all chilled beam coil connections with compressive type over push fit (this will ensure water ingress protection should heating failure and pipe contraction occur); • EN-Suite IPS Panel dampness inspection and lid installation (to assist with room permability and contribute towards better AC rates and pressure control); • Entire Room Floor and painting repairs; • Corridor CVG removal (this will reduce the risk of particulate transfer between corridor ceiling void and the clinical space, it will also improve the overall permability of the ward).  QEUH Ward 4C Solutions Paper										
	Hematology Oncology								Amber		
	Rm76 (W188)	N/A	N/A	See above	14/9/20	16/9/20	Scrubbers bought and in storage at QEUH				

Contravention Ref:	AREA	Verification date	Condition	Action Planned	Start Date	Finish date	Progress	R	A	G
	Rm75 (W185)	N/A	N/A	See above	17/9/20	19/9/20	As above			
	Rm74 (W183)	N/A	N/A	See above	19/9/20	21/9/20	As above			
	Rm73 (W180)	N/A	N/A	See above	22/9/20	24/9/20	As above			
	Rm72 (W175)	N/A	N/A	See above	25/9/20	27/9/20	As above			
	Rm71 (W172)	N/A	N/A	See above	27/9/20	29/9/20	As above			
	Rm70 (W170)	N/A	N/A	See above	30/9/20	2/10/20	As above			
	Rm69 (W166)	N/A	N/A	See above	3/10/20	5/8/20	As above			
	Rm68 (W165)	N/A	N/A	See above	5/10/20	7/10/20	As above			
	Rm67 (W162)	N/A	N/A	See above	8/10/20	10/10/20	As above			
	Renal Transplant									
	Rm 51 (W157)	N/A	N/A	See above	11/10/20	13/10/20	As above			
	Rm 52 (W155)	N/A	N/A	See above	13/10/20	15/10/20	As above			
	Rm53 (W154)	N/A	N/A	See above	16/10/20	18/10/20	As above			
	Rm54 (W152)	N/A	N/A	See above	19/10/20	21/10/20	As above			
	Rm 55 (W149)	N/A	N/A	See above	21/10/20	23/10/20	As above			
	Rm56 (W147)	N/A	N/A	See above	24/10/20	26/10/20	As above			
	Rm57 (W144)	N/A	N/A	See above	27/10/20	29/10/20	As above			
	Rm58 (W143)	N/A	N/A	See above	29/10/20	31/10/20	As above			

Contravention Ref:	AREA	Verification date	Condition	Action Planned	Start Date	Finish date	Progress	R	A	G
	Rm59 (W140)	N/A	N/A	See above	1/11/20	3/11/20	As above			
	Rm60 (W138)	N/A	N/A	See above	4/11/20	6/11/20	As above			
	Rm61 (W135)	N/A	N/A	See above	6/11/20	8/11/20	As above			
	Renal									
	Rm62 (W134)	N/A	N/A	See above	9/11/20	11/11/20	As above			
	Rm63 (W130)	N/A	N/A	See above	12/11/20	14/11/20	As above			
	Rm64 (W130)	N/A	N/A	See above	14/11/20	16/11/20	As above			
	Rm65 (W130)	N/A	N/A	See above	17/11/20	19/11/20	As above			
	<u>Objective & Output</u> • Maintain the current ACH rates as per the recent ventilation verification; • Lowered risk of dust ingress and support a superior clinical environment; • Improvement in Air Quality.									
NOC COSHH reg 7 (1) (3) High Dependency Unit/ Intensive Care Unit	<u>Action</u> - Bring forward the verification program of all 10 isolation rooms within HDU/ITU which is currently on going but will now conclude due to existing coved 9 admission pressures, then the intention on successful completion of this is to conduct the following: Under existing build parameters; • protect each patient occupied bed space to the Ward standard of the SHTM03-01 part A, which is 10 ACH and 10 Pascal from any CCU department to dirty corridor; - o achieve this by removal of CVGs and replace with a ceiling tile (which has now been carried out); - o pinning the existing suspended ceiling; - o seal the IPS columns; - o adjust the door gaps while fitting draft excluder drop down; - o modify and re balance the ventilation plant control strategy to achieve 100% output.									

Contravention Ref:	AREA	Verification date	Condition	Action Planned	Start Date	Finish date	Progress	R	A	G
	Assuming clinical permission, infection control endorsement and no financial restriction (hence the employment of significant resources), estates anticipates a turnaround time of three weeks per HDU/ITU area establishing an 18 week program that would be variable dependant on success rate and clinical pressures. This is detailed below;  HSE HDU/ICU Summary Briefing Pap									
	<u>HDU 1</u> <u>(ICU 1)</u> (Beds 1-10)	6 July 2019	POOR	As above	23/11/20	11/12/20	Communication made with Senior Clinical Staff with initial agreement to carry out these works. These will be finalised nearer the time to take into account current position of patient group. COVID-19 has affected this start/completion date.	Amber		
	<u>HDU 2</u> (Beds 11-20)	15 July 20	GOOD	As above	18/1/21	29/1/21	<u>Area re-validated 15 July 20</u> Communication made with Senior Clinical Staff with initial agreement to carry out these works. These will be finalised nearer the time to take into account current position of patient group. COVID-19 has affected this start/completion date.			
	<u>HDU 3</u> <u>(ICU 3)</u> (Beds 21 – 30)	6 July 19	POOR	As above	14/12/20	11/1/21	Communication made with Senior Clinical Staff with initial agreement to carry out these works. These will be finalised nearer the time to take into account current position of patient group. COVID-19 has affected this start/completion date.			

Contravention Ref:	AREA	Verification date	Condition	Action Planned	Start Date	Finish date	Progress	R	A	G
	<u>HDU 4</u> <u>(ICU 4)</u> (Beds 31 – 40)	15 July 20	AVERAGE	As above	1/2/21	12/2/21	<u>Area re-validated 15 July.</u> Communication made with Senior Clinical Staff with initial agreement to carry out these works. These will be finalised nearer the time to take into account current position of patient group. COVID-19 has affected this start/completion date.			
	<u>HDU 5</u> (Beds 41 – 49)	7 July 20	AVERAGE	As above	15/2/21	26/2/21	<u>Area re-validated 7 July 20</u> Communication made with Senior Clinical Staff with initial agreement to carry out these works. These will be finalised nearer the time to take into account current position of patient group. COVID-19 has affected this start/completion date.			
	<u>HDU 6</u> (Beds 50 – 59)	15 July 20	AVERAGE	As above	3/3/21	17/3/21	<u>Area re-validated 15 July 20</u> Communication made with Senior Clinical Staff with initial agreement to carry out these works. These will be finalised nearer the time to take into account current position of patient group. COVID-19 has affected this start/completion date.			
	<u>Objective & Output</u> Improve each area of HDU/ICU fabric permeability and ability to rebalance the ventilation plant in order to achieve design. Dirty utilities & prep rooms would also be included within this exercise so not to impede the established regimes of the patient areas.									
NOC COSHH reg 7 (1) (3) Paediatric Intensive Care Unit	<u>Action:</u> - Remove Ceiling Ventilation Grills (CVG’s) only; - Maintain the current ACH rates as per the recent ventilation verification; - Remaining patient 4 bedded room 1-4 rebalanced to achieve the compliant Air change rate while having a positive 2 pascal pressure cascade from room to corridor, this can be achieved by modifying the extract rates to reduce pressure while maintaining 10 ACH per hour and the standard for particulate dilution.									

Contravention Ref:	AREA	Verification date	Condition	Action Planned	Start Date	Finish date	Progress	R	A	G
	Include remaining 4 bedded areas. Dirty utilities & prep rooms would also be included within this exercise so not to impede the established regimes of the patient areas.  QEUH PICU QEUH PICU Permeability Works Solutions Analysis									
	Bed Spaces 1-4	15 Sept 19	GOOD	N/A	N/A	N/A	Completed as per derogation	Amber		
	Bed Spaces 8 - 11	6 July 19	GOOD	As above	7/9/20	11/9/20	Includes associated dirty utility room			
	Bed Spaces 13 - 16	15 Sept 19	GOOD	N/A	N/A	N/A	Completed as per derogation			
	Bed Spaces 19 - 22	6 July 19	GOOD	As above	14/9/20	17/9/20	Includes associated dirty utility room			
	Room 7	1 st Nov 19	GOOD	N/A	N/A	N/A	Completed			
	Room 8	1 st Nov 19	GOOD	N/A	N/A	N/A	Completed			
	<u>Objective & Output</u> With an agreed ‘derogation’ to the SHTM03-01 Part A guidance, signed off by the AE(V), ICT and the respective Service Lead, this will achieve a compliant and suitable ventilation set up for the current and future patient groups that do & will occupy PICU within the RHC while ensuring that clinicians have the most flexibility possible to place and treat a specific patient group within that space.									

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Short Report

Potential infection control risks associated with chilled beam technology: experience from a UK hospital

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SUMMARY

Energy efficiency technologies are now a feature in hospital design, with active chilled beams an example of one in use worldwide. Such innovations have clear benefits but there is a paucity of information with respect to any infection control risks. We describe our experience of chilled beam technology from one of our hospitals where we faced challenges with cleaning and episodes of water ingress including condensation. We highlight the importance of infection control risk assessment in relation to new technologies and the implementation of appropriate risk mitigation.

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Introduction

While active chilled beam technology is in use in hospitals globally including Scandinavia, Australia, and USA, their introduction has been largely driven by energy-saving advantages [1]. Active chilled beam technology delivers fresh air to the patient bedroom and is designed to integrate into suspended ceiling systems. Primary air from the supply ducting passes through nozzles into the room. The air movement creates low pressure and draws air back in from the room over the cooling coils. This is termed secondary (entrained) air and mixes with the primary air to be redelivered through diffusers (Figure 1).

In addition to energy conservation, advantages include thermal comfort and quiet operation [2]. Acknowledged disadvantages are the production of condensation and cleanliness

issues [2]. Furthermore the large amounts of bedding used in healthcare settings can lead to the abundance of lint, which can become trapped within the beams [2]. There is a paucity of published data on infection control risks of chilled beam technology with no infection outcome-based clinical trials. Concerns remain regarding the impact of the recycled pathway of airborne pathogens intrinsic to the active chilled beam concept [3,4]. The American Society of Heating, Refrigerating and Air-Conditioning Engineers (2017) notes that chilled beams should not be used in intensive care units, protective isolation or source isolation rooms, toilets, procedure rooms, delivery rooms, endoscopy rooms, or clean rooms due to 'cleaning difficulty and potential for build-up of contamination'. The recirculation within the room interferes with the concept of a clean-to-dirty pathway for clean diluting air to remove pathogens from the contaminated air. There is potential for recirculation of pathogens within the breathing zone of patients and staff but this is an area of active research with computer modelling and other technologies and may depend on factors such as aerosol size, other heat sources in the room and human plume influences on air movements [5].

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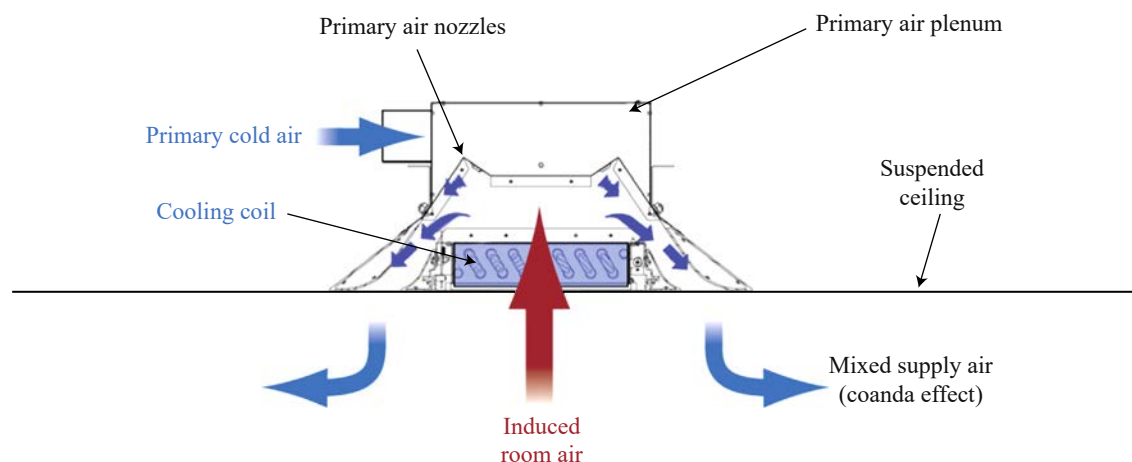


Figure 1. Active chilled beam technology. From: <https://tacoadvancedhydronics.wordpress.com/category/radiant-cooling-chilled-beams/>.

Current UK and Scottish Health Technical Memorandum guidelines for ventilation in healthcare premises are non-specific and give little guidance as to the suitability of chilled beam technology within healthcare premises [6]. However, the neutropenic and source isolation room concept are incompatible with chilled beams by token of the mandatory unimpeded clean-to-dirty pathway. Where chilled beams are in use in hospitals, guidance states that control settings should ensure that external components of the beam are always above the dew point. With reference to cleaning, access for cleaning and the impact of maintenance requirements should be considered [6]. We would recommend that water safety groups include chilled beam technology as a water source and that these are identified as a risk during the design phase as well as during maintenance. Our hospital has 1677 beds with active chilled beams installed in all patient rooms apart from the critical care and bone marrow transplant units.

Methods

Since our hospital opened in 2015 we have made a number of observations in relation to chilled beam technology which may have infection control implications.

Results and discussion

Cleaning

There have been issues with both access to clean and cleaning frequency. This is a clear disadvantage to the technology in a large hospital. The risk is intrinsic to the design which relies on entrained air from the room space, carrying fibres, skin squames and aerosols passing over the fins of the coils to be cooled/heated. This particulate matter tends to collect and stick to the metal (Figure 2). Others state that as the fin surfaces of an active chilled beam unit are relatively well gapped, dust and dirt particles tend not to bridge the fin surface; this does not reflect our experience [7].

The models in use in our hospital are not of the kind that allow easy removal of the entire beam for full-scale cleaning and decontamination. Cleaning is cumbersome and required on

a six-week rotation due to visible build-up of dust, despite manufacturers suggesting six months to yearly. Access to clean can be problematic when patients are occupying the room, as the chilled beam is situated directly above the patient's bed. High patient turnover makes chilled beam cleaning impracticable as part of the standard discharge clean.

No filter is present, so all recirculated air will either carry with it the pathogens back into the room or deposit on to the beam. This poses an even greater risk when condensation drips

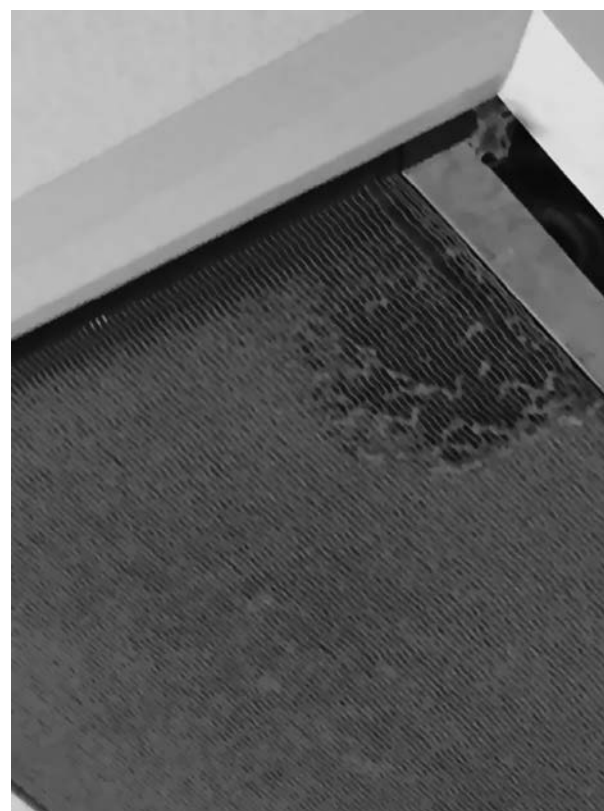


Figure 2. Photograph of chilled beam.

Box 1

Organisms isolated from dust in chilled beams

Micrococcus sp.
 Coagulase-negative staphylococci
Bacillus sp.
Moraxella catarrhalis
Exophiala dermatitidis
Penicillium sp.
Rhodotorula sp.
 Hyaline fungi
Aspergillus sp.
Panteoa agglomerans
Veillonella sp.
Stenotrophomonas sp.
Acinetobacter sp.
Paenibacillus pabuli
Klebsiella pneumoniae
Psychrobacter phenylpyruvicus

through the accumulated dust, as has occurred on several occasions.

Surface swabs from the chilled beams in our hospital have grown multiple organisms (Box 1). These include: (i) skin commensals in keeping with skin squame contamination (raising the possibility of meticillin-resistant and -susceptible *Staphylococcus aureus* also being present and recirculated); (ii) fungi, in keeping with moisture and a carbon source being present in the collected dust; (iii) enteric organisms: in keeping with possible airborne particles of bacteria entering into patient room from toilet and collecting on beams; (iv) environmental Gram-negative bacteria, in keeping with circulating moisture- and dust-borne environmental organisms. Surface swabs were undertaken in one of our general wards following reports of leaking from the chilled beams and observations of dust. These were plated directly on to blood agar, cysteine–lactose and electrolyte-deficient (CLED) agar and Sabouraud plates. In total, areas of the chilled beams from 19 rooms were swabbed. Prior to cleaning, 22 out of 49 (45%) samples were positive. In the two weeks post cleaning, four swabs out of 42 were positive (9%).

This is evidence of the potential biohazard posed by pathogens in the accumulated dirt on the fins of the beam and in keeping with the theoretical risk of airborne pathogens stagnating in the beam instead of being removed from a clean-to-dirty pathway. The likelihood is that as time goes on there will be an increasing bioburden of pathogens building up on the coils presenting an increasing hazard, particularly when combined with condensation events but not restricted to these [5].

Condensation, water leaks, and water contamination

Condensation should not occur on chilled beams and this is a prerequisite for safe functioning in healthcare [1,5,8]. The design and monitoring should be set up to eliminate this risk. Riffat states that ‘when the panel surface temperature is lower than the dew point of room air, condensation on panel and pipe surfaces occurs, which can lead to damage from dripping water

and an unacceptable room air condition’ [1]. This is potentially serious in healthcare settings, particularly with immunocompromised patients. Condensation encourages mould and bacterial growth posing an infection hazard even in small amounts [9]. The degree of hazard depends on the bioburden, the environmental conditions, patient characteristics and effectiveness of the air change dilution effect. We have noted frequent condensation events: most have involved two or three beams in one ward area at a time, but on one occasion 106 rooms throughout the building were affected at the same time. It is not clear if this is due to temperature settings being too low for the dew point or if the dehumidification was planned to be in the air handling unit and is not present in some. Alteration to the dew point to operate above it has been undertaken to mitigate this risk and we have not been made aware of any further issues.

Our experience is not unique, with condensation issues being documented outside healthcare settings in office buildings and a school [10]. These were due to leaks in the duct system preventing sufficient air from reaching the beams [10].

As chilled beams use a water supply system within the hospital, with potential for leakage into clinical areas, the water supply requires temperature monitoring and attention to biocide usage if the water becomes contaminated. The circulating water system poses a *Legionella* spp., *Pseudomonas* spp. and other waterborne pathogen risk.

Leakage of supply water in our hospital has occurred from fittings. This phenomenon is supported by microbiology testing which isolated *Pseudomonas oleovorans* from the beam water system and from swabs from the leakage, external to the beam. This is also crucially backed by a history of water ingress to rooms. Whereas condensation on the beam causes ‘indoor rain’ as tiny droplets of condensation coalesce on the fins and fall into the room, leakage from the piping drips into the rim and drips from a corner in a gravity-directed pathway with the fins remaining dry [7]. *Pseudomonas aeruginosa* has also been isolated from the circulating water in our hospital chilled beam system.

There is no prospectively designed clinical trial based on infection rates that would give evidence for suitability of the use of this chilled beam technology in healthcare settings. Comparison for the UK context would need to be between full fresh air supply with and without chilled beams with standard cleaning methods and measuring healthcare-associated infection rates prospectively. The basis for the advantage of the chilled beam system in the published validation based on computer modelling and prototype testing was that conventional air-conditioning in hospitals included recirculation and indefinite pressure regimes, which is not the starting point in the UK [5]. The validation did not consider infectious aerosols emitting from a patient or infectious doses of various pathogens, nor did it include a comparison of different air change rates.

The proper functioning of a chilled beam system has been described as a balancing act, with temperature, humidity, volumes of outside air and occupancy all playing a role. Hospitals using chilled beam technology should be aware of the potential issues with access to clean, cleaning frequency, and the possibility of condensation or water leaks and subsequent risks from contaminated dust and water. Staff should be encouraged to report any condensation or water leakage events. Chilled beams should be included on a cleaning

schedule and frequency should be determined according to levels of dust build up. Infection control teams should consider chilled beams as a potential environmental source when investigating incidents/outbreaks.

A limitation of our report is that our experience is based on observations from a single centre only and may not reflect experience elsewhere. Further studies are required to delineate the infection control risks associated with such energy-saving efficiency methods which are likely to feature more commonly in future hospital builds.

In conclusion, when designing new hospitals, consideration should be given to the potential infection control risks associated with such energy-saving initiatives, with early involvement of the infection control team to ensure that risks are fully delineated and risk mitigation measures implemented. We would value more detailed reference to chilled beam and other energy efficiency technologies within national specifications for healthcare premises.

Conflict of interest statement

None declared.

Funding sources

None.

References

- [1] Riffat SB. Review of research into and application of chilled ceilings and displacement ventilation systems in Europe. *Int J Energy Res* 2004;28:257–86.
- [2] Buck CR. Chilled beams in healthcare patient rooms. Available at: <https://www.hpac.com/air-conditioning/article/20928375/chilled-beams-in-healthcare-patient-rooms>; 2013 [last accessed May 2020].
- [3] Khankari K. Comparative analysis of overhead air supply and active chilled-beam HVAC systems for patient room. Chicago: ASHRAE Winter Conference; January 2015. Conference Paper D-CH-15-C016.
- [4] Yuguo L, Tang J, Noakes C, Hodgson M. Engineering control of respiratory infection and low energy design of healthcare facilities. *Sci Technol* 2015;21:25–34.
- [5] ANSI/ASHRAE/ASHE Standard 170-2017: Ventilation of health care facilities. Available at: <https://blog.ansi.org/2020/04/ansi-ashrae-170-2017-health-care-ventilation/> [last accessed April 2020].
- [6] Scottish Health Technical Memorandum 03-01. Health facilities Scotland. 2014.
- [7] Alexander D, O'Rourke M. Design considerations for active chilled beams. *ASHRAE J* 2008;9:50–8.
- [8] Devlin N. Validation of an active chilled beam design for a healthcare facility. In: Proceedings of building simulation; 2011. Available at: http://www.ibpsa.org/proceedings/BS2011/P_1289.pdf [last accessed April 2020].
- [9] Palasaz J. To filter or not to filter. An engineer's perspective of application of chilled beams in healthcare environments. Available at: <https://primeraeng.com/posts/chilled-beams/> [last accessed May 2020].
- [10] Aeroseal case studies. Don't let air leaks rain on the chilled beam parade. Available at: <https://aeroseal.com/air-duct-sealing-blog/project-air-leaks-rain-on-the-chilled-beam/> [last accessed April 2020].

**NEW SOUTH GLASGOW
HOSPITALS**

**SPECIFICATION
VENTILATION SYSTEM**

Ref: ZBP-XX-XX-SP-524-303

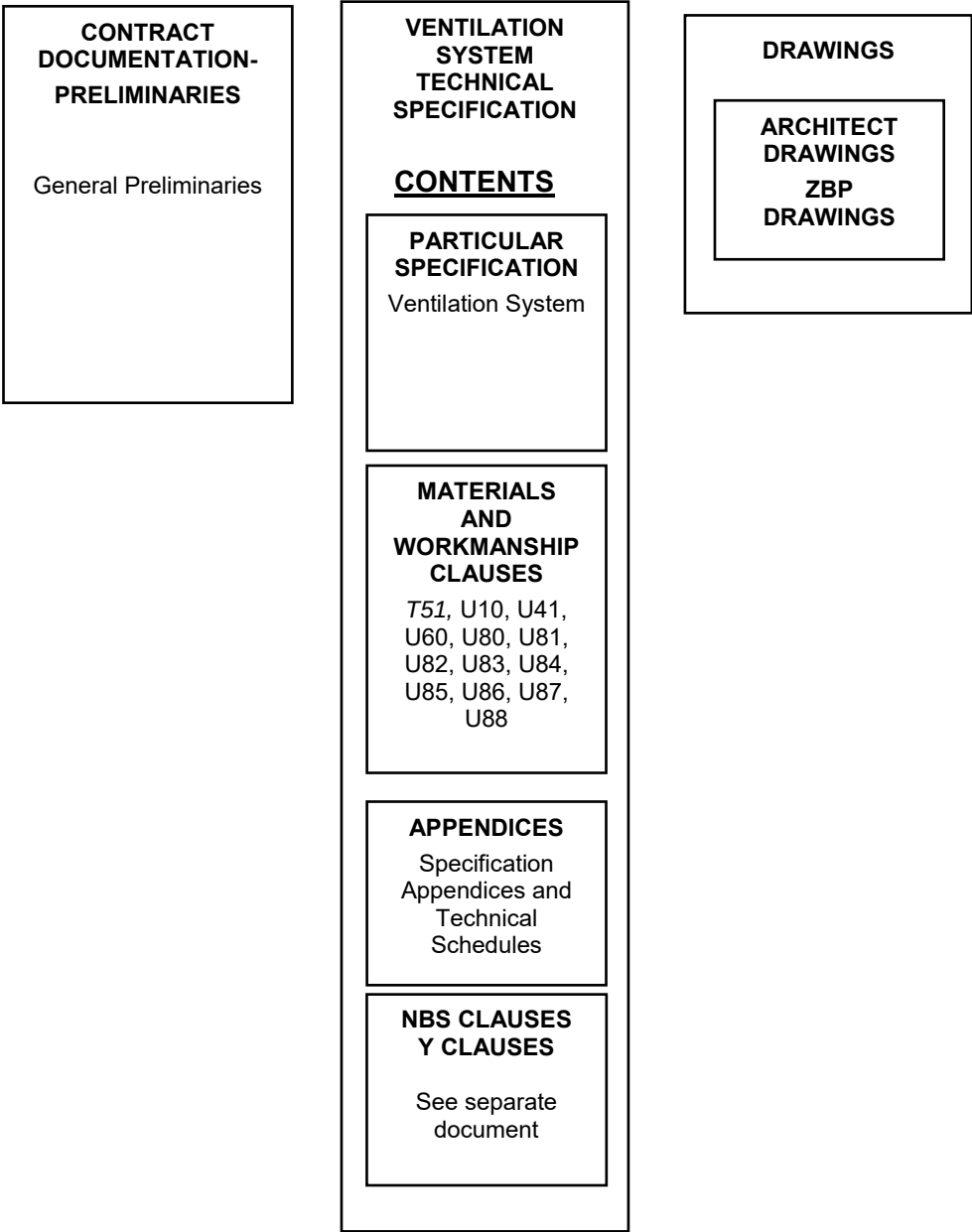
Status: Construction T3

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Date: November 2012



OVERALL FRAMEWORK OF TENDER DOCUMENTATION
VENTILATION SYSTEM TECHNICAL SPECIFICATION



**NEW SOUTH GLASGOW HOSPITALS
VENTILATION SYSTEM**

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1.0 GENERAL INTRODUCTION

Purpose of Document

The manufacture, supply, installation, wiring, setting to work and commissioning of the works described in this document shall be undertaken by the Mechanical and Electrical Contractor and is referred to in this document as "Sub-contractor".

To carry out the development of the design, the Sub-contractor shall obtain the necessary supporting documentation including but not limited to that listed in Appendix A.

This specification shall be read in conjunction with all other mechanical and electrical engineering services specifications and the Architectural drawings.

2.0 SCOPE

The scope of work covered by this Specification shall include the following:-

- Ventilation System, including:-
 - Kitchen extract equipment
 - Fan coil units
 - Variable air volume terminal units
 - Local air conditioning systems
 - Air ductwork and ancillaries
 - Air handling units
 - Fans
 - Air filtration
 - Heating and cooling coils
 - Heat recovery
 - Air treatment
 - Silencers and acoustic treatment
 - Air terminal devices

3.0 SPECIFIC EXCLUSIONS

The following is specifically excluded from the scope of this Specification:-

- BMS and automatic control systems
- Insulation
- Louvres in external façade
- Kitchen canopies/hoods

4.0 INTERFACES AND DEMARCATIONS

The Ventilation Systems shall be provided as a complete working system serving the Adult and Children's Hospitals.

The Sub-contractor shall provide information to other parties for power supplies, controls and fire alarm system interfaces.

5.0 APPLICABLE STANDARDS

All elements of the works shall be in accordance with the requirements of current legislation, regulations and industry standards unless otherwise stated.

The Ventilation System shall accord with all appropriate Hospital Technical Memoranda, Codes of Practice and relevant British and European Standards and Appendix A.

The equipment supplied shall conform to all relevant standards and regulations in force. The equipment shall be supplied with relevant Declarations of Conformity to certify compliance with the EMC directive 89/336/EEC-92/31/EEC and the Machinery Safety Directive 89/392/EEC-91/368/EEC-93/44/EEC. Also the equipment and installation shall comply with all relevant statutory requirements in force at the time:

6.0 DESIGN CRITERIA

LV power characteristics: 400/230 V, 3-phase, 50 Hz, 230 V, 1-phase, 50 Hz.

External Design Conditions

	Winter	-6°C sat
	Summer	26.2°C db 18.5°C wb
For operating theatre plant		30°C db 20°C wb
Sizing for refrigeration plant		30°C
Primary MTHW Flow Temperature		105°C
Primary MTHW Return Temperature		75°C
Secondary LTHW Flow Temperature		75°C
Secondary LTHW Return Temperature		60°C

Primary MTHW Operating Pressure	4.5 Bar
Secondary LTHW Operating Pressure	<i>Refer to pressurisation plant schedule</i>
Primary Chilled Water Flow Temp (at EC)	6°C
Primary Chilled Water Return Temp (at EC)	14°C
<i>Primary Chilled Water Flow Temp (at PHE)</i>	7°C
<i>Primary Chilled Water Return Temp (at PHE)</i>	13°C
Secondary Chilled Water Flow Temperature	8°C
Secondary Chilled Water Return Temperature	13°C
Chilled Beam Flow Temperature	15°C
Chilled Beam Return Temperature	18°C
Primary Chilled Water Operating Pressure	3.0 Bar
Secondary Chilled Water Operating Pressure	<i>Refer to pressurisation plant schedule</i>
Limiting noise criteria <i>at site boundary</i>	<i>Refer to Acoustic Consultant's Report</i>
<i>Room noise criteria</i>	<i>Refer to Acoustic Consultant's Report</i>

For ventilation/air change rates *used in the design*, the Sub-contractor shall refer to the ADB sheets.

7.0 LIAISON

The Sub-contractor shall include for liaison with:-

Health and Safety Professionals. As well as the Health and Safety requirements of this specification, the Sub-contractor shall include for close liaison with Health and Safety professionals including the Hospital's Health and Safety Advisors and the CDM Co-ordinator and shall comply with the CDM Regulations and all Health and Safety Regulations.

The Contractor. The Sub-contractor shall liaise with the Contractor through whom all communications must flow. Drawings and other documentation shall be available via the Contractor. The Sub-contractor shall include for liaison with members of the Contractor's team with an interest in the planning and administration of the Ventilation System.

Other Specialist Sub-contractors. The Sub-contractor shall liaise with other specialist Sub-contractors as necessary to ensure that all interfaces and co-ordination between the Fire Detection and Alarm System and other systems are allowed for. This shall include but not be limited to:-

- Building Management System specialist
- Fire Alarm and Detection specialist
- Other disciplines for co-ordination
- Fire Protect Systems specialist
- Kitchen Specialist

The Hospital. The Sub-contractor shall include for liaison in conjunction with the Contractor with members of the Hospital's team with an interest in the planning and administration of the Ventilation System.

The Architect. The Sub-contractor shall include for review of the Architect's plans and elevations and shall liaise as necessary with the Architect to assist with the production of these drawings. The Sub-contractor shall ensure that the plans and elevations are co-ordinated with the Ventilation Systems, in terms of such issues as space and access. The Sub-contractor shall provide all services input into the reflected ceiling plans for review to the Architect.

The Fire and Risk Engineer. The Sub-contractor shall follow the recommendations of the Fire and Risk Engineer in the production of the drawings. This shall include a review of the Fire Strategy and other documents when locating fire dampers, smoke dampers and the requirement for fire rated ductwork.

Building Control. The Sub-contractor shall liaise, with and adhere to, the requirements of the Building Control Officer.

Any other member of the Project and Trust teams concerned with the planning and administration of the Ventilation System.

8.0 SYSTEM DESCRIPTION

The mechanical ventilation and air conditioning systems shall comply with HVAC DW144, 154, TR19, BS 5726 (updated), and descriptions and requirements set out below.

8.1 Background to Ventilation and Air Conditioning Installations

The building is largely sealed with limited openable windows in order to control the internal environment within the spaces and limit the impact of odours from the Scottish Water works adjacent to the site.

The Hospital shall be mechanically ventilated:-

- Throughout all internal rooms that have no access to natural ventilation
- Perimeter areas where mechanical ventilation is required for clinical reasons
- Perimeter areas where mechanical ventilation is required for operational and environmental control reasons
- Deep plan perimeter areas where necessary to assist the natural ventilation

The various departments to match their function shall be served by a number of ventilation air handling systems.

In general, each air handling system shall be served by packaged air-handling units containing all components necessary (e.g. fans, coils, filters, etc.) to provide the correct environmental control of those spaces/rooms served.

Active chilled beams and fan coil units shall also be provided for comfort cooling in areas where there is a need for separation or where high heat gains make these a more appropriate choice of systems.

Various types of room are included within this project and are described elsewhere. These are:-

- Wards
- Isolation rooms
- Outpatient type departments
- Operating theatres
- Critical care departments
- Comfort cooled areas (e.g. diagnostic imaging)
- Catering facilities
- Safety cabinet extracts
- Computer rooms and data hub rooms

Carbon Target

The hospitals have a stringent carbon target of 80kg/m² per annum and the engineering services have been designed with this strictly in mind. The Sub-contractor shall not deviate from the

proposed designs without consulting with the Contractor and providing evidence on how the deviation impacts on energy usage and hence the carbon target.

Fan Motors

All fan assemblies shall incorporate fan impeller and motors selected to provide the most energy efficient solution conforming to Section 6 regulations and shall be fitted with IE2 efficiency motors to EN 60034-30:2009 as standard, and suitable for operation in ambient temperatures of 40 degrees C.

System Resistance

The carbon target of 80kg/m² per annum requires that, for example, system pressure loss is limited to reduce fan power.

The detailed design calculations for fan resistance have been based on assumed pressure drops through in-line components which are stated in the specification or equipment data sheets. The Sub-contractor's selection of components shall ensure that the pressure drop of a component does not exceed that assumed in the calculations. The Sub-contractor shall also take care in finally detailed the ductwork routes to avoid potential causes of high pressure drop that may have a detrimental effect on ultimate fan performance. Upon completion of the Sub-contractor's installation drawings the Sub-contractor shall recalculate the whole system pressure drop, including all components to verify that the design calculated pressure drop has not been exceeded. For the purposes of calculating the system resistances the following allowances have been made in the figures in the equipment schedules:

Grille	25 Pa
Dampers	20 Pa
Heater Battery	20 Pa
Louvre	25 Pa
Plant Room Attenuator	50 Pa
Cross Talk Attenuator	25 Pa
Cowl	50 Pa
HEPA Filter	450 Pa

All rectangular radiused bends: $r/w = 0.5$

All circular radiused bends: $r/d = 1$

System performance

The Sub-contractor shall supply and install services and equipment to perform as per specification.

The Sub-contractor shall submit details of all mechanical equipment for comment and place orders in a timely fashion to ensure delivery as per programme.

Where a particular manufacture is specified, the Sub-contractor shall include for that manufacturer.

Where considered appropriate, provide for equivalent standard alternatives to be offered for consideration.

This must be done in a timely manner and the Sub-contractor shall provide all details including but not limited to:

- Detailed description
- Cost comparison
- Technical comparison
- Thermal comfort comparison
- Carbon emission and energy usage comparison
- References to standards
- References to SHTM/HTMs

Completion

The Sub-contractor shall protect the system from damage or interference during the works.

The Sub-contractor shall test, and clean the system as per TR/19.

The Sub-contractor shall submit O&M and record information via Zutec.

The Sub-contractor's defects and liability period shall be as the contract prelims.

940 OPERATING TOOLS

- Tools: Supply tools for operation, maintenance and cleaning purposes.
 - Quantity: 2 sets.

T51 CLIMATIC CEILINGS AND BEAM SYSTEMS

GENERAL

In clinical spaces and bedroom accommodation local heating and sensible cooling, where required, is to be provided via 4-pipe ceiling mounted enclosed active chilled beams. The devices shall be complete with dedicated controls enabling temperatures to be varied within each treated space.

In circumstances where sensible cooling units cannot meet the heat gains, then fan coil units are to be used.

The controls shall comprise of local room mounted temperature sensor/controller operating 2-port electrically operated valves in response to user inputs to raise or lower the room temperatures. The controls shall incorporate sequencing to avoid simultaneous heating and cooling to minimise energy input.

The emitters shall be provided with their own dedicated chilled water circuit operating at temperatures optimised for the chilled beams whilst minimising the risks associated with condensation within the device.

The active chilled beams shall be installed in series with radiant panels, where required, on the dedicated heating circuit serving the areas with 4-pipe chilled beams.

The Sub-contractor shall allow for supplying samples and constructing mock-ups for comment. This shall include ceiling mock-ups for the chilled beams.

The Sub-contractor shall allow for witness testing the devices, in a mock up single bedroom, in the manufacturer's thermal laboratories to ensure the comfort condition requirements can be achieved. This shall include simulation loads in the space and readings from hot wire anemometers and turbulence probes at pre-determined points within the space.

CFD calculations will not be accepted in isolation as method of proof for meeting the comfort requirements.

The comfort conditions shall be tested, as above, in accordance with BS EN ISO 7730 and shall prove that a category A room can be provided.

All emitters shall have smooth easy clean surfaces with no sharp edges or dirt collecting gaps.

All emitters shall be suitable for hospital application.

Access doors and hatches shall be provided for service and maintenance purposes.

All elements of the work shall be in accordance with the requirements of current legislation, regulations and industry standards.

The installation shall also comply with all relevant Code of Practice and British standards.

210 DESIGN

- System designs to be completed: Active chilled beam systems.
- Testing standards:
 - Capacity: To BS EN 14240.
 - Comfort: To BS EN ISO 7730.
- Proposals: Submit drawings, technical information, calculations and manufacturer's literature.

PRODUCTS

The chilled beams shall be installed as per drawings, specification and manufactures instructions.

The chilled beams shall have low velocity air distribution into the space to prevent draughts and noise.

Beams shall come complete with the manufacturer's connection terminal card, valves, actuator, condensation sensor and terminal box with input and output terminals, *and volume control damper on the primary air inlet.*

310 CLIMATIC BEAMS, ACTIVE

The active chilled beam shall have a galvanised steel case with combined cooling and supply air unit for flush installation within suspended ceiling.

The cooling capacities of the chilled beams shall be controlled by regulating the water flow rate according to the control signal from the room temperature controller.

Heating and chilled water connections shall be provided with 2-port control valves. Local pipework shall also include flexible connections, self-sealing pressure tapings, air vents and drains.

An integral anti-condensation sensor shall be provided on the chilled water flow pipe to close the control valve in the event of the chilled water temperature falling below 15°C.

For more details of the control of the active chilled beams the Sub-contractor shall refer to the relevant BMS controls specification.

The main pipelines of the cooling and heating water circuits should be installed above the beam in order to enable venting of the pipework.

Each beam shall have a measurement tap for static pressure measurement, to enable measurement of the supply airflow rate.

Chilled beams shall be of the enclosed hygienic type, with the beam casing sized to integrate with a standard T shaped grid. The return air grille panel shall be removable from within the treated space with all internal components capable of being cleaned without further dismantling. The performance criteria for the active chilled beams is provided below:

Chilled Beam Reference		CB/W1/L1	CB/W1/L2	CB/W1/L3	CB/W1/L4	CB/W1/L5	CB/W1/L6
Nominal Size		600 x 600	600 x 1200	600 x 1200	600 x 1200	600 x 1200	600 x 1200
Heating	Water LVT HTG F/R	60/50	60/50	60/50	60/50	60/50	60/50
	Output (Water Only)	1000	1480	1000	1480	1570	1570
	Design Water Flowrate F/R	0.024	0.036	0.024	0.036	0.037	0.037
	Maximum Coil ΔP	10	10	10	10	10	10
	Primary Supply Air Temperature	16	16	16	16	16	16
	Room Design Temperature	22	22	22	22	22	22
Cooling	Water CB CHW F/R	15/18	15/18	15/18	15/18	15/18	15/18
	Output (Water Only)	430	430	780	780	480	900
	Design Water Flowrate F/R	0.034	0.034	0.063	0.063	0.038	0.071
	Maximum Coil ΔP	10	10	10	10	10	10
	Primary Supply Air Temperature	18	18	18	18	18	18
	Room Design Temperature	26	26	26	26	26	26
Air	Primary Airflow	40	40	40	40	40	40
	Maximum Total Static Pressure	80	80	80	80	100	100

The beam casing shall have a stove enamelled finish in white to RAL 9010.

- Type: Enclosed hygienic type.
- Manufacturer: The Sub-contractor is to provide technical submissions for review.
- Flexible connectors: Provide connectors to allow each panel to be lowered for inspection and maintenance.
- Casing:
 - Material: galvanised steel case.
 - Material thickness: Submit proposals.
 - Surface treatment: hygienic with no burrs.
 - Perforations: Standard Manufacturer's plate.

EXECUTION

The Sub-contractor shall ensure all works carried out shall be done in a safe manner and comply with Health and Safety Regulations. This shall include clean and tidy working and working in confined spaces. The Sub-contractor shall protect the chilled beams from damage or interference during the works

620 SETTING OUT

- General: Co-ordinate with ceiling system to maintain the beams and ceiling panels accurately, continuous and even.
- Alignment: Straight and parallel to walls or setting out lines.
- Infill and access units, integrated services: Fit correctly and align.
- Support: Manufacturer's standard. The Sub-contractor shall liaise with the Architect in locating the grilles and diffusers on the architectural reflected ceiling plans as necessary.

630 INSTALLING CLIMATIC BEAMS

- General: Position accurately, parallel to outside wall.
- Alignment: Level in relation to ceiling.
- Mounting: Recessed, Any imperfect Beams scratched or damaged surfaces, or fixing screws having damaged heads or scratched plating, shall be rejected and must be replaced free of charge with satisfactory work before the contract shall be taken over as completed. Beams shall be installed level with the ceiling line and square with adjacent ceiling tiles. Where direct fixing to the ceiling is not inherent to the ceiling layout, the Sub- Contractor shall ensure that adequate concealed supports are provided to ensure that beams are installed at the correct level and square with the surrounding ceiling and adjacent luminaires. All beams shall be supplied in a fully finished condition and shall be provided with protective covering during building operations, and subsequently removed by the Sub-contractor.
- Support: Provide chains to take the weight of the beams when lowered for inspection.

U10 VENTILATION SYSTEMS

ALL AIR SYSTEMS

These shall be low velocity systems with air being distributed throughout the building in galvanised sheet steel ductwork via ceiling voids and riser duct spaces terminating in ceiling or wall diffusers as appropriate.

On full fresh air systems, heat recovery devices shall be provided, to exchange heat between exhausted extract air and incoming fresh air wherever significant energy savings can be achieved.

Generally, temperature control shall be by means of room or duct-mounted sensors which shall operate, via the automatic control system software the control valves on the hot water and chilled water to the heating and cooling coils respectively (refer to BMS specification for further details).

Areas shall be controlled in zones or as individual rooms as necessary to achieve the conditions required by the ADB Sheets.

Space shall be provided in all units for future incorporation of activated carbon filters to control odours entering the ventilating systems. Space shall also be included to upgrade the pre-filter from panel filters to bag filters.

Supply plants shall incorporate panel type coarse pre-filters followed by high efficiency bag filters. Absolute HEPA (high efficiency particulate air) terminal filters shall be provided only for 'ultra clean' areas such as UCV Theatres, Pharmacy Aseptic Suite and as a future allowance for isolation rooms. Some isolation rooms incorporate HEPA filters on the extract system.

Full humidity control, including humidification and dehumidification, shall be provided only in critical air-conditioned clinical areas such as the Pharmacy Aseptic Suite or wherever close control of humidity is required for the successful operation of sensitive equipment, e.g. computers, as advised by the ADB Sheets. Space shall be included within Operating Theatre air handling units for the provision of humidification in the future. Since the anticipated requirement for humidification is limited this shall be provided by electric steam injection humidifiers.

Air pressure regimes for theatre suites shall be designed in accordance with the guidance provided in SHTM 03-1 employing wall mounted pressure stabilisers.

Air volumes have been established by consideration of heat gains or losses and also the air change rate necessary for comfort and safety as appropriate for the activity carried out in each area. Relative air pressures between rooms shall be maintained to suit the activity concerned, by design of the supply and extract air volumes, and use of pressure relief equipment where necessary to prevent cross infection or transfer of unpleasant odours between areas, as required by the ADB sheets.

Heat recovery shall be provided between the supply and extract systems. The hospital ventilation systems shall be in accordance with SHTM 03-01 Ventilation in health care premises, DW 144 and DW 143.

The ventilation system including all AHU's, fan's, diffusers, dampers and grilles shall meet the design noise and vibration criteria.

The ventilation and cooling system shall be zoned with each air handling system being served by packaged air-handling units containing all components necessary (e.g. fans, coils, filters, etc.) to provide the correct environmental control of those spaces/rooms served.

The philosophy of the system is to provide energy efficient operation with areas of the hospital operating on a similar time and clinical nature being served from the same system, and to maintain a sensible level of availability, such that in the event of plant breakdown or maintenance, limited areas of ventilation are lost. Air handling plants shall have availability reinforced by the provision of duplicate motors or fans, which shall automatically changeover to maintain the ventilation requirements.

The Sub-contractor shall take care in finally co-ordinating the ductwork routes to avoid potential causes of high pressure drop that will have a detrimental effect on ultimate fan performance.

All ventilation controls must be capable of being fully interrogated by the building management system through the independent network protocol.

WARDS

The ventilation systems serving ward areas shall provide treated air to internal spaces, clinical spaces and make-up air for sanitary accommodation.

Make up air for en suite WC accommodation shall be introduced directly into the associated bedroom and via active chilled beam units to maintain the required space temperatures.

The beams shall be complete with dedicated controls enabling temperatures to be varied within each treated space. The controls shall comprise local digital room mounted temperature sensor/controller operating 2-port electrically operated valves in response to user inputs to raise or lower the room temperatures.

Air shall be extracted from spaces by either the clean or dirty extract systems as appropriate. Heat recovery shall be provided between the supply and extract systems. The type of recovery system employed shall depend on the area being served. Refer to system drawings and schedules for details.

The ward tower shall use different facades of the building for intake and exhaust air. The podium plantrooms shall use roof turrets for extract air and vertical wall louvres for supply air. This strategy should avoid short circuiting or contamination of the supply air and also meet the BREEAM requirement for separation. The Sub-contractor shall exercise caution when locating any other extracts or gas scavenging exhaust to ensure the supply intakes are not contaminated.

The tower shall be zoned to match the different load profiles with each finger being served by three AHU's. e.g. the external facade with higher solar gains, the central zone and the facade with lower solar gains. Each AHU shall serve four floors in this configuration. The centre circulation are shall have two zones each served by a different AHU, again each

AHU shall serve four floors.

ISOLATION ROOMS

Each lobbied isolation room shall be provided with its own dedicated ventilation system in line with SHBN 04.

Each system ventilation plant shall filter, heat and cool the air and supply it to the room lobby at the required temperature, as dictated by a sensor in the bedroom.

Air shall be transferred to the room via a wall mounted pressure stabiliser and then extracted from the suite via the bedroom and en suite WC, and ducted by fire-clad ductwork to a dedicated extract fan in the plantroom.

Each extract fan unit shall comprise of an isolation damper and a centrifugal cased extract fan, with the motor located out of the air stream, and the exhaust duct shall discharge 3.0 metres above roof level. In the Level 2 plantroom serving the Critical Care Ward it is not possible to achieve a safe discharge height of 3.0 metres above roof level. In this case the extract air shall be HEPA filtered through 'safe change' filter units in the plantroom before being discharged to atmosphere with all other ventilation exhausts.

Due to the small size of the plants, heat recovery is not considered viable and shall therefore not be provided.

Isolation rooms supply air terminals shall be capable of having terminal HEPA filters fitted at some future date. The air handling unit fan shall be capable of overcoming the additional resistance imposed by the HEPA filter by a simple speed change on the motor inverter.

OUTPATIENT TYPE DEPARTMENTS

The ventilation systems serving outpatient areas shall provide heated air to internal spaces, clinical spaces and make-up air for sanitary accommodation.

Active chilled beams shall generally be provided to individual spaces to provide independent control of heating and cooling requirements.

Air shall be extracted by clean and dirty extract systems.

Heat recovery shall be provided between the supply and extract systems.

OPERATING THEATRES

Each operating theatre shall be provided with a dedicated ventilation system.

Each system ventilation plant shall filter, heat and cool the air and supply it to the suite of rooms, and arranged to allow individual temperature set point adjustment and indicated on the associated surgeon's theatre panel (refer to BMS specification).

The pressure regimes between the spaces in each theatre suite shall be maintained by a combination of supply and extract rates to each space, and pressure stabilisers located in the walls.

Heat recovery shall be provided between the supply and extract systems. Out of hours

setback shall be provided by reducing the air volumes and temperature set points.

In theatres with a requirement for Ultra Clean Ventilation (UCV), a specialist shall be employed to undertake the provision of the UCV canopy in accordance with SHTM 03-1.

Ancillary areas associated with the Operating Theatre department shall be served from a dedicated plant.

CRITICAL CARE DEPARTMENTS

Critical care departments such as ITU/HDU shall be provided with dedicated ventilation systems.

The supply air ventilation plant shall heat and cool the air as required by the control system to provide the correct condition in the various rooms/zones.

Final temperature control to the spaces shall be achieved by terminal reheaters controlled from user adjustable sensors within each space. Heater batteries shall be located wherever possible in plant areas, but where heaters can only be provided in the ceiling void of the occupied space they shall be located away from patient occupied spaces, i.e. bed spaces.

Heat recovery shall be provided between the supply and extract systems.

COMFORT COOLED AREAS

Departments where space temperature control is required, such as the Emergency Centre, Diagnostic Imaging, etc. cooling shall be provided by treated air to clinical spaces and spaces with high equipment gains.

The department shall be arranged in a number of zones to suit the control requirements, varying heat gains and use of the spaces.

Particular areas that have high-density heat gains shall be provided with terminal cooling in the form of fan coil units to achieve the required space conditions.

The supply air ventilation plant shall heat or cool the air as required by the control system to provide the correct condition in the various rooms/zones.

All AHU's and fans shall be suitable for hospital application refer to drawings and schedules for further details.

SAFETY CABINET EXTRACT SYSTEMS

The Pharmacy shall be served by separate extract systems serving the general areas whilst extracts from safety cabinets shall be handled by individual contaminated extract systems.

The design of the general extract system shall be co-ordinated with the associated supply system and contaminated extracts to maintain suitable pressure levels and ensure the Clean Room requirements of the Aseptic Suite are maintained.

The Aseptic suite is a "clean space" and as such shall be installed and commissioned as per SHTM 03-01 AND HBN 14-01. equipment shall be fully commissioned to validate their

function and achievement of performance.

QUENCH PIPES

The Quench pipes serving the MRI machines shall be installed by the sub-contractor in accordance with a design and specification produced by the MRI supplier/installer. The route of the pipes shall be as shown on the drawings and they shall be insulated and terminate in accordance with the recommendations given by the MRI supplier/installer. The Quench pipes are required to be continuous and therefore the pipe structure and insulation shall maintain the required 2 hour fire integrity.

130 MECHANICAL SUPPLY VENTILATION SYSTEM

Supply air from central air handling plant shall be delivered through the ductwork systems to the areas served, and discharged via ceiling mounted diffusers.

Supply and extract air handling plants shall be of a packaged construction with a double skin casing complete with thermal/acoustic insulation material between the two skins. Units shall house filters, coils, fans and motorised inlet dampers, etc. Heat recovery devices and humidifiers shall also be incorporated where required. External fan motors shall be provided to all units with some unit types having twin motors.

All AHU's and fans shall be suitable for hospital application. Refer to drawings and schedules for further details.

- Location of plant: Various locations throughout the building.
- Type of system: Multizone, constant volume.
- External air intake terminals: Architectural louvres.
- Air filters: In air handling units, as section U81.
 - Accessories: As schedule.
- Heat recovery: In air handling units, as section U81/U85.
- Air handling units: As section U81 and schedules.
 - Fabrication: Construction, as section U81.
- Supply fans: As schedule.
- Acoustic treatment: Rectangular silencer, as section U87.
- Air ductwork and ancillaries: Ductwork, Fire rated and smoke extract ductwork and fittings, as section U80.
 - Accessories: Dampers, fire and smoke, metal ductwork, as section U80.
- Thermal insulation on supply air ductwork: As section Y30.
- Vibration isolation mountings: Spring isolators, as section Y31.
- Reheat batteries: As schedules and drawings.
- Room supply air terminal devices: Chilled beams, grilles and diffusers as specified.
- Controls: All ventilation controls must be capable of being fully interrogated by the building management system through the independent network protocol.
- Completion:
 - Identification of ductwork and equipment: As section Y32.
 - Testing and commissioning:
 - Ductwork pressure testing, as section U80;
 - Air distribution system commissioning, as section Y50; and
 - Performance testing, as section Y50.

140 MECHANICAL EXTRACT VENTILATION SYSTEM

Extract air from the area concerned shall be drawn through a ductwork system to extract fans in the roof plantrooms for discharge to atmosphere, or returned to the air handling plant for recirculation.

- Room extract air terminal devices: As drawings.
- Air ductwork and ancillaries: Fire rated and smoke extract ductwork and fittings, as section U80 and Smoke extract ductwork, as section U80:
 - Accessories: Dampers, fire and smoke, metal ductwork, as section U80 and Flexible ductwork, as section U80.
- Thermal insulation on extract air ductwork: As specified.
- Vibration isolation mountings: Spring isolators, as section Y31.
- Heat recovery: Plate recuperator, as section U85 or thermal wheel, as section U85 depending on AHU type.
- Acoustic treatment: Rectangular silencer, as section U87.
- Extract fans: The extract fan shall have twin motors depending of fan type.
- External exhaust air terminals: Architectural louvres
- Controls: All ventilation controls must be capable of being fully interrogated by the building management system through the independent network protocol.
- Completion:
 - Identification of ductwork and equipment: As section Y32.
 - Testing and commissioning:
 - Ductwork pressure testing, as section U80;
 - Air distribution system commissioning, as section Y50; and
 - Performance testing, as section Y50.

150 TOILET EXTRACT VENTILATION SYSTEM

Potentially contaminated dirty air extract systems shall be discharged at, or above, roof level.

Dirty extract shall be provided to extract air from toilets, bathrooms, cleaners' rooms and dirty utility areas. Extract plants shall either form part of the general area air handling unit or be separate extract fan units.

Air shall be extracted via grilles in the individual rooms and ducted by galvanised sheet steel ductwork similar to that provided for the general supply and extract systems to extract fans in the plantrooms. Make up air shall be via the main ventilation system.

Separate dirty extract units shall be manufactured heavy gauge aluzinc corrosion resistant steel. The general construction is to Class A leakage.

The fan unit shall be supplied complete with all manufacture control accessories to be fully integrated into the BMS.

The fan unit shall be provided with an integrated commissioning/speed control to accurately commission the system. The commissioning set up facility directly controls the integrated speed control/frequency inverter.

Heat recovery shall be used for the larger dirty extract systems.

Where toilets or bathrooms are in isolated positions, not convenient to central ducted systems, small units operated by light switch control shall be used

- Room extract air terminal devices: Air transfer grilles and diffusers, as specification.
- Air ductwork and ancillaries: Sheet metal ductwork and fittings, circular, as section U80 and Sheet metal ductwork and fittings, rectangular, as section U80:
 - Accessories: Dampers, fire and smoke, metal ductwork, as section U80 and Flexible ductwork, as section U80.
- Thermal insulation on extract air ductwork: Not required
- Vibration isolation mountings: Spring isolators, as section Y31.
- Acoustic treatment: Circular silencer, as section U87 and Rectangular silencer, as section U87.
- Extract fans: Twin Toilet extract fans run and standby, as section U82.
- External exhaust air terminals: Architectural louvres.
- Controls: All ventilation controls must be capable of being fully interrogated by the building management system through the independent network protocol.
- Completion:
 - Identification of ductwork and equipment: As section Y32.
 - Testing and commissioning:
 - Ductwork pressure testing, as section U80;
 - Air distribution system commissioning, as section Y50; and
 - Performance testing, as section Y50.

160 KITCHEN EXTRACT VENTILATION SYSTEM

Ventilation to the central catering areas shall be provided to deal with the requirements on the cooking equipment to reduce odours and limit temperatures within the space.

Contaminated air extract systems shall be discharged at, or above, the tower roof level at high velocity as appropriate.

Ventilation make-up air shall be provided to balance the extracted air.

There shall no recovery from kitchen hood extract due to the difficulties with grease laden air.

The kitchen canopies shall be supplied and installed by the kitchen specialist and do not form part of these works. The Sub-contractor shall liaise with the kitchen specialist, so as to agree requirements. All the main kitchen extract hoods to be the capture/entrainment type. This type of canopy entrains the contaminant air by supplying fresh air over the kitchen island. This shall reduce extract air flow rates and hence save energy. The hoods and supply air shall also have a set back position when the kitchen is not in use. This shall reduce air flows when the kitchen is not in use and energy consumption

- Air ductwork and ancillaries: Fire rated and smoke extract ductwork and fittings, as section U80. All kitchen extract systems to DW172:
 - Accessories: All kitchen hood extract ductwork to be fire rated.
- Thermal insulation on extract air ductwork: Not required.
- Vibration isolation mountings: Spring isolators, as section Y31.
- Acoustic treatment: Sub-contractor's specialist to examine.
- Extract fans: Centrifugal belt driven, as section U82.
- Completion:

- Identification of ductwork and equipment: As section Y32.
- Testing and commissioning:
 - Ductwork pressure testing, as section U80;
 - Air distribution system commissioning, as section Y50; and
 - Performance testing, as section Y50.

EXECUTION

The Sub-contractor shall ensure all works shall be done in a safe manner and comply with Health and Safety Regulations. This shall include clean and tidy working and working in confined spaces.

All supply and extract ventilation systems should be clearly labelled. The label should identify both the AHU and the area that it serves. The lettering should be at least 50 mm high and be mounted in an easily visible place near the fan of the unit. Any sub-systems and the principal branch ducts should be similarly labelled. The direction of air flow should be clearly marked on all main and branch ducts.

630 INSTALLING DUCTWORK ON AIR HANDLING UNITS

- Air discharge: Connect ductwork to allow air to straighten as it leaves the air handling unit.

U41 FAN COIL UNITS

310 FAN COIL UNITS

Fan coil units shall be complete with dedicated controls enabling temperatures to be varied within each treated space. The units shall, where applicable, include heating. The controls shall comprise local room mounted temperature sensor/controller operating 2-port electrically operated valves in response to user inputs to raise or lower the room temperatures.

All Fan coil unit motors shall be fitted with built in Thermal overload protection.

- Performance: To BS 4856.
- Manufacturer: Sub-contractor's choice
 - Product reference: Sub-contractor to provide technical proposals.
- The Sub-contractor shall examine all layout drawings, schematics and schedules, in order to ascertain duties and required temperatures.
- Fan speed: Low.
- Fan motors: EC type with a Specific Fan Power less than 0.8 watts per litre/second
- Noise levels: As fan coil schedule.
- Electrical supply type: As fan coil schedule.
- Casings: As manufacturer's standard for application.
- Mounting: As manufacturer's standard for application.
- Finish: As manufacturer's standard for application.
- Ductwork connections: Sub-contractor to provide proposals.
- Access: Provide access to filter, fan and motor, valves and controls.
- Drip tray:
 - Position: Under coil, and under control valve where fitted.
 - Material: Corrosion resistant.
 - Condensation: Insulate external faces to prevent.
- Controls: All ventilation controls must be capable of being fully interrogated by the building management system through the independent network protocol.
- Accessories: As Fan coil schedule.

EXECUTION

The Sub-contractor shall ensure all works carried out shall be done in a safe manner and comply with Health and Safety Regulations. This shall include clean and tidy working and working in confined spaces.

610 FAN COIL UNIT DRAIN LINE

- Drain connections: Connect drain line flush with bottom of drip tray.
- Drain line: To discharge via a suitable dry type trap.

U60 LOCAL AND ROOM AIR CONDITIONING SYSTEMS

GENERAL

Generally ventilation and comfort cooling shall be from central systems. Where this is not possible because of the remoteness of the area from the main plant, the particular use of the space, or high cooling loads, local systems shall be used. The Sub-contractor shall ensure that these systems are installed to the same high standard as the main system.

PRODUCTS

All elements of the work shall be in accordance with the requirements of current legislation, regulations and industry standards. The installation shall also comply with relevant British Standards. The Sub-contractor shall provide working drawings for the installation and issue them for comment before work commences.

340 COMPUTER ROOM AIR CONDITIONING UNITS (CRAC)

The two main server room air-conditioning systems shall be feed from the main chilled water system. Computer rooms shall each be provided with independent systems via dedicated secondary chilled water circuits having their own plate heat exchangers and circulating pumps.

CRACs shall be floor standing 'downflow' type and CRACs must be capable of being fully interrogated by the building management system through the independent network protocol.

To comply with these directives appropriate national & harmonised standards have been applied. These are listed on the Declaration of Conformity, supplied with each product.

Unit cabinets shall be manufactured from galvanised sheet steel coated with epoxy baked powder paint to provide a durable finish. Internal strength and rigidity shall be provided by a welded space frame constructed of channel profile folded steel. Cabinets shall be lined internally with fire resistant 20mm foam (UL94 V0) for thermal and acoustic insulation. Cabinets shall meet the Hospital acoustic and vibration requirements. The cabinet doors are full height, hinged and key lock secured. Door arrangement shall allow flexible door opening/removal for improved access. Doors shall have rubberised door seals reduce sound breakout and eradicate leakage.

The units shall have large surface area coil(s) to optimise airflow and heat transfer, manufactured from refrigeration quality copper tubes with mechanically bonded aluminium fins.

Fins shall be coated with a non-stick acrylic film to provide additional corrosion protection and efficient surface water removal for improved performance.

Coil headers shall be circuited to ensure low water pressure drops. The cooling coils shall be mounted over a full width stainless steel condensate tray. Chilled water flow shall be via a factory fitted 3 port modulating control valve.

All coils shall be Factory pressure tested to 20Bar.

Fans shall be backward curved impellers, direct drive centrifugal fan assemblies with integral rotor mounted motor which is statically and dynamically balanced for quiet operation. Designed for high corrosion resistance, the impellers are laser welded aluminium with galvanised rotor and die cast aluminium EC power module. An inbuilt EC fan control module shall allow the fan to modulate from 15-100%.

Filters shall be 97mm pleated disposable panel filters in a rigid frame. Conform to BS EN 779-G4.

Access and removal from unit front. An adjustable diaphragm pressure switch fitted across the filter assembly shall monitor pressure drop which shall initiate a filter dirty alarm.

The control panel shall have fan motor contactors and overloads, transformer, sub circuit protection, volt free contacts, mains and inter-connecting terminals. The panel shall be fitted within the cabinet and be hinged for easy access to other components within the unit. The electrical control panels shall be wired to the latest European standards and codes of practice.

To ensure complete unit isolation of the electrical panel during adjustment and maintenance a door interlocking isolator is provided as standard.

Units shall be fitted with the microprocessor controller which shall have a real time clock and a communication port plus networking and Bac Net BMS connections. A backlit LCD door mounted display keypad assembly shall be fitted to view the unit status and allow operator adjustment.

The condensate pump shall have a reservoir with a capacity of 5 l/m at a head of 10.8m.

Leak detection tape suitable for sensing water droplets shall be supplied loose for remote mounting on site.

- Sub-contractor to provide technical proposals.
- Arrangement: Vertical.
- Casing: Steel frame with acoustically lined steel panels.
- Finish: Manufacturer's standard.
 - Colour: Manufacturer's standard.
- Controls: All controls must be capable of being fully interrogated by the building management system through the independent network protocol.

Each server room shall be provided with the following:

- Room sensible cooling capacity 200 kW
- Number of units (N+1) 5 No.
- Sensible cooling capacity per unit 50 kW
- Sensible Heat Ratio 1.0
- Chilled water temperatures at unit Flow 8°C
Return 14°C
- Chilled water flow rate per unit 1.94 litres/second
- Maximum coil/valve pressure drop 60 kPa
- Inlet air design conditions 22°C 50% RH
- Nominal air flow per unit 3.75 m³/s

EXECUTION

The Sub-contractor shall ensure all works carried out shall be done in a safe manner and comply with Health and Safety Regulations. This shall include clean and tidy working and working in confined spaces.

U80 AIR DUCTWORK AND ANCILLARIES

During installation the ductwork shall be installed to a PDI (Protection, Delivery & Installation) as defined in the HVCA (2005) TR/19 – Guide to good practice: internal cleanliness of ventilation systems'.

A Specialist Cleaning Operation shall be performed on all ductwork systems installed serving Clinical Areas, in accordance with the guidelines of Section 9 – Verification of Cleanliness, HVCA TR/19.

The cleanliness of the ductwork installation shall be confirmed and documented by means of the post clean verification test procedure outlined in Section 9.5 of HVCA (2005 TR/19).

300 CLASSIFICATION

Ductwork shall be classified as described in Table 1 of DW/144, as follows:-

- Plantroom and main riser ductwork: Class B
- Distribution ductwork at each floor Class: A

The ductwork sub-contractor shall clearly indicate on the manufacturing and installation drawings the classification of the ductwork proposed.

All ductwork shall meet the leakage criteria given in the Building Regulations Section 6 which requires it to meet the requirements of HVCA DW/143.

10%, chosen at random, of Class B ductwork shall be selected by the Contractor for testing.

Ductwork branch connections shall be shoe type as fig 106 in DW144, spigot type branches shall not be acceptable.

The Sub-contractor shall ensure that sufficient dampers are provided to regulate and balance the system. Dampers on grilles or diffusers shall be used only for balancing of external air distribution devices in a common branch. All dampers shall be sufficiently rigid to prevent vibration within the systems, when absorbing the additional available pressure of the system.

PRODUCTS

A specialist ductwork Sub-contractor shall be employed by the Sub-contractor to fabricate install and test a range of ductwork that shall be used for general ventilation, air conditioning or comfort cooling.

305 DAMPERS, FIRE AND SMOKE, METAL DUCTWORK

The ductwork system shall be provided with fire dampers in locations corresponding to the appropriate fire separation barriers. Actuation of the dampers shall be in accordance with SHTM81 Fire Code, and the Fire Consultants Strategy Report, subject to the separation performance of the barrier.

Where actuation of the damper is via the fire alarm system the damper shall be motorised to facilitate re-opening after testing of the fire alarm system. Dampers utilising fusible link operation only shall be provided with local mechanical indicator on the side of the fire damper. Dampers with motorised operation shall be monitored via a separate electronic remote monitoring system.

Fire dampers MUST be fitted with the correct installation frame and supports.

Fire rated ductwork shall be utilised where the use of fire dampers is inappropriate.

The smoke damper control panel must be capable of being fully interrogated by the building management system through the independent network protocol.

Smoke control dampers shall be provided in the positions as indicated on the drawings and shall be suitable for mounting in the horizontal or vertical plane. They shall be certified by the manufacturer to have been tested to the temperature time curve of BS ISO 10294, for a period of 4 hours with a classification of ES 240 in the fully closed position with power off.

Smoke control dampers shall have factory fitted installation frames to HVCA 10.1.83 specification and the sub-contractor shall allow for all additional framing, supports and bracing securing the damper to the structures, to the satisfaction of the Building Control Officer.

All smoke control dampers shall be supplied with a factory fitted actuator, complete with integral micro switches and controlled mechanical fail safe operation of not more than 20 seconds.

The totally enclosed precise movement with British Standard 5588: Part 9999: 1999 should be held in the open position by means of a thermally actuated device set to operate at approximately 74 °C. Automatic smoke and fire control dampers are fire rated dampers as they are held in the reset (Open) position by a thermally actuated device.

The totally enclosed precise movement opposed blade drive shall be positioned out of airstream for protection against damage, be hard wearing and free running.

The control mode/damper connection shall be by means of the drive interface mechanism, which shall be totally independent of the ductwork.

Automatic smoke release dampers with their appropriate control modes shall have spring fail-safe open operation.

The Sub-contractor shall be responsible for allocating a unique reference number to each damper per system and produce a schedule for the purposes of carrying out the inspection and testing of all installed smoke/fire dampers. Upon completion of the tests, the certificates, with the schedule must be issued confirming that all dampers have been inspected and function correctly in accordance with the manufacturer's data sheets. The ductwork Sub-contractor is to allow for subsequent demonstration of all fire/smoke dampers to a witnessing party. Access door requirements as DW144 Appendix M require unique numbers to be identified on the fire damper and also on installation / record drawings, damper control graphics and within a schedule to be included in the O& M instructions.

The Sub-contractor shall be responsible for ensuring the mechanical inspection and testing of all smoke/fire dampers installed on the contract is carried out with the smoke damper control specialist testing and in attendance same time. Upon completion of the tests, the certificates must be issued for confirming that all the dampers have been inspected and that they function correctly in accordance with the manufacturer's data sheets.

The dampers shall comply to Class A and B of Eurovent Document 2/2 and Test Procedures for Classes A, B and C of HVCA Ductwork Specification DW144.

305A DAMPERS, FIRE AND SMOKE, METAL DUCTWORK

The slam shut curtain fire dampers shall have a stainless steel folding curtain having unbroken movable joints, stainless steel constant tension closure springs for positive closure and stainless steel peripheral gasketing.

The self resettable, latching removable release mechanism cassette, shall ensure the closure of the stainless steel curtain under full fire conditions. The housing shall be galvanised steel fully welded spigotted type casing suitable for square, rectangular, circular or flat oval connections.

The spigotted casing with continuously welded corners and spigot connections makes these dampers suitable for inclusion into air distribution systems to the test methods of Eurovent Class A, B & C and HVCA Ductwork specification DW144.

- Standard: To BS EN 1366-2.
- Type: Multi-blade.
- Manufacturer: Sub-contractor to submit proposals.
 - Product reference: Sub-contractor to submit proposals.
- Material: Stainless steel.
- Accessories: External visual indication of fire damper blade position.
- Fusible links fusing temperature: 72°C.

310 DAMPERS, NON-RETURN

Non return dampers shall be installed as shown on the drawings. They shall automatically shut off individual sections of an air conditioning system.

The damper shall be selected for the type of system (constant or variable volume).

- Standard: To BS EN 1751.
- Manufacturer: Sub-contractor to submit proposals.
 - Product reference: Sub-contractor to submit proposals.
- Leakage through closed blades: Class 0.
- Casing leakage: Sub-contractor to submit proposals.
- Pressure: Sub-contractor to submit proposals.
- Material: Galvanized sheet steel frame and aluminium blades.

330 DAMPERS, SHUT OFF

Shut of dampers shall be suitable for air conditioning and ventilation systems requiring air control and low closed blade leakage characteristics. For standard low/medium pressure and velocity systems.

Air control and system balancing shut-off dampers shall comprising of stainless steel aerodynamic blades with synthetic trailing edge blade seals, synthetic blade end bearings and stainless steel top and side spring tempered flexible gasketing. Dampers to have a maximum closed blade leakage of 27 l/s at 1000 Pa when measured on a 1000mm wide x 1000mm high damper. Housed in a galvanised mild steel frame having integral peripheral flanges.

- Standard: To BS EN 1751.
- Manufacturer: Sub-contractor to submit proposals.
 - Product reference: Sub-contractor to submit proposals.
- Leakage through closed blades: Sub-contractor to submit proposals.
- Casing leakage: Sub-contractor to submit proposals.
- Pressure: Sub-contractor to submit proposals.
- Setting: Sub-contractor to submit proposals.
- Material: Galvanized sheet steel.
- Control method: Electric and electronic.

340 FLEXIBLE DUCTWORK

Flexible ductwork shall not be used in runs that are more than 1.0m. Fixed ductwork shall terminate not less than 450mm from terminal equipment. Actual lengths of flexible ductwork when fully extended shall not exceed 125% of the connection distance.

Where the flexible ductwork is to be insulated, this shall be factory applied of a type approved for the application and to the thermal conductivity equivalent to the adjacent thermal insulation, and shall be Class O fire rated.

- Standard: To HVCA DW/144.
- Manufacturer: Sub-contractor to submit proposals.
 - Product reference: Sub-contractor to submit proposals.
- Material: As specification U10.

370 *PRESSURE STABILISERS*

Pressure control flaps/pressure stabilisers are to be installed as shown on drawings. The flap/stabiliser shall accurately control the differential air pressure between adjacent rooms, and the blades close fully as soon as the pressure differential drops below the required level. This diverts the airflow to pass through an open door forcing back airborne contamination.

The damper shall come with a Standard Finish: RAL9010 powder coated white with antimicrobial protection as standard.

Bearings shall be stainless steel ball roller type sealed for life ball bearings. Pressure Control Range shall be 3 - 50 Pa with a setting accuracy of +/- 1 Pa. Where required the

flap/pressure stabilisers shall come complete with fire/fire smoke damper.

The fire/smoke damper shall be standard smoke/fire damper integrity tested to BS EN 1366 for 245 minutes - ES classification (ES245). The fire/smoke damper shall be enclosed in a case with the flap/stabiliser as one unit and the entire case shall be powder coated white with antimicrobial protection as standard. The fire damper must be compatible and be capable of being controlled by the fire damper control panel/system.

- Manufacturer: Sub-contractor to submit proposals.
 - Product reference: Sub-contractor to submit proposals.
- Material: Stainless steel flap and adjustable balance weight assembly.
- Wall mounting casings material: Sub-contractor to submit proposals.
- Control pressure of balance weight: Sub-contractor to submit proposals.

380 ACCESS DOORS

An access panel shall be provided adjacent to all items of in-line equipment that require either regular servicing or intermittent access.

Access doors shall not generally be less than 450 mm long by the full width of the duct on sizes up to 450 mm wide. For ductwork sizes up to 600 mm wide, access door shall not be less than 450 mm x 450mm clear opening. Ductwork sizes for 600 mm-900 mm shall have not less than 600 mm x 450 mm access doors. For ducts with longest dimensions below 300 mm Level 2 access doors DW/144 Table 25 shall apply. For ductwork with sides longer than 900mm access door sizes shall be agreed with the Sub-contractor. Where man access into ductwork is possible then the supports and fixing shall be suitable to support the weight of an occupant and tools. Access doors shall be installed adjacent to all coils and batteries for inspection and cleaning.

Access and inspection opening locations shall be in accordance with Part 7 of DW/144 and suitable to comply with the requirements of TR/19 with the exception of above and the following.

All doors shall be fitted with rust-resistant quick release fasteners and those in the riser shafts shall be supplied with an approved retaining device fixed to door and frame. Access doors shall be capable of withstanding the respective system test pressures referred to in Table 1 of DW/144.

All access doors are to be pre-insulated and shall be constructed and installed in such a manner that the internal face of the duct and door is maintained when fixed. On insulated services all access doors shall be fitted with raised stools which shall be equal to the depth of the insulation. For tender purposes assume insulation thickness of 38 mm. All insulation finishes shall be extended to the neck size of the access door with the access doorframe returns exposed on the surface of the insulation finish.

Ductwork test holes shall be required to be drilled in the locations recommended in SHTM 2025/03-01 (Commissioning) and identified by the commissioning engineer. Test holes shall be drilled and located in accordance with the requirements of BSRIA Application Guide 3/89 Section C3.2 at the positions confirmed by in situ marking or marked up ductwork drawings. Each test hole to be sealed with a top hat grommet. Locations shall not be limited to those described.

Access doors, panels and covers other than those regarded as standard practice (see

DW/144) shall be marked on the manufacturers drawings issued for comment or noted below or in other sections of this specification, including type to be used.

Details of large access openings shall be agreed and shall be:-

Fitted in readily accessible locations and suitable for the purpose.

Provided to the sizes, requirements and positions recommended in DW/144 and this specification and on the drawings, utilising suitable proprietary products, which meet the relevant pressure classifications. Provided adjacent to duct mounted filters, cooling coils, fans, heating coils, humidifiers, and all dampers including hand fire and smoke dampers to facilitate easy cleaning and maintenance.

For air-conditioning (A.C) systems access doors provided for Level 3 access and for other ventilation systems Level 2 access is provided all as indicated on DW/144 Table 25.

Access doors shall be sealed, to ensure an airtight seal with a soft EDPM full-face gasket secured to the ductwork with an approved adhesive. Fire rated to match the standard of ductwork in which they are installed. Insulated in all thermally insulated ductwork to match the insulation value of the associated lagging and maintain the vapour barrier.

FABRICATION

Ductwork used for general ventilation system (including air-conditioning and comfort cooling) shall be manufactured from sheet steel and may be rectangular, circular or flat oval as indicated on the scheme design drawings. Ductwork constructed from an alternative material shall be agreed with the Contractor and clearly indicated on the scheme drawings. Ductwork, shall generally be constructed from zinc coated Steel as described in DW/144.

The specialist ductwork Sub-contractor shall be responsible for:-

Reviewing associated Architects and Structural Engineers drawings to confirm routes, availability of supports etc. Site measuring built structures to confirm suitability of routes, co-ordination (with the structure).

Provision of manufacturing/installation and builderswork drawings associated with the ductwork system.

Provision of support details and proposed locations. This shall be via manufacturing drawings and mark-ups on Architectural/Structural engineers' scheme drawings.

Co-ordination and installation of all ductwork components not directly supplied by the ductwork Sub-contractor.

Manufacture and supply of all ductwork, and associated components. Installation, air leakage testing, and component operation testing of the ductwork systems and their associated equipment. Preparation of as-fitted ductwork drawings - issued as electronic copy and hard copy at a scale of 1:50 or 1:25.

All the forgoing responsibilities shall be co-ordinated and integrated within the agreed programme of installation.

520 FIRE RATED AND SMOKE EXTRACT DUCTWORK AND FITTINGS

Where indicated on the scheme drawings or where passing through fire rated rooms/enclosures, ductwork shall be of fire rated construction equal to the room/enclosure through which it passes, in accordance with the Fire Consultant's Strategy Report and NHS Fire Code SHTM 81. The Sub-contractor shall review the fire strategy and architects drawings.

The location of the fire enclosing structures and their value (in hours) are indicated on the Architects drawings.

The ductwork shall be constructed as a complete system to provide the rated protection for stability, integrity and insulation when tested in accordance with SHTM 81 and BS. Any components within the system shall maintain the overall integrity in accordance with the test procedures.

Where ductwork services penetrate fire rated walls and cavity barriers, the penetrations shall be sealed after installation by the main contractor using a proprietary fire sleeve/sealant as manufactured by specialists.

The ductwork systems shall be fire stopped where appropriate. Where plastic ductwork is specified the ductwork Sub-contractor shall supply and fit to ductwork intumescent sleeves for the main contractor to finish too.

The ductwork shall be constructed as a complete system to provide the rated protection for stability, integrity and insulation when tested in accordance with BS476 Part 24. Any components within the system shall maintain the overall integrity in accordance with the test procedures.

All fire rated ductwork shall be constructed and installed by a specialist supplier who shall certificate the complete system to the approval of the Local Authority Building Control Officer.

The standard of fire stopping shall give greater or equal fire resistance as the construction through which the service penetrates. Where sheet steel or rolled steel section sealing flanges are required the ductwork Sub-contractor shall provide them.

Cleanliness and leak tests shall be as main ductwork section.

- Standard: To HVCA DW/144.
- Fire resistance to BS 476-24: As this specification.
 - Stability: To meet room requirements.
 - Integrity: To meet room requirements.
 - Insulation: To meet room requirements.
- Accessories:
 - Materials: Compatible with ductwork.
 - Finish: Match ductwork.

530 PLASTICS DUCTWORK AND FITTINGS, CIRCULAR (No plastic ductwork shall be used without prior written agreement of the Contractor)

- Standard: To HVCA DW/154.

- Environmental conditions for plastics ductwork: As drawings.
- Material: As drawings.
- Regulating dampers: As drawings.
- Flexible joint connections: Fit on fan inlets and outlets and at building expansion joints.
- Hangers and supports
 - Strength requirements: To BS EN 12236.
- Access openings: As required.

550 SHEET METAL DUCTWORK AND FITTINGS, CIRCULAR

Standard components shall be used wherever practical. Circular ductwork supports shall be as Figures 65 (drop rod studding only) or 66(DW/144).

- Standards: To HVCA DW/144, BS EN 1506 and BS EN 12237.
- Air leakage testing: As classification requirement.
- Special installations: Not applicable.
- Material: Suitable for system and as drawings.
- Construction: Spirally wound.
- Regulating dampers:
 - Balancing type: Suitable for system and as drawings.
 - Operation: Suitable for system.
 - Material: Suitable for system.
- Flexible joint connections: Fit on fan inlets and outlets and at building expansion joints.
- Hangers and supports
 - Strength requirements: To BS EN 12236.
- Access openings:
 - Function:
 - Inspection;
 - Cleaning; and
 - Maintenance.
 - Sizes: As DW 144 and Part U10.

560 SHEET METAL DUCTWORK AND FITTINGS, RECTANGULAR

Any duct with an aspect ratio greater than 4:1 shall be supplied with a central splitter. For all slide-on flange systems (Mezz or similar) with bolted corners, joints on all systems to be further secured with intermediary fastenings to the Manufacturer's recommendations. Only full girth stiffeners shall be used. Dimpling, self-tapping screws and piercing screws shall not be used as fasteners on ductwork. Turning vanes shall be double skinned as (DW/144) and attached to ductwork using guide rails as indicated in DW/144. Access doors are required in accordance with HVCA guide TR/19 Tables 2 and 3.

The ductwork Sub-contractor may use radius bends as Figure 29 (DW/144) as an alternative, enabling turning vanes to be omitted.

- Standards: To HVCA DW/144 and BS EN 1505.
- Air leakage testing: As classification requirement.
- Special installations: Not applicable.
- Material: Suitable for system and as drawing.
- Regulating dampers:
 - Balancing type: Suitable for system and as drawing.
 - Operation: Suitable for system.

- Material: Suitable for system.
- Flexible joint connections: Fit on fan inlets and outlets and at building expansion joints.
- Hangers and supports
 - Strength requirements: To BS EN 12236.
- Access openings:
 - Function:
 - Inspection;
 - Cleaning; and
 - Maintenance.
 - Sizes: As DW 144 and Part U10.

EXECUTION

The Sub-contractor shall ensure all works carried out shall be done in a safe manner and comply with Health and Safety Regulations. This shall include clean and tidy working and working in confined spaces.

610 GENERAL

- Cut edges on ductwork, flanges and supports: Smooth and burr free.

630 INSTALLATION OF PLASTICS DUCTWORK

- Standard: To HVCA DW/154.
 - Other requirements: Generally no plastic ductwork shall be used.
- Installing flexible joint connections: Minimize pressure drop.

640 INSTALLATION OF SHEET METAL DUCTWORK

- Standard: To HVCA DW/144.
 - Other requirements: Hangers and supports shall be generally as Table 15 of DW/144 or with manufacturer's proprietary devices with the following qualifications.
- Installing flexible joint connections: Minimize pressure drop.

650 SUPPORT OF AIR TERMINALS UNITS IN CEILING GRIDS

- Standard: To HVCA DW/144.
- Special supports: Supply and extract grille/ diffuser supports shall be as manufacturers detail.
- Position: The Sub-contractor is responsible for the co-ordination of the reflected ceiling layout.

670 DUCTWORK SUPPORT FOR VAPOUR SEAL CONTINUITY

- Method of support:

The horizontal bearers shall be steel profiled section such as Uni-strut or similar proprietary support system. The horizontal bearers shall have a galvanised finish, and plastic end-caps. A medium density Class O rubber or EDPM gasket shall be provided between the ductwork and the support bearer horizontal surface. The gasket shall not fully deform under load. The ductwork Sub-contractor shall calculate the support system

selected. Horizontal supports shall not be used as secondary supports for additional services without prior approval. Calculations shall include the additional loads imposed by the agreed additional services. Multi-tier ductwork runs shall all be supported on individual horizontal bearers with single length common support rods sized for the combined load of all ducts being supported. Multiple section drop rods shall not be accepted. Insulated ducts with vapour sealing shall be provided with a timber or composite material isolating member between ductwork and the support bearer, either horizontally (rectangular ductwork) or circumferential (circular/flat oval ductwork).

The isolating member shall be the full depth of the insulation and shall have the insulation finish/vapour seal and where applicable encasement extended without a break at least 1 duct width or diameter either side of the support channel. The isolation rubber gasket shall also be included. The ductwork Sub-contractor shall include an allowance for insulation on all faces of ductwork when setting out in horizontal and vertical planes. Supports or bearers, that interrupt or penetrate the insulation or vapour seal, shall not be accepted.

The ductwork Sub-contractor shall provide a standard sheet of support details cross referenced with the manufacturing and installation drawings. Where cantilever brackets or other special forms of support are indicated, they shall be structurally strong enough to take the load and to transfer the imposed load to the building structure. The Contractor may require design and supporting calculations for comment prior to manufacture.

690 DRAINAGE OF DUCTWORK

- Ductwork: Install to drain entrained moisture
- Joints: Lap to minimize moisture leakage.

700 TEST HOLES

- Location: In accordance with CIBSE Commissioning Code Series A and HVCA DW/144.

710 CONTROLS AND SENSING EQUIPMENT

- Install sensors and test points to suit specialist control and sensing equipment.

720 WEATHERPROOFING

- All duct work penetrations to the external shall be weathered by the main Contractor.

740 INSTALLING CONTROL EQUIPMENT

- General: Fit sensors, damper motors and other control equipment.

760 ACCESS TO DAMPERS FOR RESETTING AND MAINTENANCE

- Location: Provide access to damper mechanisms on fire dampers; smoke dampers; combined smoke and fire dampers; and volume control dampers through access doors, false ceilings etc. Where more than one fire damper is installed in a frame provide access to all fire dampers.
- Fire links: Provide access so that they can be replaced.

790 DUCTWORK CLEANLINESS & VERIFICATION

Refer to section U80 above.

915 CLEANING OF KITCHEN EXTRACT SYSTEMS

- Cleaning: In accordance with HVCA TR/19.
- Method of test: Deposit thickness test.
- Method of cleaning: As section 7 TR/19.
- Post clean verification of cleanliness report: Submit.

940 AIR LEAKAGE TESTING OF MEDIUM PRESSURE DUCTWORK

- Standard: To HVCA DW/144.
- Procedure: Carry out tests. Submit report.
- Extent: Random testing of 10% maximum of the ductwork system.
- Test pressure: To HVCA DW/144.
- Documentation: Submit calculations used to arrive at the allowable loss for the section to be tested.

950 AIR LEAKAGE TESTING OF PLANT ITEMS

- Standard: To HVCA DW/144.
- Procedure: Include in-line plant with certificate of conformity for pressure class and air leakage classification for system under test.

960 FIRE DAMPER SPARES

- Fusible links: Supply spares.
 - Quantity: 4 no full set of spares.

U81 AIR HANDLING UNITS

PRODUCTS

Packaged supply and extract air handling plants shall be provided as defined in the schedules of equipment and as indicated on the drawings, or as defined further in this specification.

The air handling unit and fan supplier shall select the internal components of the plants, such that the overall system resistance does not result in system fan power being excessive.

The Sub-contractor shall obtain from his proposed supplier calculations to demonstrate that the Building Regulation requirements for Specific Fan Power, etc are being met along with his technical submission.

All items of the AHU plant and system controls must be capable of being fully interrogated by the building management system through the independent network protocol.

310 AIR HANDLING UNITS

The supply and extract air handling plant shall in all respects comply and align with the requirements and recommendation detailed within the Health Technical Memoranda (SHTM/HTMs), in particular SHTM/HTM 2025/03-01 and 08-01, except where specifically noted within this specification.

The AHU shall be arranged so that the majority of items are under positive pressure. Any item of plant requiring a drain should be on the positive pressure side of the fan.

AHU Plants shall be of a rigid, air tight, assembly and constructed in unitary form or consist of standard modular components, assembled to ensure even airflow throughout plant with no by-passing of active components. Sealing strips shall be provided between all component parts. Factory joints shall be fully tightened and all necessary sealing strips, nuts, bolts and washers etc. being provided for site made joints. The units shall be suitable for operating against closed dampers, i.e. no flow conditions during normal and fire operation. Panels penetrated by service pipes, electrical cables etc. shall be sealed together with all joints having an air leakage integrity at design pressure which is not less than the integrity of the associated ductwork systems.

The units shall incorporate gradual change section pieces between sections to minimise pressure drops, with spacing of components to manufacturer's recommendations to ensure satisfactory operation at each stage and allow access for inspection, cleaning and maintenance. The inside surfaces shall have smooth and easy clean finishes free from structural projection. The location of fan motor, fan belts, filters etc. shall be as detailed in the schedules and on the drawings.

All modular constructed plants shall be provided with purpose made base frames. Bases shall be of sufficient height to accommodate drainage traps from dehumidifiers, humidifiers etc. All plants shall be provided with sufficient access panels/doors and viewing windows to allow maintenance and repairs to be carried out. Coils used in air-handling units shall be rated in accordance with EN 1216. On larger plants, split/multiple coils shall be used.

Construction shall be such as to withstand maximum fan static pressure without deformation and with panel deflection of not more than 1/120 of maximum panel dimension under operating conditions.

Energy recovery shall be via a plate heat exchanger or thermal wheel (fitted with a purge sector), depending on the type of unit. Cleaning access shall be required to both sides of any energy-recovery device.

Where units incorporate humidifying plant, recuperators or cooling coils, the internal surfaces of the units liable to be affected by any free water produced shall be protected by anti-corrosion paint (white) or a similar finish. Such units shall have adequate drain trays to collect water; the drain trays shall be extended, or other means of collection shall be provided to ensure the removal of any water deposited or condensed in adjacent sections.

Trays collecting cooled water shall be insulated to prevent condensation on the outer surface. All the surfaces/features shall be suitable to withstand regular cleaning with a water solution containing 5ppm chlorine, such as 316 stainless steel. Internal sloping surfaces for humidifier and cooling coil sections to fall to drain. All drains shall be provided with glass U-traps suitable to withstand twice the negative/positive pressure produced by the fan and have a screwed access for cleaning and filling as indicated in TM13 (Minimising the risk of Legionnaire's disease) and as further defined in Department of Health Guidance Notes. Certified type test performance certificates shall be issued on completion of plant testing for fans, coils, filters and electric motors etc. Fire rating type test certificates shall be provided for filters. Individual pressure testing certificates shall be provided for coils. Specific fan performance curves shall be provided and these are to relate to the unit ESP with clean filters.

All wiring from fans is to be taken through the unit casing and a 2 metre tail left for connecting to inverters supplied by the controls specialist

Viewing ports and internal illumination shall be fitted to facilitate routine inspection of the AHU. Viewing ports should be at a convenient height so that temporary ladders are not required. Internal illumination should be provided by fittings to at least IP55 rating. Fittings shall be positioned so that they provide both illumination for inspection and task lighting. All of the lights in a unit shall be operated by a single switch.

Space for the future installation of impregnated carbon filters shall be provided in all supply AHUs due to the Hospital site being in the same district as the Scottish Water sewerage works. The type of carbon filters and hence space allowance shall also be capable of dealing with intermittent smells from the helicopter landing pad. Space shall also be included for upgrading the G4 panel pre-filters to F7 grade when the carbon filters are fitted.

The AHU's manufacture shall allow for the pressure drop caused by the carbon filters and F7 pre-filter in their calculations.

- Standard: To BS EN 13053.
- Sub-contractor to provide technical submissions for review. These are to include workshop drawings.
- Construction: Double skin.

320 AIR CONTROL DAMPERS

Motorised low leakage shut off dampers shall be located immediately behind the intake and discharge of each supply and extract system respectively. They shall be of the opposed blade type, opening through a full 90° and must close automatically in the event of power failure or plant shutdown to prevent any reversal of the system airflow.

A manually operated isolating damper should be installed between the main AHU and its distribution system to enable the unit to be isolated when cleaning is in progress.

- Function: Shut off.
 - Damper position: Dampers are to be rigid, with square connections fitted with end and edge seals of a flexible material and with minimal play in linkages. The leakage on shut-off should be less than 2%.
- Damper control: Motorized.
- Type: Multi-blade damper, opposed blade.
- Material: Manufacturer's standard.
- Ancillaries Locking device and Position indicator.

330 FILTERS

Filters shall be securely housed and sealed in well-fitting frames that minimise air by pass.

Mounting frames should be designed so that the air flow pushes the filter into its housing to help minimise air bypass. Mounting frames shall be capable of being withdrawn so that the filter can be changed without having to reach into the unit.

Neither the filter media, nor any material used in the construction of the filters, should be capable of sustaining combustion

All filters sections should be provided with direct reading dial type gauges marked with clean and dirty sectors to visually show filter status.

A complete spare set of filters shall be provided at handover. Filter grades to be as schedule.

Refer to section U83.

340 HEAT RECOVERY

Heat recovery shall be provided to air handling units and be of the type as indicated on the schedules.

Refer to section U85.

350 HUMIDIFIERS

Packaged steam humidifiers shall be provided to air handling units as indicated on the schedules.

Space shall be included within Operating Theatre air handling units for the provision of humidification in the future.

Refer to section U86.

360 PREHEATERS

Duties as schedule.

Frost coils shall be plain tube without fins, where practical. Where this is not practical coils with fins at 6mm spacing shall be used.

Refer to section U84.

370 COOLING COILS

Duties as schedule.

Refer to section U84.

380 REHEATER

Duties as schedule.

Refer to Section U84.

390 FANS

Fans shall be selected to limit the total system (supply and extract fans) specific fan power, as described in the 'Non-Domestic Heating, Cooling and Ventilation Compliance Guide – Section 10. External system resistances for air handling units and fans are given in the schedule.

Fans shall be centrifugal fans with backward curved aerofoil blades, and give an efficiency of not less than 78%.

Fans shall be positioned to 'blow through' the central plant so that the cooling coil and humidifier drains shall be under positive pressure.

Where a centrifugal fan is located with an open intake, the clear distance between the suction opening and the nearest wall should be not less than half the diameter of the inlet. If two fans with free inlets are positioned within the same chamber, their adjacent suction openings should be at least 1 diameter apart.

Fan/s and drive/s shall be provided with mounting frames and isolation mountings.

Motors shall be located externally. On externally driven fans, drive connection or belts shall be provided with airtight seals to prevent leakage. Externally driven fans shall have suitable anti-vibration mountings and frame with flexible connections to the fan sections of the unit. Fan-drive trains, whether supply or extract, should be easily visible without the need to remove access covers.

Fan drives shall be protected by a mesh guard.

All fans shall be controlled by inverter speed control drives supplied by the controls specialist.

Fans shall be capable of being direct start with fixed speed and manual operation in the event of a computer control system failure or software fault.

Particularly attention shall be given to critical care systems serving operating suites, high dependency care units of any type, isolation facilities, laboratories and pharmaceutical production suites in this regard.

- Performance: In accordance with BS 6583.
- Type of fan: Centrifugal.
- Motor mounting: The fan motor shall be external to the air stream.
- Blow through units: Arrange section to allow uniform velocity profile downstream.

Refer to Section U82.

405 ATTENUATOR

Where attenuators are located within the air handling unit they shall be the same cross sectional area as the AHU and have diffusion plenums as necessary.

Cleaning access should be provided at both ends of any attenuator unit.

Attenuators shall meet SHTM/HTM 2025/03-01 and this specification.

The splitters shall be fitted with 0.8mm mild steel galvanised bull nosed entries and exits to reduce pressure drop.

Normally the attenuators shall be installed with the splitters in the vertical plane. However in some circumstances, i.e. close to a vertical bend it may be necessary to install with splitters horizontally. In those circumstances the splitters shall be suitably stiffened to prevent flexing and restriction of the airway.

Refer to section U87.

FABRICATION

The Sub-contractor shall submit details of all mechanical equipment for comment and place orders in a timely fashion to ensure delivery as per programme

The Sub-contractor shall protect the AHU's from damage or interference during the works.

The AHU's shall be blanked off when delivered to site to prevent dust entering the AHU.

The Sub-contractor shall include for the services of the manufacturer's skilled services engineers to start up, test and check all the AHU's and controls. This shall include all tests to prove that all the AHU equipment is working with and responding to the clients BMS network and head end. The units when commissioned shall be "Set Up" to give maximum efficiency. The AHU's shall be witnessed by the Contractor before the plant shall be accepted from the Sub-contractor. The Sub-contractor shall allow for instruction of the

clients representative on the working of the equipment.

510 AIR HANDLING UNIT CASING CONSTRUCTION

Supply air handling plants shall be of a packaged construction with a double skin casing, complete with thermal/acoustic insulation material between the two skins. Units shall house filters, coils, fans and motorised inlet dampers, etc. Heat recovery devices shall also be incorporated as detailed in the AHU schedule.

Vibration isolation shall be provided in the form of spring anti-vibration mountings located under fan and motor bases with flexible connections from the fan discharge and the adjoining ductwork.

- Standard: To BS EN 1886.
- Details: The sub-contractor is to submit shop drawings and details of dimensions and weight for review.
- Thermal performance of casing, to form part of the technical submission.
- Acoustic insulation of casing: To form part of the technical submission.
- Fire protection: To form part of the technical submission.
- Material: To form part of the technical submission.
 - Finish: To form part of the technical submission.
- Air handling unit feet: Base to suit AHU and depth of drain and pipe fall.
- The Sub-contractor is to allow space to integrate the BMS controls into each air handling unit, to serve that respective AHU, and liaise with the BMS Specialist to integrate this.

520 AIR HANDLING UNIT ACCESS

- General: Provide access openings and covers complete, including opening devices.
- Seal: To prevent excessive air leakage.
- Seal durability: For normal maintenance operations over at least 10 years.
- Access type: Access doors/hatches as appropriate and where indicated on the drawings or called for in SHTMs, shall be provided complete with handles, locks, keys and latches to the same standards of construction and finish of unit.

Where the unit is large enough for a maintenance engineer to enter the unit, facilities for local maintenance isolation of equipment and opening the doors from the inside shall be provided.

The doors should be large enough e.g. 500mm minimum to allow easy access. Items requiring infrequent access such as attenuators may be via bolted on, lift off panels All doors/panels shall be provided with seals to prevent air leakage.

Access shall be provided as a minimum to fan chamber, dampers, filters, humidifiers and both sides of heating and cooling coils.

Internal lights and double glazed viewing windows shall be provided into fan chambers, either sides of coils, humidifier sections and where indicated on the drawings. Fittings within the unit shall be to IP55 standard and be operated from a single switch.

Additionally, the cladding shall be capable of being easily removed as is necessary to obtain access for necessary inspection and maintenance and also for removal of large items of equipment.

All necessary items shall be assembled by means of nuts, bolts, anti-vibration lock

washers or approved quick release fastenings. Access doors on isolation suite extract shall have biohazard label affixed.

EXECUTION

610 COMPONENT ASSEMBLY

- Sealing: Provide gaskets between air handling unit sections to prevent air leakage from casing.
- Site drilling of air handling unit: Not permitted.

620A ACCESS

- Access space: Position air handling units to allow space for maintenance and access.

Access for servicing shall be as manufacture recommendations and drawings.

As a minimum the Sub-contractor shall allow the width of the AHU for withdrawing the coils.

630 COIL INSTALLATION GENERALLY

- Venting and draining: Set out pipeline to and from the coils to allow venting and draining of the coils and piping.
- Support: Do not support pipeline and valves on coil connections.
- Access: Allow space to inspect and maintain the coils on both sides.

640 HOT WATER COILS INSTALLATION

- Expansion: Connect pipeline to allow free expansion of headers and tubes.

650A DRAIN LINES INSTALLATION

- All items of plant that could produce moisture must be provided with a drainage system.

The system shall comprise a drip tray, glass trap, air break and associated drainage pipework. All parts of the drainage system must comply with SHTM 03-01.

The drip-tray should be constructed of stainless steel, and be so arranged that it shall completely drain. To prevent 'pooling', it is essential that the drain connection should not have an up-stand; and that a slope of 1 in 20 in all directions should be incorporated to the drain outlet position. The tray must be completely accessible or, for smaller units, easily removable for inspection and cleaning.

Where traps are fitted to plant located outside or in unheated plant rooms trace heating shall be required. The trace heating must not raise the temperature of the water in the trap above 5°C.

660 SERVICES CONNECTIONS

- Entry points: Seal around electrical cable and pipeline entry points to prevent air leakage.

- Flexible cables: Provide between fan motor and local isolator.

670 ISOLATION OF AIR HANDLING UNITS

- Electrical connections: Provide means of isolating air handling units electrically.
- Pipe connections: Provide means of isolating pipelines to air handling units.
- Steam: Provide means of isolating steam to humidifier when access door is opened.

680 SUPPORT FOR AIR HANDLING UNITS

- Method: Purpose made raised frame, with sufficient clearance for drains and traps.

COMPLETION

During the flushing of the pipework system the AHU coil must be by passed or disconnected.

Under no circumstances shall the Sub-contractor flush through the coils

The units shall be supplied initially with one complete set of spare filters and a further set is to be offered for handover to the client at the end of the contract. This set should be carefully packed and labelled for each plant and filter type.

Alongside each filter gauge a permanent label is required with the following information:-

- Type (pre, bag, final etc.)
- Grade
- Size
- Clean PD (at full speed)
- Dirty PD (at full speed)

910 PRE-COMMISSIONING OF COILS

- Preparation:
 - Remove protective covering.
 - Check frost protection and drain if heat is not available in freezing conditions.
 - Straighten fins.
- Cleaning and chemical treatment: Use chemicals compatible with the materials in the coils.

920 AIR LEAKAGE TESTING

- Testing: In accordance with HEVAC Guide to air handling unit leakage testing.

930 TESTING

- Test location: On site before incorporation in works. (Selected factory testing/inspection may be carried out)
- Test results: Submit.

U82 FANS

PRODUCTS

All fans shall be type tested to BS.848 and a type test certificate shall be provided for each type of fan supplied. All fan duties shall be at an air density of 1.2 kg/m³ at 1.01325 bar and 15°C. Fan outlet velocities shall not exceed 10.00 m/s. Each fan shall be provided with dedicated fan performance curves, with the duty selection, absorbed power requirements, motor selection and sound power levels clearly indicated.

All fans shall be selected for low noise.

All fans shall be low energy type.

All fan's and system controls must be capable of being fully interrogated by the building management system through the independent network protocol.

All fans are to be inverter driven.

310 AXIAL FLOW FANS

Axial flow fans shall be of the long case pattern with a heavy gauge mild steel casing galvanised after fabrication, flanged and drilled at each end.

The impeller shall be of multi-blade aerofoil section constructed from die cast aluminium or heavy-duty steel. The hub design shall allow for manual adjustment of the blade pitch angle. Multi-stage axial fans shall be arranged with contra-rotating stages.

The impellers shall be directly driven through a totally enclosed motor with ball or roller bearing to suit the application. The fan motor shall be sized so that a blade pitch angle adjustment of the impeller of up to 2° shall be possible without a change of motor. During assembly of each fan the fan impeller shall be statically balanced to a level of 4.5 mm/s RMS at the fan feet. All bearing lubrication shall be extended to the outside of the casing. Axial fans shall be complete with anti-vibration mounts, flexible connections and matching flanges for duct connection and bellmouths and guards where fans are in free air. Motor terminal boxes shall be external to the casing and provide protection to IP55 as defined in BSEN.60529.

- Performance: To BS 848-1.
- Sub-contractor to provide technical proposals for review.
- Mechanical safety: To BS 848-5.
- Electrical safety: To BS EN 60335-2-80.
- Dimensions: To BS 848-4.
- Operating conditions:
 - Environment: Sewerage works nearby.
 - Air density: 1.20 kg/m³.
- Operation: As schedule and drawings.
- Inspection doors: Fit airtight inspection doors giving access to drive motors and other components requiring regular servicing and maintenance.
- Motor and drive: Match fan.
- Material:
 - Casing: Manufacturer's standard. Sub-contractor to submit proposals.

- Impeller: Manufacturer's standard.
- Anti-vibration mountings: Manufacturer's standard. Sub-contractor to submit proposals.
- Flexible duct connections: Manufacturer's standard. Sub-contractor to submit proposals.
- Accessories: As schedule and drawings.

320 CENTRIFUGAL FANS

Fan units shall be installed as detailed on drawings and fan schedules. External fans shall be weatherproofed and suitable for conditions.

The assembly is dynamically balanced to DIN ISO 1940. Motors shall be constructed from aluminium and be suitable for speed control.

Fans shall be suitable for horizontal through to vertical shaft operation. Supplied IP55, with removable drain plugs.

Sealed for life bearings lubricated with wide temperature range grease. Motors shall be fitted with thermostat overheat protection as standard. Three phase motors shall be suitable for inverter speed control down to 20% of full speed where specified.

Fans shall be fully cased, complete with an externally mounted pre-wired electrical terminal box. Casings shall be from sheet steel with integral pre-drilled inlet flanges.

Casings shall have a galvanised finish to provide a high corrosion resistance

- Performance: To BS 848-1.
- Sub-contractor to provide technical proposals for review.
- Mechanical safety: To BS 848-5.
- Electrical safety: To BS EN 60335-2-80.
- Dimensions: To BS 848-4.
- Operating conditions:
 - Environment: Sewerage works nearby.
 - Air density: 1.20 kg/m³.
- Operation: As Fan schedule.
- Motor and drive: Match fan.
- Casing: Manufacturer's standard. Sub-contractor to submit proposals.
- Inspection doors: Fit airtight doors in scroll and cover.
- Mounting: As Fan schedule and drawings.
- Material Galvanized sheet steel.
- Anti-vibration mountings: Manufacturer's standard. Sub-contractor to submit proposals.
- Flexible duct connections: Manufacturer's standard. Sub-contractor to submit proposals.
- Accessories: As Fan schedule.

350 ROOF MOUNTED FANS

The roof mounted extract/supply fans shall be located in the positions indicated on the drawings and in accordance with the relevant fan schedule. It shall be a low profile cowl manufactured in flame retardant GRP.

The roof fan shall suit the roof profile.

The fan shall be supplied complete with backdraught shutters, bird guard, purlin box curb,

hand guard, specific details of the curb and purlin shall be confirmed by the main Sub-contractor.

The Sub-contractor shall make due allowance for supporting the fan via the provision of purpose made trimmers between purlin. The trimmers shall be sized to adequately support the weight of the fans.

The fan shall be supplied with all the control interfaces to integrate with the clients BMS system.

- Performance: To BS 848-1.
 - Inlet and outlet arrangement: Sub-contractor to provide technical proposals for review.
- Sub-contractor to provide technical proposals for review.
- Mechanical safety: To BS 848-5.
- Electrical safety: To BS EN 60335-2-80.
- Dimensions: To BS 848-4.
- Operating conditions:
 - Environment: Sewerage works nearby.
 - Air density: 1.20 kg/m³.
- Operation: As Fan schedule and drawings.
- Motor and drive: Match fan.
- Anti-vibration mountings: Manufacturer's standard. Sub-contractor to submit proposals.
- Flexible duct connections: Required.
- Flexible electrical connection: Fans electrical power shall be rated for outdoor use.
- Accessories: As Fan schedule.

355 SMOKE EXTRACT FANS.

Fans shall be the bifurcated type are indicated or required, the motor shall be outside the airstream. Motors may be placed between the two halves of the casing using ambient air for motor cooling. Where hot gases, vapours or corrosive fumes are being handled, the motor bearings shall be suitable for operation at the temperatures resulting for the processes involved.

Fans shall be specially constructed for the temperature and the running duration specified during Fire/smoke condition.

- Standard: To BS EN 12101-3.
- Sub-contractor to provide technical proposals for review.
- Electrical safety: To BS EN 60335-2-80.
- Accessories:
 - Flexible connections: Required.
 - Vibration isolators: Manufacturer's standard. Sub-contractor to submit proposals.
- Control: As schedule.
- Starting device: As schedule.

360 TOILET EXTRACT FANS

Dirty extract systems shall be provided with dedicated extract fans. The fans shall be arranged for duplicate operation in a run and stand-by configuration.

The fans shall be of the centrifugal type with forward curved blades. The impellers shall be

belt driven.

Each fan shall have its own dedicated motor and drive assembly mounted on a common base frame with spring anti-vibration mounts between the frame and the unit case/framework.

The fans shall be arranged for auto changeover achieved via the BMS. On failure of the duty fan the stand-by shall start and run. The changeover shall also include the automatic activation of backdraught dampers. The fan enclosure shall be configured to allow continuous operation of the stand-by fan while the failed unit is removed for repair or replacement. The fan and motor shall be removed as a common assembly.

The fans shall be housed in a common heavy gauge aluminium casing arranged for ducted inlet and outlets.

The units shall be provided with airflow and failure monitors suitable for interfacing with the BMS. Auto changeover shall be undertaken by the BMS.

- Performance: To BS 848-1.
 - Inlet and outlet arrangement: As drawings.
- Manufacturer: Sub-contractor to provide technical proposals.
 - Product reference: Sub-contractor to provide technical proposals.
- Sub-contractor to provide technical proposals for review.
- Electrical safety: To BS EN 60335-2-80.
- Operation: As schedule
- Electrical supply type: As schedule.
- Accessories:
 - Access panel: Removable panel
 - Controls: Speed controller to match fan, refer to BMS for further details.
 - Silencer.
 - Backdraught damper.
 - Anti-vibration mount.
 - Guards.

370 CONSTRUCTION AND HANDLING

- Casings: Rigid, so there is no drumming under operating conditions.
- Lifting: Provide lifting eyebolts or similar facilities on fans or sections heavier than 20 kg.

EXECUTION

610 INSTALLATION

- Fixing: Use fixing points provided. Do not strain the fan structure when bolts are tightened.
- Orientation: Mount impeller shaft horizontally.
- Alignment: Install fan to allow optimum air flow path.

U83 AIR FILTRATION

PRODUCTS

Filters may be provided in separate plant section of the air handling unit or, if specified, as part of a common section. Filter banks shall be provided with mounting frames to suit standard commercially available filter cells, arranged for side or front withdrawal as per schedules.

Air filter shall be constructed shall not be capable of supporting combustion.

Gauges shall be provided across each filter. Tees and branch tubing should be fitted so that the controls specialist to fit a separate dirty filter warning pressure switch.

All filters shall have a Filter dirty alarm to the BMS.

Alongside each filter gauge a permanent label is required with the following information:-

- Type (pre, bag, final etc.)
- Grade
- Size
- Clean PD (at full speed)
- Dirty PD (at full speed)

One complete spare set of filter media for each plant shall be provided at handover, being carefully packed for storage and labelled for respective plant and filter types.

The Sub-contractor shall supply and install services and equipment to perform as per specification. The Sub-contractor shall submit details of all mechanical equipment for comment and place orders in a timely fashion to ensure delivery as per programme.

Where a particular manufacture is specified, the Sub-contractor shall include for that manufacturer.

Where considered appropriate, provide for equivalent standard alternatives to be offered for consideration.

This must be done in a timely manner and the Sub-contractor shall provide all details including but not limited to.

- Detailed description
- Cost comparison
- Technical comparison
- References to standards

310 PRIMARY FILTERS

Filter media shall be manufactured from 100% recycled materials. Filter media shall be a cotton and synthetic blend, lofted to a uniform depth, and formed into a uniform radial pleats.

A welded wire grid, treated for corrosion resistance, shall be bonded to the downstream side of the media to maintain the radial pleat and prevent media oscillation.

An enclosing frame, of biodegradable board shall provide a rigid and durable enclosure.

The frame shall be bonded to the media to prevent air bypass.

The manufacturer shall provide evidence of facility certification to ISO standard.

- Performance: To BS EN 779.
- Filter type: Sub-contractor to submit proposals.
- Manufacturer: Sub-contractor to submit proposals.
 - Product reference: Sub-contractor to submit proposals.
- Duty:
 - Air flow rate: Sub-contractor to submit proposals.
 - Air velocity: Sub-contractor to submit proposals.
 - Initial filter pressure drop: Sub-contractor to submit proposals.
 - Final filter pressure drop: 150 Pa.
 - Filter class: As schedules.
 - Filter height, width and limiting depth: As schedule and drawings.
 - Conditions: Sewerage works nearby.
- Flammability: Non-flammable for duration of recommended working life.
- Casing: Manufacturer's standard.
- Access: As specification.
- Filter mounting frames: Purpose made, rigid, with building-in ties where filter is mounted in walls or partitions.
- Allow for future upgrade to grade F7 bag filter when carbon filter is fitted.

320 SECONDARY FILTERS

Bag or extended surface type filters shall be provided to the required grade or better as specified, in the Equipment Schedules with maximum air velocity at face not exceeding 2.5 m/s. Filter media shall be manufactured from 100% recycled media.

Filters shall be fully self-supporting without external ties or stiffening frames. Filters shall inflate fully, shall not sag or flutter, nor have effective medium area reduced by obstruction due to contact with other filter faces or housing surfaces when operating between 60% and 110% of design air volume for constant volume systems or between the specified minimum and maximum air volume rates for multi-speed systems. Bag shall be short or normal length as noted in the Schedule of design criteria.

- Performance: To BS EN 779.
- Filter type: Bag.
- Manufacturer: Sub-contractor to submit proposals.
 - Product reference: Sub-contractor to submit proposals.
- Duty:
 - Air flow rate: Sub-contractor to submit proposals.
 - Air velocity: Sub-contractor to submit proposals.
 - Initial filter pressure drop: Sub-contractor to submit proposals.
 - Final filter pressure drop: 250 Pa.
 - Filter class: Sub-contractor to submit proposals.
 - Filter height, width and limiting depth: Sub-contractor to submit proposals.

- Flammability: Non-flammable for duration of recommended working life.
- Casing: Rigid.
- Access: Sub-contractor to submit proposals.
- Filter mounting frames: Purpose made, rigid, with building-in ties where filter is mounted in walls or partitions.
 - Material: Sub-contractor to submit proposals.

330 HIGH EFFICIENCY PARTICLE ARRESTOR (HEPA) FILTERS

High efficiency particulate air filters (HEPA/absolute) shall remove virtually all particles from air.

HEPA filters shall be H14 (EU 14) (unless otherwise Specified) with an efficiency of 99.995% @ MPPS.

HEPA filters shall be of the replaceable panel type with leak proof seals. They shall be installed in a manner that permits on site validation of the filter and its housing. This shall involve the release of a Dispersed Oil Particle (DOP) challenge smoke through an injection point upstream of the filter and a measurement of the DOP penetration across the downstream face.

A photometer shall be used to detect leaks.

The Method of testing/Validation with DOP shall be as set out in HTM 03-01.

Filter housing and seal (generally Housing shall be Electro zinc plated steel painted white RAL 9010, seal shall be Silicone or Polyurethane gel) shall be suitable for application.

- Standard: To BS EN 1822.
- Manufacturer: Sub-contractor to submit proposals.
 - Product reference: Sub-contractor to submit proposals.
- Use of conditioned space: Sub-contractor to submit proposals.
- Duty:
 - Maximum air flow rate: Sub-contractor to submit proposals.
 - Air velocity: Sub-contractor to submit proposals.
 - Filter height, width and limiting depth: Sub-contractor to submit proposals.
- Filter media: HEPA filter media - Group H.
- Filter class: H14.
- Filter casing: Provide with gasket fitted to casing.
- Filter material: As above.
- Flammability: Non-flammable for duration of recommended working life.
- Access: Access shall be provided for filter change and DOP test.
- Filter frame material: To suit application, as schedule.

350A IMPREGNATED CARBON FILTERS (INFORMATION FOR SPACE ALLOCATION ONLY)

Due to the Hospital site being in the same district as the Scottish water Sewerage works it is considered that large amounts of natural ventilation is not a practical solution.

The Sub-contractor shall allow for a specialist consultant to test the air and advise on the type of impregnated carbon to be utilised.

Carbon filters shall remove gases and vapours from the air stream and are graded

according to the range of substances they can remove.

Carbon filters shall be impregnated carbon suitable for the atmosphere on the site.

The carbon used shall have the correct dwell time for the conditions. This shall include the sewage works and the helicopter exhaust.

All kitchen extract fans shall also be provided with carbon filters.

The Sub-contractor's specialist shall also select filters for these systems.

- Manufacturer: Sub-contractor to submit proposals.
 - Product reference: Sub-contractor to submit proposals.
- Duty:
 - Air flow rate: Sub-contractor to submit proposals.
 - Air velocity: Sub-contractor to submit proposals.
 - Initial filter pressure drop: Sub-contractor to submit proposals.
- General: Provide absorbent bed filled with uniform thickness of activated carbon granules constructed to prevent settlement. Provide bonded carbon cells to prevent pinholing.
- Media type: Sub-contractor to submit proposals.
- Casing: Provide casing with removable panels.
- Casing material: To suit application, as schedule.

370 EDGE SEALS

- Function: Prevent air by-passing filters. Seals must remain effective after removal and replacement of cells.

380 PRESSURE GAUGES

Each filter shall have a Filter dirty alarm Filter status and Filter dirty alarm. This shall be compatible with the client BMS system:

- Type: Dial.
- Manufacturer: Sub-contractor to provide technical proposals.
 - Product reference: Sub-contractor to provide technical proposals.
- Gauge markings: Positions equivalent to 'Filter Dirty' and 'Filter Clean' conditions.
- Pressure differential switch: Provide for visual or audio warning of 'Filter Blocked Condition'.

390 TERMINAL FILTER HOUSINGS

- Terminal filter housing shall be easy to maintain, clean housing, able to accept a range of standard diffusers and grilles. The diffuser and colour shall match the other supply and extract diffusers.

Before any HEPA filters are installed the ductwork system shall be suitably clean.

The terminal housings shall have:

Polyester power coat finish
Limited travel filter clamps

DOP/Pd sample port
Installation hanging brackets
Fully welded flange
Top or side circular inlet

Damaged filters must not be install in the system.

- Filters housed: HEPA and ULPA.
- Housing seals: Gaskets between holding frames on banks of filters. Seal filters into steel casing.

395 FILTER SAFE-CHANGE UNITS

Where indicated on the drawings supply and install safe change housings complete with all pre and main filters. All housings to be manufactured from seam welded carbon steel with 2 pack epoxy coat finish.

Each filter assembly shall have the following features:-

- Inlet and outlet ductwork connections and support feet.
- Inlet and outlet tight shut off dampers.

Tight shut off dampers shall have seals to KTA 3601 or DIN 25414 (maximum leakage 0.01m³/hr x m² with a pressure differential of 2000Pa). The dampers shall be pressure tight to 5000Pa. The damper mechanism shall be designed such that after closure no energy is required to keep the damper in a closed position. The case and blades of the unit shall be constructed of sheet stainless steel to BS 1449 – Grade 304 – S11 Finish 2B. Bearing assemblies shall be stainless steel or brass. Damper blade sealed shall be neoprene foam rubber material, temperature resistant up to 80°C.

- Manometer points across each filter housing with manometer fitted across the hepa filter. Tappings to be configured to allow for BEMS monitoring of hepa filter condition. Manometer to be mounted on the assembly framework.
- 2 No. stainless steel cam bars for filter location.
- Aerosol sampling point in bottom spigot.
- All necessary safe change bag and retaining ring sets.
- All filter assemblies shall be factory pressure tested to a pressure of 2500Pa for minimum 1 hour and a test certificate provided.
- Leak test devices to DIN 1946 shall also be provided to allow maintenance staff to ensure replacement filters are properly seated prior to operation.

Each unit shall have:

- Minipleat high capacity absolute filters, 610 x 610 x 292mm deep with MDF case, efficiency to BS EN 1822 grade H14, 99.995%. All filters throughout the development shall be a common grade.

- Hardened case pre-filters 610 x 610 x 60mm to BN 779 grade G7.
- Upon completion of installation, a site validation test shall be carried out to achieve a maximum of 0.005% penetration and certificate provided.

EXECUTION

610 INSTALLING FILTER FRAMES

- Fixing: Securely fasten frames to ductwork walls.
- Gaps around the frames: Seal with mastic sealant.

620 INSTALLING FILTERS

- Mounting: Clamp securely against sealing gasket to prevent leaks.

630 INSTALLING PRESSURE GAUGES

- General: Fix external to unit to allow easy observation, within 3 m of filter.

U84 HEATING AND COOLING COILS

PRODUCTS

To facilitate maintenance access, auxiliary wet batteries should be located above corridors or other non-critical areas and not above patient occupied spaces. Access doors shall meet the requirements in section U80.

310 LOW TEMPERATURE HOT WATER HEATING COILS

Hot water coils shall be installed as shown on drawings.

Tubes are arranged in a staggered pattern with respect to adjacent rows to provide maximum heat transfer efficiency.

Return bends are the full thickness and diameter of the coil tubes to provide unrestricted flow and undiminished strength. Access for cleaning must be provided to both sides of all coils and batteries.

All water batteries shall be designed to ensure equal flow through all circuits. The water flow and return connections together with the airflow direction shall be permanently marked on the casing. All coils shall be supplied complete with vents and drains. Provision shall be made for expansion of the tubes and for effective venting of the coils.

Coils shall be arranged so as to facilitate removal of the coils without draining local pipework

On large coils, multiple or split coils shall be used to ease installation, repair and maintenance operations.

Heat exchanger finned surfaces shall extend the full width of the coil casing. Coils shall be suitably protected against corrosion with due regard to the geographical location of the coil and local atmospheric conditions. Sealing devices shall be provided around the casing to prevent air by-pass

Casings shall be galvanised sheet steel with angle framing at each end drilled ready to receive the counter flanges on the connecting ductwork. Coils shall be supported so that their weight is not transmitted to ductwork and so they can be removed without disturbing adjacent ductwork. Inspection doors shall be provided on both the upstream and the downstream sides of the coils.

All coils shall be tested at the manufacturer's works or an approved testing laboratory and rated for thermal performance to BS EN 13053 and certificates provided. These tests shall also include confirmation of water pressure drops at the design flow rates. These pressure drops shall be from pipework pressure topping on the flow and return connections external to the unit.

The maximum water system pressure drop shall be 25 kPa. The maximum air pressure drop across the coil shall be 20 Pa. Any site tests that show either pressure drops above this level shall require the replacement of the coil.

Where auxiliary/ret - heater-batteries are located in false ceilings, they should be fitted

with a catch tray and leak detection alarm. The catch tray shall be installed under both the battery and the control valve assembly to protect the ceiling from leaks. The moisture sensor and alarm shall be fitted in the tray and shall alarm the clients BMS in the event of a leak.

- Performance: To BS 5141-2 and BS EN 1216.
- The Sub-contractor shall submit proposals for review.
- Materials: Solid drawn copper tubes with copper fins.
- Tube wall thickness: At least 0.7 mm.
- Fin thickness (minimum):
 - Aluminium: 0.4 mm.
 - Copper: 0.3 mm.
- Fin spacing (maximum): As schedule.
- Thermal expansion: Allow for movement.
- Casing finish: Galvanized mild steel.
- Access doors: Hinged, airtight and watertight for maintenance.
- Draining and venting: As specification.
- Water test pressure: Up to 2.1 MPa or 1.5 times the working pressure, whichever is greater.
- Packaging: Fit protection for fins before despatch.
- Protection: Fit blank flanges or caps to pipe connections after manufacture.
- Accessories: As schedule.

320 CHILLED WATER COOLING COILS

Access for cleaning must be provided to both sides of all cooling coils. The coil shall have electro tinned fins.

Coils frames and casings shall be manufactured from stainless steel.

Pipe Connections shall be screwed up to 50mm, flanged above. Maximum velocity over the coils shall be 2m/s.

The coil shall have an eliminator.

All cooling coils shall be fitted with their own independent drainage system. The system shall comprise of a stainless steel drip-tray, glass trap, air break and associated drainage pipework.

The drip tray shall be arranged to drain completely and prevent pooling.

The drain connection shall not have an up-stand. A slope of 1 in 20 in all directions shall be incorporated to the drain outlet position.

Where coils are greater than one metre high intermediate drain trays shall be provided.

The AHU base shall be high enough to accommodate the trap and pipe work fall.

The tray shall be completely accessible or for inspection and cleaning.

Each drip-tray should be provided with its own drain trap. The drain trap should be of the clear (borosilicate) glass type.

The trap should have a means for filling and should incorporate couplings to facilitate removal for cleaning. It should be located in an easily visible position where it shall not be subject to casual knocks. The pipework connecting it to the drainage tray should have a continuous fall of not less than 1 in 20.

Water from each trap must discharge via a clear air gap of at least 15 mm above the unrestricted spill-over level of either an open tundish connected to a drainage stack via a second trap, or a floor gully. A support should be provided to ensure that the air gap cannot be reduced. Drainage pipework shall be copper.

A baffle or similar device must be provided in the drip-tray to prevent air bypassing the coil, and the tray should be large enough to capture the moisture from the eliminator, bends and headers.

The cooling-coil control valve should close upon selection of low speed, system shut-down, low airflow or fan failure.

The maximum water pressure drops across the coils shall be 30 kPa. The maximum air pressure drops across the coils shall be 80 Pa. Any site tests that show pressures above either of these levels shall require the replacement of the coil.

- Performance: To BS 5141-1 and BS EN 1216.
 - Duty: Refer to drawings and schedules.
 - Materials: Solid drawn copper tubes with copper fins, all electro-tinned.
 - Tube wall thickness: At least 0.7 mm.
 - Fin thickness (minimum):
 - Aluminium: 0.4 mm.
 - Copper: 0.3 mm.
 - Casing:
 - Finish: Stainless steel
 - Return bends: Provide removable covers. Lag and vapour seal the bends.
 - Eliminator plates: Install downstream of all coils.
 - Draining and venting: As specification.
 - Access doors: Hinged, airtight and watertight for maintenance.
 - Water test pressure: Up to 2.1 MPa or 1.5 times the working pressure, whichever is greater.
 - Packaging: Fit protection for fins before despatch.
 - Protection: Fit blank flanges or caps to pipe connections after manufacture.
 - Accessories As schedule.
- Airflow: Evenly distributed over face area of coil (to be verified at commissioning)
 - Air velocity: Ensure it is below level at which moisture carryover occurs.

340 ELECTRIC HEATER BATTERIES

Generally electric heating batteries are to be avoided. Their use should be restricted to low power use (for example trimming control).

Where used, electric heaters shall be provided with high temperature cut out protection with automatic reset.

The Sub-contractor is to provide technical submissions for review.

- Casing material: Aluminium.
 - Casing finish: Natural.
- Access doors: Hinged, airtight and watertight for maintenance.
- Heating elements: Mount on removable terminal plate.
 - Type: As schedule.
- Terminal boxes: Welded steel.
- Safety cut-out switch: Automatic reset, wired in series or via contactor with heating elements.
- Controls:
 - Fan interlock to prevent heater operating without fan running.
 - Run-on timer to allow airflow to cool heater before switching off fan.
- Air flow detector switch: Wired in series with other safety devices.
 - Type: Differential pressure.
- Accessories: Heater batteries to be thyristor controlled.

EXECUTION

During the flushing of the pipework system all coils must be by passed or disconnected. Under no circumstances shall the Sub-contractor flush through the coils

610 INSTALLATION

- Equipment, controls and instruments positioned next to heating coils: Protect from thermal radiation.
- Fixings: Support coils independently of ductwork.

620 ELIMINATOR PLATES INSTALLATION

- General: Fit to allow removal from coil casing.

630 DRAIN TRAP INSTALLATION

- Air break: Locate between trap outlet and drainage system.
- Traps under suction: Install the outlet below the inlet by a depth equivalent to at least one and a half times working pressure.
- Traps under positive pressure: Install inlet and outlet at same level.

U85 HEAT RECOVERY

Thermal wheel heat exchangers shall be incorporated within extract air plants handling uncontaminated air (non hygro-scopic type). These plants shall also include main dirty air extract plants. The heat exchangers shall transfer heat energy within the extract air to a pumped circulation water heat recovery system. Heat exchangers within the fresh air plants shall utilise the recovered heat to pre-heat incoming fresh air.

Where the use of thermal wheel heat recovery units have been found to be inappropriate plate recuperator systems are to be employed.

The heat recovery systems shall be configured to operate at all times when useful energy can be recovered and used by the various air plants.

PRODUCTS

310 PLATE RECUPERATORS

- The Sub-contractor is to submit proposals for review based upon details shown on drawings, schematics and schedules.
- Efficiency: minimum 55%.
- Heat transfer plates: Manufacturer's standard for application. Sub-contractor to provide technical submission.
- Coating: Manufacturer's standard for application.
- Access doors: Hinged, airtight and watertight for maintenance.
- Accessories:
 - Face and bypass dampers;

330 THERMAL WHEELS

- The Sub-contractor is to submit proposals for review based upon details shown on drawings, schematics and schedules.
- Efficiency: minimum 65%.
- Rotor: Non-hygroscopic.
- Access doors: Hinged, airtight and watertight for maintenance.
- Accessories:
 - Adjustable purging sector;
 - By-pass damper;
 - Matching ductwork flanges;
 - Return air damper; and
 - Speed controller.

EXECUTION

630 INSTALLING DRAIN TRAPS

- Air break: Locate between trap outlet and drainage system.
- Traps under suction: Install the outlet below the inlet by a depth equivalent to at least one and a half times working pressure.
- Traps under positive pressure: Install inlet and outlet at same level.

U86 AIR TREATMENT

Full humidity control, including humidification and dehumidification, shall be provided only in critical air-conditioned clinical areas such as the Pharmacy Aseptic Suite or wherever close control of humidity is required for the successful operation of sensitive equipment, e.g. computers.

Only steam injection manifold-type humidifiers are considered suitable for use in health building air-conditioning systems. Water humidifiers of any other type shall not be used.

The local steam generator must be fed with potable quality water. Should the humidifier be unused for a period exceeding 48 hours, it must be capable of automatically draining its water content, including that contained in the supply pipework, right back to the running main and leave itself empty. The humidifier shall have overriding controls separate from the normal plant humidistat.

Their purpose is to prevent excessive condensation in the conditioned space when starting up. A time delay shall be incorporated into the humidifier control system such that the humidifier does not start until 30 minutes after the ventilation/plant start-up. In addition, a high limit humidistat shall be installed to limit the output of the humidifier so that the saturation in the duct does not exceed 70%.

The humidifier control system should ensure that the humidifier is switched off when the fan is not running.

- Type: Steam from self contained boiler.
- Water quality: As schedule.

PRODUCTS

310A STEAM HUMIDIFIERS

- Manufacturer: The Sub-contractor is to submit proposals for review.
 - Electrical supply type: Three phase.
- Steam source: Local Electric.
- Safety of appliance: To BS EN 60335-2-88.
- Material: Corrosion resistant.
- Access doors: Hinged airtight and watertight for maintenance.
- Safety signs: On access door, a label reading 'Isolate steam supply before opening' in letters at least 25 mm high.
- Accessories: Manufacturer's standard

EXECUTION

610 INSTALLATION

- Discharge: Install humidifiers so that air flow is uniform over cross-section of ductwork.
- Position: Do not install next to air heating coils.

620 CONDENSATE CONNECTIONS

- General: Arrange condensate lines so that back pressure does not exceed manufacturer's recommendations.

630 THERMAL EXPANSION

- General: Connect pipelines to take up thermal expansion without stressing humidifiers.

640 INSTALLING DRAIN TRAPS

- Air break: Locate between trap outlet and drainage system.
- Traps under positive pressure: Install inlet and outlet at same level.

650 FIXINGS

- General: Support humidifiers from building structure on zinc coated steel supports, independently of adjacent ductwork. Provide separate supports for components mounted outside casings.

U87 SILENCERS AND ACOUSTIC TREATMENT

PRODUCTS

The attenuators including cross talks, shall be selected and installed by the Sub-contractor. The Sub-contractor shall appoint a specialist to select these, using the noise criteria detailed elsewhere. The permissible pressure drop on cross talk attenuators is 25 Pa and 50 Pa on other attenuators. The Sub-contractor is to provide technical submissions for the silencers and acoustic treatment.

310 CIRCULAR SILENCERS

Silencers shall be installed generally as indicated on the drawings.

Silencers shall be of the size, configuration, capacity and acoustic performance required to meet the specified acoustic criteria.

All circular silencers shall be constructed with a galvanized steel casing. All casing seams and joints shall be lock formed and sealed. All fixings to the casing to be with blind rivets to eliminate leakage.

The silencer infill to be covered in ICI Melinex or similar to prevent particle migration. The membrane shall have a 25 year service life.

- Performance requirements: To BS EN ISO 7235 and BS EN ISO 11691.
- Casing: galvanised sheet steel minimum thickness 0.8mm
- Splitters: galvanised perforated sheet screen minimum thickness 0.8mm with an open area of at least 23%.
- Lining material: Inert, fire proof, inorganic and non- hygroscopic minimum density 48kg/m³.
- Markings: Show direction of air flow on silencer.

320 RECTANGULAR SILENCERS

Silencers shall be installed as indicated on the drawings.

Silencers shall be of the size, configuration, capacity and acoustic performance required to meet the specified acoustic criteria.

All Rectangular silencers shall be constructed with a galvanized steel casing. All casing seams and joints shall be lock formed and sealed. All fixings to the casing to be with blind rivets to eliminate leakage.

The silencer infill to be covered in ICI Melinex or similar to prevent particle migration. The membrane shall have a 25 year service life.

- Performance requirements: To BS EN ISO 7235 and BS EN ISO 11691.
- Casing: galvanised sheet steel minimum thickness 0.8mm
- Splitters: galvanised perforated sheet screen minimum thickness 0.8mm with an open area of at least 23%.
- Lining material: Inert, fire proof, inorganic and non- hygroscopic minimum density 48kg/m³.
- Markings: Show direction of air flow on silencer.

330 AIR TRANSFER AND CROSS TALK ATTENUATORS

Cross Talk attenuators shall be installed in the ductwork in locations shown in the plans.

The performance of the attenuators is to be such that the privacy to be maintained between adjacent spaces.

The attenuator shall control noise in particular speech via the ductwork.

The Sub-contractor shall submit calculations for examination *by the acoustic consultant*.

All cross talk silencers shall be constructed with a galvanized steel casing. All casing seams and joints shall be lock formed and sealed. All fixings to the casing to be with blind rivets to eliminate leakage.

The silencer infill to be covered in ICI Melinex or similar to prevent particle migration. The membrane shall have a 25 year service life.

- Performance requirements: To BS EN ISO 7235 and BS EN ISO 11691.
- Casing: galvanised sheet steel minimum thickness 0.8mm
- Splitters: galvanised perforated sheet screen minimum thickness 0.8mm with an open area of at least 23%.
- Lining material: Inert, fire proof, inorganic and non- hygroscopic minimum density 48kg/m³.
- Markings: Show direction of air flow on silencer.

The cross talk attenuator shall be installed / located to avoid flanking ideally places in the ductwork as it passes through the wall separating rooms.

350 ACOUSTIC INSULATION

The Sub-contractor's acoustic specialist shall examine the need for acoustic lagging. Acoustic lagging shall be provided and fitted where necessary to the outside of the ductwork to achieve an enhanced Sound Reduction Index (SRI) of ductwork and hence reduce noise break in or break out.

The lagging shall consist of mineral wool density not less than 48kg/m³ and not less than 50mm thick.

The mineral wool shall be covered with an outer skin typically lead weighed PVC material or 0.8mm thick galvanised mild steel. All joints shall be suitably sealed to maintain acoustic integrity.

The lagging shall be securely fixed to the pipework / ductwork using mechanical fixings.

- Material: Lightweight mineral wool.
- Outer covering: As specification.

EXECUTION

610 ACOUSTIC LININGS

- Access: Where personnel access is provided, protect acoustic linings to prevent damage.

U88 AIR TERMINAL DEVICES

PRODUCTS

Air terminals shall be provided as indicated on the drawings, or as defined further in this specification.

The Sub-contractor shall co-ordinate the reflected ceiling plan.

The Sub-contractor shall appoint a specialist supplier to provide the selections and schedules for the air terminal devices. The Sub-contractor's specialist shall select the grilles and diffusers using the locations and air volumes shown on the drawing. The Sub-contractor shall submit these for review.

All diffusers and grilles shall be selected for quiet operation, using the noise criteria specified.

The Sub-contractor shall provide samples of each type of air terminal device for review.

Neck velocity shall not exceed 2.5 m/s on any terminal device (diffusers/grilles etc).

310 AIR TERMINAL DEVICES, SPECIALIST UCV HOODS

The UCV shall be a Vertical-flow type system and meet all requirement of SHTM/HTM 2025/03-01 including table 6.

The return air grilles/diffusers shall be sited so as not to cause short circuiting. The Sub-contractor shall comply with SHTM/HTM 2025/03-01 to this regard.

The Sub-contractor shall ensure that each face or each corner of the theatre shall have an air path to provide good air circulation and to prevent entrainment in the clean zone. Air velocities for and over the UCV shall be as SHTM/HTM 2025/03-01 as a minimum. UCV systems shall come complete with HEPA filters. A set of new filters shall be issued to the client following commissioning of the unit.

The final filters shall be installed in a leak-proof housing in a manner that allows the terminal unit, filters and their seals to be validated. A challenge test shall be carried out during commissioning to prove the effectiveness of the complete installation. Challenge test shall be as manufactures recommendations and the Method of testing/Validation with DOP shall be as set out in HTM 2025/03-01.

The UCV shall have direct-reading pressure gauges for each final filter and a return-air filter to capture the relatively coarse particles that would otherwise significantly reduce the life of the final filter. The return air filter shall be G3 grade to BS EN 779 as a minimum.

The UCV shall not exceed NR 50. Any in line attenuation shall non-particle-shedding and fire-resistant.

Lighting for the UCV shall be as CIBSE lighting guide LG2 and BS EN 12464-1.

Operating luminaires should comply with the photometric requirements detailed in relevant sections of BS EN 60601.

The lighting level shall be even throughout and luminaries shall not adversely affect the air flow.

The functions of the canopy circulation fans shall be continuously monitored by a BMS control unit.

Additional to this the UCV system shall have

- a set-back facility that shall reduce the air supplied through the UCV terminal to a volume that equates to an amount not less than 25 air changes per hour of the operating room's gross volume whilst still leaving the supply AHU operating at full speed;
- a facility to turn off the entire system, the supply AHU and the UCV terminal (an emergency stop is not required);
- a read-out sufficiently large to be clearly visible from the operating table that shows the temperature of the air being supplied by the UCV terminal;
- a read-out sufficiently large to be clearly visible from the operating table that shows the relative humidity of the air being supplied by the UCV terminal;
- a red indicator light that shall illuminate when either the supply AHU or the UCV terminal fails; either or both are switched off or the AHU and UCV terminal are at set-back;
- an amber indicator light that shall illuminate when the UCV terminal is at set-back and the supply AHU is running;
- a green indicator light that shall illuminate when both the supply AHU and UCV terminals are operating at full speed;
- a blue indicator light that shall illuminate when the UCV terminal's HEPA-filter resistance causes the air delivered to fall below 80% of the design flow rate.
- Performance:
 - Mixed flow applications: To BS EN 12238.
 - Sound power levels: To BS EN ISO 5135.
- Performance requirement to SHTM.
- Material: Stainless steel.

325 AIR TRANSFER GRILLES

Transfer grilles shall be non-vision type and sized for a maximum face velocity of 1.5 m/s.

- Grille type: Non-vision.
- Accessories: Transfer grilles shall not be installed in a fire rated door/wall.
Transfer grilles in operating theatres shall incorporate a volume control damper to allow adjustment to room pressure

330 DIFFUSERS

Ceiling diffusers shall be installed as shown on the drawings. The diffuser shall be a square ceiling diffuser for flush mounting, comprising diffuser face with mitred perimeter border.

Louvre face diffusers shall be of the four way pattern and shall have adjustable cores to provide horizontal or vertical distribution. The air pattern shall be achieved via the use of directional blanking plates within the body of the diffuser and shall not be visible from the diffuser face. The diffuser shall be suitable for incorporation in a standard ceiling tile grid

without overlapping the tile-supporting bar. Diffusers shall be complete with a security chain between the diffuser body and the core and an earth bonding tag.

Ceiling diffusers shall be suitable for direct replacement of 600 x 600 ceiling tiles or an overall size relative to the selected neck size for fitting within a cut tile.

Branches serving individual diffusers shall be provided with a manual volume control damper supplied and fitted by the ductwork sub-contractor, in addition to the grille damper where supplied. The duct mounted volume control damper shall be located as close as possible (within 1 duct diameter) of the take-off with the main branch duct.

Where extract is required via ceiling mounted devices louver face diffusers shall be used. The diffusers shall be similar in construction and appearance to the supply diffusers.

The diffuser shall have fixed air control blades, central fixing screw with decorative cap and an opposed blade damper adjustable from the front face.

The plenum box shall be galvanised sheet metal with a rubber lip seal.

The plenum box shall have fixings for suspending the assembly from the ceiling slab.

The plenum boxes shall be suitable for side or top entry as required.

The diffuser face shall be extruded aluminium sections, natural anodised rear ancillaries in formed sheet steel, surfaces phosphate treated and stove-enamelled.

Supply and extract diffusers shall be at a distance from one another to prevent short circuiting. Supply diffusers shall be located away from one another to prevent two opposing air streams meeting and causing drafts, the individual velocities shall not be greater than 0.25 m/s.

- Performance:
 - Mixed flow applications: To BS EN 12238.
 - Sound power levels: To BS EN ISO 5135.

340 LAMINAR FLOW PANELS

Laminar flow panel diffusers shall be provided in operating theatres with a footprint that encompasses the operating site to produce a downward-displacement parallel-flow air distribution.

Diffusers, of all patterns, to operating theatres shall achieve the required velocity at the operating table position of between 0.2 and 0.3 metres per second, and achieve good air distribution throughout the remainder of the room. Particular care shall be taken to ensure that in a heating mode air discharge velocity overcomes the buoyancy of the air to achieve the required velocity at the operating table position.

The ventilation distribution arrangement must take priority over the layout of luminaires and pendants, etc.

350 TOILET SUPPLY AND EXTRACT VALVES

Extract with toilets, bathrooms and showers shall be via exhaust air disc valves. Each valve shall be constructed from sheet steel and provided with a stove-enamelled finish. The centre disc valve core shall be mounted on a threaded adjustable centre spindle complete with locking nut to provide air volume flow rate adjustment.

The centre disc assembly shall be mounted in a profiled outer ring complete with an edge seal and tamperproof sub-frame.

Generally each valve shall be installed within a cut tile. Each valve shall not require a plenum but shall be connected into a section of rigid ductwork before any flexible is used.

Each branch connecting to individual valves shall be provided with a manual volume control damper fitted as close to the upstream branch connection as possible.

360 DIFFUSERS, LINEAR

Linear diffusers shall be installed as shown on drawings.

They shall be made from aluminium extrusion, natural anodised.

Diffusers shall come complete with end caps and air control blades.

The diffusers shall have a rear mounted plenum box fitted with a side entry spigot and suspension brackets to hang the complete assembly from the ceiling.

The plenum box shall be fitted with a volume control damper adjustable from the diffuser face and be made from galvanised sheet steel.

- Performance:
 - Mixed flow applications: To BS EN 12238.
 - Sound power levels: To BS EN ISO 5135.
- Diffuser: Slot.
- Material: Aluminium.
 - Finish: Anodized.

370 DIFFUSERS, SWIRL

The swirl diffusers shall be adjustable in square or circular face plates with swirling horizontal discharge of supply air with high induction.

Diffusers shall consist of a pressed front face with radially angled air discharge sections incorporating adjustable directional air control blades.

Diffusers shall be complete with a plenum box with circular top or side entry spigots and volume control damper. The Plenum box shall be supplied with fixed hanging brackets.

The face plate shall be galvanised sheet steel with the surfaces pre-treated and powder coated white (RAL 9010).

The control blades shall be made from Polystyrol coloured black or white as Architects

specification.

The plenum box is made from galvanised sheet steel with a rubber lip seal.

The plenum box shall be galvanised sheet metal with a rubber lip seal.

The plenum box shall have fixings for suspending the assembly from the ceiling slab.

The plenum boxes shall be suitable for side or top entry.

Supply and extract diffusers shall be at a distance from one another to prevent short circuiting. Supply diffusers shall be located away from one another to prevent two opposing air streams meeting and causing drafts, the individual velocities shall not be greater than 0.25 m/s.

- Performance:
 - Mixed flow applications: To BS EN 12238.
 - Sound power levels: To BS EN ISO 5135.
- Material: Galvanized steel.
 - Finish: Epoxy resin powder/ hardener coating.

380 MEDICINEMA FLOOR DIFFUSERS

The Medicina shall be served by floor mounted displacement diffusers.

The diffusers shall be as Krantz DB-E.

390 GRILLES

Grilles shall be installed as shown on the drawings.

The grilles shall be made from extruded aluminium sections. The finish shall be as Architects RAL number. Grilles shall be selected for quiet operation.

Grilles, shall have corner mitres and rear perimeter sealing strip with profiled front blades.

Sub frames shall be used where required.

- Performance:
 - Mixed flow applications: To BS EN 12238.
 - Displacement flow applications: To BS EN 12239.
 - Sound power levels: To BS EN ISO 5135.

400 CEILING VENTING GRILLES (CVG)

Ceiling venting grilles shall be provided along the main distribution routes for medical gas and natural gas pipework.

Ceiling venting grilles shall be of similar construction and arrangement to the supply diffusers. The diffuser body only shall be provided for these items.

The minimum size of CVGs shall be 150 x 150mm.

410 PLENUM BOXES, CEILING OR WALL MOUNTED

Plenum boxes shall be made of 0.7mm Galvanised steel plenum.

Spigot construction shall be a top or side entry plenum option robustly fabricated plenums shall come complete with all necessary fixing angles for drop rod support.

- Duty: To match grille and diffuser.
- Configuration: Single plenum box or a series of plenum boxes butted together to form a continuous length.
- Construction: Sturdy and rigid with circular inlet spigots of 65 mm minimum length.
- Fixing: Incorporate means for fixing to, or suspending from, building or other construction.

EXECUTION

610 INSTALLATION

- General: Do not distort air terminal devices. Fix securely.
- Air leakage: Prevent. Seal joints with self adhesive foam strip or equivalent.
- Appearance: Finish visible edge joints neatly. Do not leave sharp edges and protruding screws.

620 FIXING CIRCULAR AND RECTANGULAR DIFFUSERS

- Method: As per manufacturers instructions and specification.

640 FIXING LINEAR AND SLOT DIFFUSERS

- Method: As per manufacturers instructions and specification.

650 FIXING FLOOR MOUNTED SWIRL DIFFUSERS

- General: Fit flush with finished floor.
- Method: As per manufacturers instructions and specification.

660 FIXING GRILLES

- Method: As per manufacturers instructions and specification.

670 OPERATION

- General: Fit so that moving parts operate correctly and removable cores can be taken out and replaced.
- High level and ceiling applications: On removable cores, provide safety wires with quick release ends.

680 BLANKING PLATES

- Location: Where needed to restrict projection of air flow from section of grille or diffuser.

APPENDIX A
SUPPORTING DOCUMENTATION

In order to carry out the design, the Sub-contractor shall require access at least to the documentation listed below.

The following information is, or shall be, available from the Contractor:-

1. Standard General Conditions and Preliminary Clauses
2. All ZBP Layout Drawings, Schematics, Specifications and Schedules
3. Nightingale Associates: Fire Strategy Drawings
4. Nightingale Associates: Building Plans
5. Nightingale Associates: Building Sections
6. Nightingale Associates: Wall Elevations
7. Nightingale Associates: Reflected ceiling plans
8. ZBP: Automatic Controls and Building Management System Specification :
ZBP-XX-XX-SP-660-401 to 406
9. ZBP: Fire Detection and Alarm Specification : ZBP-XX-XX-SP-572-214
10. ITPD Documentation and Appendices

Drawings for other specialist systems shall be developed by other Sub-contractors during the detailed design period and shall be made available by the Contractor

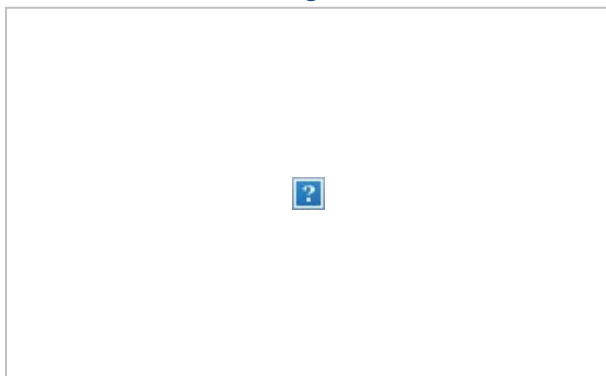
From: [STORRAR, Ian \(NHS NATIONAL SERVICES SCOTLAND\)](#)
To: [Gallacher, Alan](#); [Purdon, Colin](#)
Cc: [RANKIN, Annette \(NHS NATIONAL SERVICES SCOTLAND\)](#); [INKSTER, Teresa \(NHS GREATER GLASGOW & CLYDE\)](#)
Subject: 2019-08-08 QEUH & RCH chilled beams
Date: 08 August 2019 10:02:14
Attachments: [image003.jpg](#)

Alan, Colin

I have had another look at ZUTEC this morning and the chilled beam reference is different from that which we discussed yesterday (although that reference is in ZUTEC too).

The Parasol units have the ability for dew point control on the units as far as I can tell. For the critical/augmented control areas this may prove to be a better option than that being currently implemented.

I cannot check if the design called for this as the design info does not appear to be there



Regards

Ian

Ian Storrar BSc CEng FCIBSE FIHEEM MIET

Head of Engineering - Health Facilities Scotland

Procurement, Commissioning and Facilities

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QUEEN ELIZABETH UNIVERSITY HOSPITAL

ADULTS WARD 6A - ROOM 1

CRITICAL VENTILATION ANNUAL VERIFICATION & INSPECTION

ADULTS WARD 6A – ROOM 1



Client:	NHS Greater Glasgow & Clyde	Client Contact:	James Guthrie
Hospital:	Queen Elizabeth University Hospital	Site Address:	1345 Govan Road, Glasgow G51 4TF
Area:	Adults Ward 6A – Room 1	AHU:	122AHU05
Room Condition:	GOOD	Report No:	B0056883
Date of Test:	11 th November 2019	Date of Last Test:	Unknown
Test Engineer & Report Preparation:	Sharon McLaughlin	Signature:	
CSSL. Reviewed By:	Ian McKenzie	Signature:	
Client Reviewed By:	James Guthrie	Client Signature:	

QUEEN ELIZABETH UNIVERSITY HOSPITAL

ADULTS WARD 6A - ROOM 1

Table of Contents

1. Scope of Works
2. Definition of terms
3. Executive Summary & Observations
4. Annual Verification Checklist
5. Supply & Extract airflow rates and air change rates
6. Room Pressure Differentials, Temperature & Noise Levels
7. Typical Schematic Layout of Bedroom 1
8. Typical Schematic of Camfil Recirculation Unit
9. Test Equipment Used
10. Calibration Certificates

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ADULTS WARD 6A - ROOM 1

Section 1 – Scope of Works

Annual Inspection of Critical Ventilation Systems

To carry out a compliance and performance inspection of all critical path ventilation systems in accordance with - Heating and Ventilation Systems - SHTM – Scottish Health Technical Memorandum 03-01: Specialised Ventilation for Healthcare Premises.

Part B: Operational management & Performance Verification.

This report is for Adults Ward 6A bedroom 1 located in the Queen Elizabeth University Hospital.

The validation of the rooms was carried out to record a baseline validation record for these rooms. This validation work followed post fitting of recirculation fans (Camfil Camcleaner 400 concealed fan units) located within the ceiling of the toilet of bedroom 1 on Ward 6A. The Camcleaner consists of a F7 pre-filter (bag) and a secondary H14 HEPA filter. See report details of fan settings, air volumes, room pressures and noise levels achieved while maintaining SHTM03-01 compliance.

QUEEN ELIZABETH UNIVERSITY HOSPITAL

ADULTS WARD 6A - ROOM 1

Section 2 – Definition of terms

Assessment of compliance with Health Building Note 26 and Scottish Health Technical Memorandum 03-01.

Poor

Air volumes and hence air-change rate is less than 75% of the design; room pressure differentials do not ensure a flow from clean to less clean areas. Supply or extract air diffusers are not clean. Pressure stabilisers not clean and/or not operating correctly. Visible faults in the fabric of the suite, doors unable to close completely, general air of neglect.

Action: Urgent management action required.

Average

Air volumes and room pressure differentials approximate to the original design values. Supply air diffusers clean but extracts visibly fouled most pressure stabilisers clean and operating correctly. Minor faults in the fabric and décor of the suite.

Action: Maintenance action required.

Good

Better than average.

Action: None.

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ADULTS WARD 6A - ROOM 1

Section 3 - Executive Summary/Observations:

The evaluation of Adult's Ward 6A – Bed 1.

- 1) To make sure the noise levels in the bedroom and en suite were compliant with SHTM03-01 which are bedroom 35db(A) & en-suite 45db(A).
- 2) Noise levels and air volumes were measured to the various fan power levels on the recirculation unit in the en-suite (sped control setting level 1-6) Speed controller at setting 3 when all compliant and final values recorded within this report.

Adults Ward 6A – Room 1				
Fan Speed Setting	En-Suite dB(A) SHTM 45dB(A)	Bedroom dB(A) SHTM 35dB(A)	Air Volume l/s	*Increased scrub value for the en- suite (ACRs)
1	35.5	33.9	10	2.6
2	35.8	34.3	15	3.8
3	39.3	34.8	58	14.8
4	47.8	45.7	113	28.9
5	50.7	48.6	136	34.7
6	54.5	52.5	163	41.6

Comments: Speed 3 for the en-suite is SHTM03-01 compliant – Speed 3 is SHTM03-01 compliant for the bedroom noise levels.

RED = Final fan speed setting used

*These are the values for enhanced scrub up in the en-suite, the values noted above are an increase scrub up rate on top of the air change rate that the en-suite extract is achieving of 8.4 air changes per hour.

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ADULTS WARD 6A - ROOM 1

Section 4 – Annual Ventilation verification Checklist

		Poor		Average		Good
Compliance with HBN & SHTM						✓
Maintenance Quality						✓
No	Survey Question	Yes	No	Comments		
1	Has the annual verification of the AHU been carried out?	✓				
2	Are windows hermetically sealed?	✓				
3	Are the ceilings in the area complete and sealed?	-	-	Suspended ceiling grid		
4	Are there any significant faults in the fabric of the rooms in the suite?		✓			
5	Are room light fittings correctly sealed?	✓				
6	Are all supply and extract air terminals visibly clean?	✓				
7	Measure and record the supply and extract air flow in the principle ducts	✓		Direct Balometer reading		
8	Measure and record the air flow at all supply and extract terminals	✓				
9	Does the derived air-change rate achieve at least 75% of the design?	✓				

Section 5 – Supply & Extract Airflow Rates & Air Change Rates

Adults Ward 6A - Room 1					
Room Reference	Design Volume l/s	Recorded Air Volume l/s	Room Volume m ³	Recorded (AC/HR)	*SHTM ACRs (AC/HR)
Bedroom (Supply Chilled Beam)	40	+41	47.6	3.1	*2.5 - 3
En-Suite (Extract)	45	-33	14.1	8.4	3

Comments: * derogated ACRs for the bedroom – SHTM03-01 is 6 air change rates.

QUEEN ELIZABETH UNIVERSITY HOSPITAL

ADULTS WARD 6A - ROOM 1

Section 6 – Room Pressure Differentials, Temperature & Noise Levels

Room Pressure Differentials

Adults Ward 6A – Room 1				
Room Reference	Target Room Pressure (Pa)	Recorded Room Pressures (Pa)	Magnehelic Gauge pre reading (Pa)	Magnehelic Gauge post reading (Pa)
Bedroom to Corridor	+ve	+1.3Pa	n/a	n/a
Bedroom to En-Suite	-ve	-0.8Pa	n/a	n/a
Comments: Room pressure is as requested for room type SHTM03-01 should be 0Pa or -ve to corridor.				

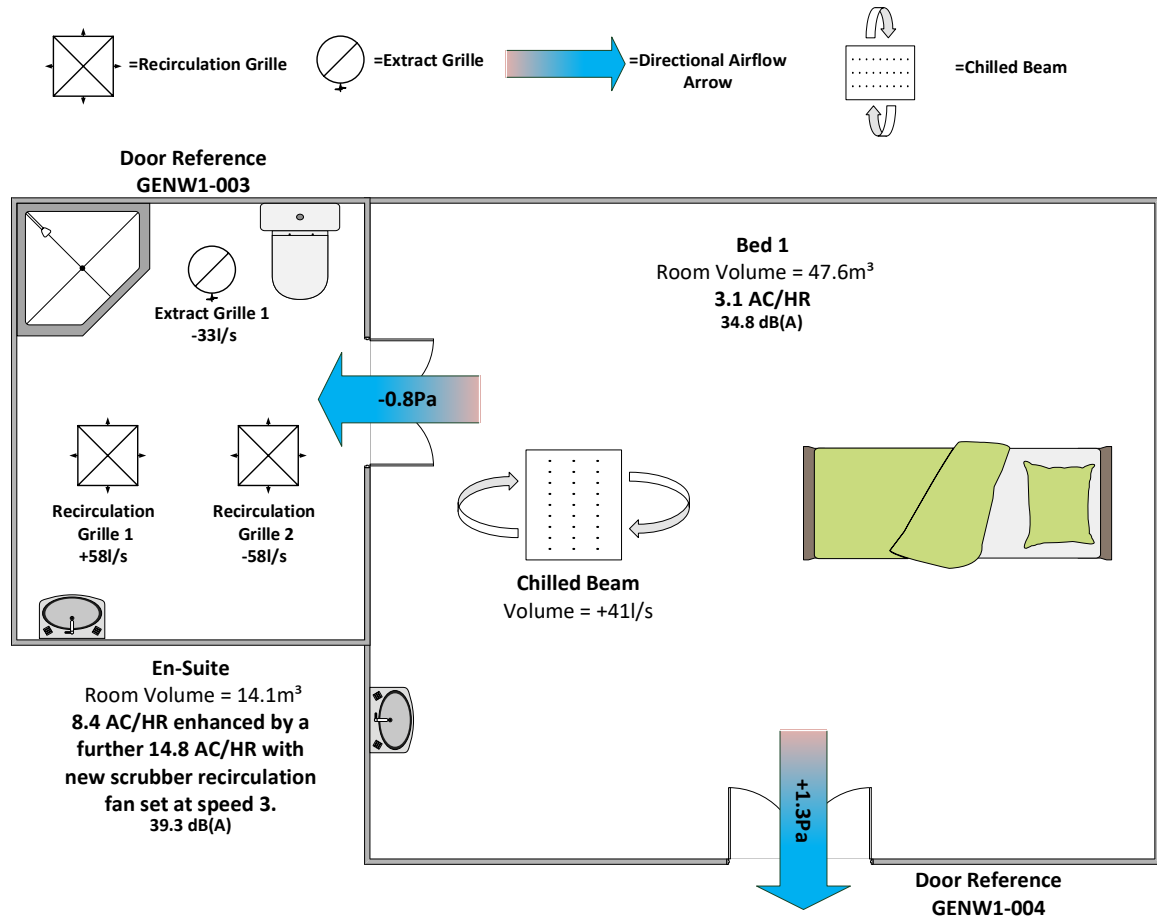
Temperature & Noise Levels

Room Reference	Door TAG Ref.:	Temperature Target 18 - 25°C	Noise Level Target <35db(A)
Bedroom	GENW1-004	23.5	34.8
En-Suite	GENW1-003	23.3	39.3
Comments: Noise levels SHTM03-01 compliant set on speed 3. Camfil fan speed set at speed 3 when values recorded on above table. WC noise level target 45dB(A)			

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ADULTS WARD 6A - ROOM 1

Section 7– Typical Schematic Layout of Adults 6A - Bed Room 1

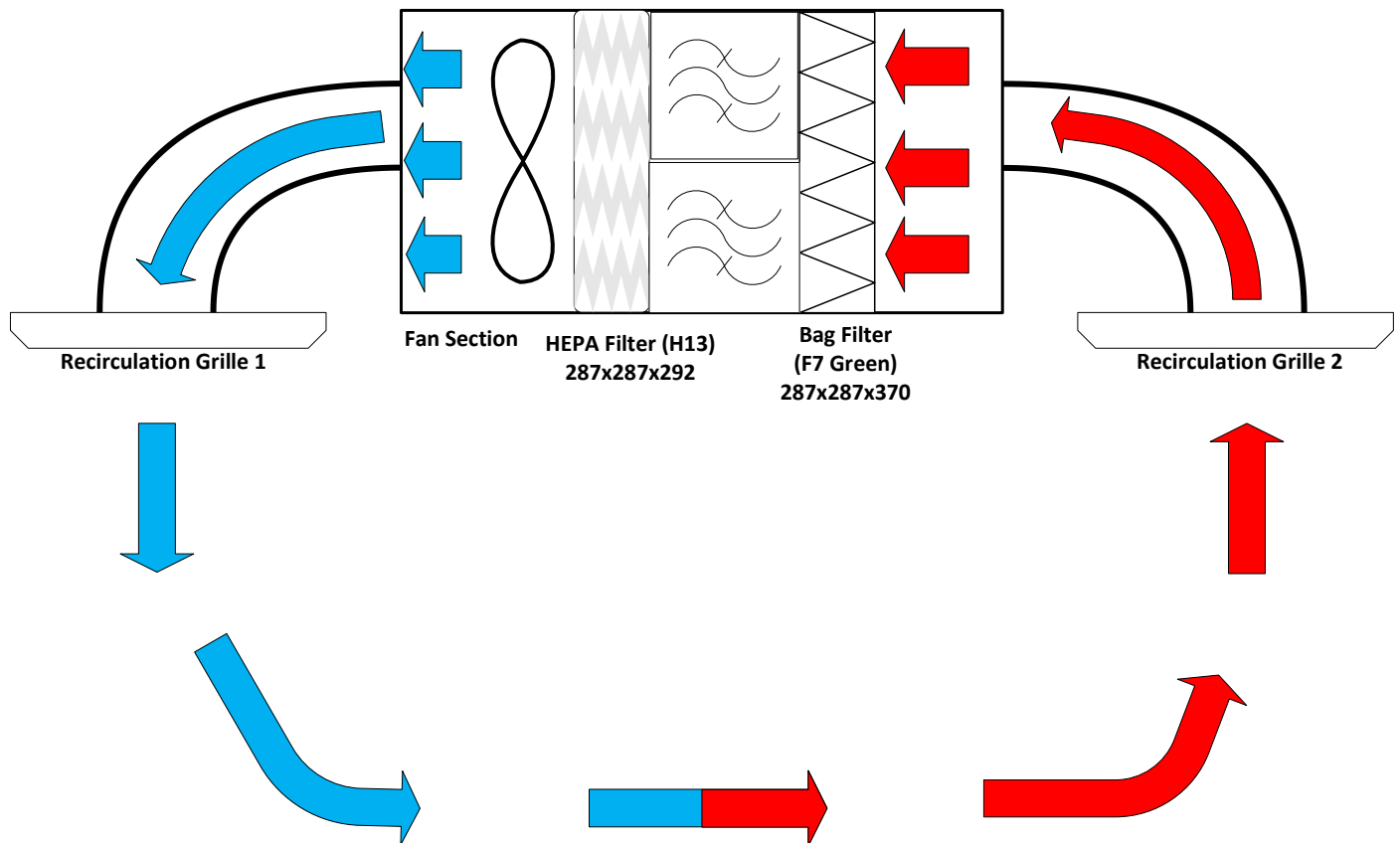


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ADULTS WARD 6A - ROOM 1

Section 8– Typical Schematic Layout of Camfil Recirculation Unit

Camfil Recirculation Unit
Ward 6A - Room 1 - En Suite
GENW1-003



QUEEN ELIZABETH UNIVERSITY HOSPITAL**ADULTS WARD 6A - ROOM 1****Section 9 – Test Equipment Used**

Type of Equipment	Serial No	Cal Due Date
Micro-manometer	8651	June 2020
Sound Meter	N850802	July 2020
Humidity & Temperature Meter	42670651	July 2020
Balometer	PH7311809008	June 2020

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ADULTS WARD 6A - ROOM 1

Section 10 – Calibration Certificates

AIRFLOW INSTRUMENTS

CERTIFICATE OF CALIBRATION
TSI Instruments Ltd., Stirling Road, Cressex Business Park,
High Wycombe, Bucks HP12 3RT England
Tel: (Int +44)(UK 0) 1494 459200 Fax: (Int +44)(UK 0) 1494 459700
http://www.tsiinc.co.uk

ENVIRONMENT CONDITION		
TEMPERATURE	67.3	° F
RELATIVE HUMIDITY	50.3	% RH
BAROMETRIC PRESSURE	29.3	inHg

MODEL	PROHOOD™ PH731
SERIAL NO.	PH7311809008

CALIBRATION STANDARDS USED	
Capture Hood Calibration System UK1	

☒ AS LEFT	☒ IN TOLERANCE
☐ AS FOUND	☐ OUT OF TOLERANCE

CALIBRATION DATA
Tolerance: $\pm (3\% \text{ of reading} + 7.0 \text{ cfm})$

TESTING POINTS	SUPPLY DATA MEASURED IN ft^3/min			RETURN DATA MEASURED IN ft^3/min		
	CALIBRATION STANDARD	INSTRUMENT OUTPUT	ALLOWABLE RANGE	CALIBRATION STANDARD	INSTRUMENT OUTPUT	ALLOWABLE RANGE
1	1898	1937	1835 - 1951	1900	1858	1836 - 1964
2	1501	1519	1449 - 1553	1502	1458	1450 - 1554
3	1197	1208	1155 - 1239	1205	1170	1162 - 1248
4	900	904	866 - 934	901	882	867 - 935
5	601	604	576 - 626	601	594	576 - 626
6	302	300	285 - 318	297	294	282 - 312
7	99	102	90 - 108	100	101	90 - 110

* Indicates out of tolerance condition

TSI does hereby certify that the above described instrument conforms to the original manufacturer's specification (not applicable to As Found data) and has been calibrated using standards whose accuracies are traceable to members of the European co-operation for Accreditation (EA) for example: UKAS, SWEDAC, DAkkS or has been verified with respect to instrumentation whose accuracy is traceable to some member of EA, or is derived from accepted values of physical constants. TSI's calibration system meets ISO-9001:2008 and meets the requirements of ISO 10612:2003.

Measurement Variable	System ID Number	Date Last Calibrated	Calibration Due Date
DC Voltage	E006072	04-25-19	04-25-20
Thermometer	E006103	04-25-19	04-25-20
Pressure	E006155	04-24-19	04-24-20
Pressure	E006095	04-24-19	04-24-20
Flow	E004015	08-14-15	08-14-19
Flow	E004017	08-12-15	08-12-19
Barometric Pressure	E006061	04-24-19	04-24-20

Calibration procedure used: 9011156

Jun. 12, 2019
Calibration Date

1060905A

QUEEN ELIZABETH UNIVERSITY HOSPITAL

ADULTS WARD 6A - ROOM 1

CERTIFICATE OF CALIBRATION

Issued by: RS Components Ltd

Date Issued: 10 Jul 2019

Certificate No.

1587874

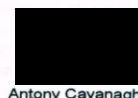


Calibration and Repair Service

DPN 175, Lammas Rd,
Weldon Industrial Est
Corby, Northants, NN17 9RS

Tel: 01536 405545
Fax: 01536 401590

Page 1 of 2 Pages



Antony Cavanagh

Client	CORRECTAIR SOLUTIONS LIMITED PAISLEY RENFREWSHIRE PA1 3RA
Instrument	FLUKE 971 Humidity & Temperature meter.
Serial No.	42670651
Client Reference	N/A
Procedure ID.	724.4193_DPM_(HYGRO95%) Rev. 1
Date of Calibration	10 Jul 2019

Equipment Used to Carry Out Calibration	Equipment ID.
Rotronic Hygrogen 2 Humidity Generator	CAL 1077
MBW 473 Dew Point Mirror	CAL 1078
MBW Dew Point Reference Probe	CAL 1079

The measurements reported in this certificate were carried out using equipment whose values are traceable to national standards.

All procedures employed and results reported are in compliance with the requirements of the International Standard ISO/IEC 17025:2005.

The management controls of the RS Calibration Laboratory are registered under the British Standard BS EN ISO 9001 : 2015 No. RS 00362.

Uncertainties

The reported expanded uncertainties are based on a standard uncertainty multiplied by a coverage factor $k = 2$, providing a level of confidence of approximately 95%.

This calibration is of a new instrument.



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QUEEN ELIZABETH UNIVERSITY HOSPITAL**ADULTS WARD 6A - ROOM 1****CERTIFICATE OF CALIBRATION**

Issued by: RS Components Ltd

Date Issued: 11 Jul 2019

Certificate No.

1588163

**RS Calibration**

Calibration and Repair Service

DPN 175, Lammas Rd,
Weldon Industrial Est
Corby, Northants, NN17 9RSTel: 01536 405545
Fax: 01536 401590

Page 1 of 3 Pages



Pamela Alvarez

Client CORRECTAIR SOLUTIONS LIMITED
NEILSTON
G78 3JA

Instrument SAUTER SU 130 Sound Meter

Serial No. N850802

Client Reference N/A

Procedure ID. 789.8902 Rev. P3

Date of Calibration 11 Jul 2019

Equipment Used to Carry Out Calibration

Bruel & Kjaer Acoustic Calibrator Type 4226

Equipment ID.

Cal 1045

The measurements reported in this certificate were carried out using equipment whose values are traceable to national standards.

All procedures employed and results reported are in compliance with the requirements of the International Standard ISO/IEC 17025:2005.

The management controls of the RS Calibration Laboratory are registered under the British Standard BS EN ISO 9001 : 2015 No. RS 00362.

Uncertainties

The reported expanded uncertainties are based on a standard uncertainty multiplied by a coverage factor $k = 2$, providing a level of confidence of approximately 95%.

Compliance to Specification

The manufacturer of this instrument doesn't state compliance with any sound level meter standard, therefore these are Reported Values Only.

This calibration is of a new instrument.



RS Components takes its environmental responsibilities very seriously and as such has printed this double sided document in black and white, on paper from sustainable sources.

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QUEEN ELIZABETH UNIVERSITY HOSPITAL

ADULTS WARD 6A - ROOM 1



DP MEASUREMENT

Unit 11, Top Angel, Buckingham Industrial Park, Buckingham, MK18 1TH
Tel/Fax: 01280 817122 e-mail: dpm@ttseries.com www.ttseries.com

CALIBRATION CERTIFICATE

CUSTOMER DETAILS:

Customer: Correctair Solutions Ltd
Customer Serial Number: N/A

INSTRUMENT DETAILS:

Model: TT570 S
Serial Number: 8651

CONDITION ON RECEIPT: New

- 1 Required repair:
2 In spec:
3 If yes to 2 adjustment:
4 If no to 2 adjustment:

CALIBRATION DETAILS:

Date Of Calibration: 12/06/19
Due Date: 12/06/20
Certificate Number: 45518

TEST ROOM CONDITIONS:

Temperature: 22°C ± 2°C

Manufacturers Specification: Readings less than 100 counts ± 2 counts

Readings greater than 100 counts ± 1% of reading ± 1 count

Manufacturer: DP Measurement

	0	40	80	160	400	800	kPa	kPa	kPa
TEST RESULTS:	0	40	80	160	400	800	1.60	3.00	6.00
Calibration Points Pa:	0	40	80	160	399	800	1.60	3.00	6.00
Indicated Readings:	0	-0.50%	-0.37%	0.00%	-0.25%	0.00%	0.00%	0.00%	0.00%
Percentage Error:									
TEST RESULTS:	0	-40	-80	-160	-400	-800	-1.60	-3.00	-6.00
Calibration Points Pa:	0	-40	-80	-160	-400	-800	-1.60	-3.00	-6.00
Indicated Readings:	0	0.25%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Percentage Error:									

Calibration Points m/sec:	0	5.0	8.2	11.5	15.0	16.3	25.8	36.5	50.0
Indicated Readings:	0	5.0	8.2	11.5	15.0	16.3	25.8	36.5	50.0
Percentage Error:	0	0.0	0.0	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%

Notes:

Equipment:

The instrument detailed above has been calibrated against equipment serial number 0047368 which in turn has been calibrated against instruments and equipment that are traceable to National Standards. (UKAS Calibration Laboratory N° 0157). The above results are obtained on the date of calibration. The percentage error quoted refers to the measured values only, with no account being taken of the instruments ability to maintain its calibration.

Velocity Range:

Is calibrated for the ellipsoidal nose (NPL Type) Pitot Static Tubes used at air density 1.20kg/m³. Air stream temperature set at 16°C and barometric pressure set at 1000 mbar on the instrument.

Calibrated by Hussein Khimji:

Page 1 of 1 ©

Version 2
07.06.2017

Associated Instrument Repairs Ltd. Trading as DP Measurement.
Company Reg. No: 3485904 VAT No: 685 868 755
Registered Office: Ebenezer House, Poole Road, Bournemouth, Dorset. BH2 5QJ.

<u>IMT or CEG</u>	<u>Action</u>	<u>Owner</u>	<u>Status</u>	<u>Completion Date</u>
CEG	Identify and block off any potential cladding breaches allowing bird ingress to plantrooms.	CP	Complete	01/03/19
IMT	Carry out deep cleaning of plantrooms at high and low level	CP	Complete	30/08/19
CEG	Seal up IPS Panels in rooms to avoid passage of air into patient rooms	CP	Complete	01/05/19
CEG	Carry out CFD analysis of helipad/helicopter interaction	IP	Complete	06/06/19
IMT	Adjust door seals to Gruffalo corridor light well	CP	Complete	22/03/19
IMT	Deep clean all evaporator units sited in Gruffalo lightwell and install netting	CP	Complete	22/03/19
IMT	Install tackmats at helipad lift to remove any contamination brought in on trolley wheels	KC	Complete	16/04/19
CEG	Produce pest control report	CP	Complete	22/03/19
CEG	Submit maintenance logs for all AHUs on Level 12	DC	Complete	
CEG	Submit maintenance logs for all AHUs serving PICU	DC	Complete	
CEG	Confirm dates of AHU shutdowns to correlate with patient infection dates	DC	Complete	
CEG	Carry out internal investigation of AHUs to check for bypass at filter housing	DC	Complete	
IMT	Change F7 filters on AHUs to F9	DC	Complete	01/03/19
CEG	Confirm no bypass of air at the filters within AHUs	DC	Complete	22/03/19
IMT	Consider removal of sedum roof material	TS	Withdrawn	...
CEG	Remove CVGs from Wards	DC	on hold	...
CEG	Fit door closers to Ward 4B bedroom doors	CP	Withdrawn	...
CEG	Check door seals between Ward 4B and 4C	DC	Complete	21/06/19
CEG	Check door seals in risers at Ward 4C	CP	Complete	21/06/19
CEG	Permit to access via external door to roof at level 4	CP	Complete	21/06/19
CEG	Produce a condition report for all flooring within shower rooms Ward 4B, 4C and 6A	CP	Complete	06/06/19
IMT	Install mobile HEPA filtration units in all high risk patient wards	DC	Complete	15/02/19
IMT	Pigeon control via trapping and helipad cull.	CP	Ongoing procedure	...
CEG	Fit active ventilation to PICU bottle store (extract fan only)	DC	Complete	
CEG	Track the processing and storage of linen and map out journey	IC	Complete	06/06/19
IMT	Survey all windows in Ward 6A and 4B for possible ingress of outside air. Repair where necessary.	JM	Complete	06/06/19
CEG	Collate information from Pest Control on "Cleaning to Pest Control Standard"	CP	Complete	26/07/19
CEG	Proposal to block of risers above and below ward 6A, 4B and 4C	DC	on hold	...
CEG	Pest control to update on timeline of cleaning PR123	CP	Complete	23/08/19
CEG	Discussion with Swisslog to gain an understanding of the pneumatic tube system operation	CP/JH	Complete	23/08/19
IMT	Leakage from Chilled Beams. Change flexible push fit connectors.	CP/DC	Complete	02/09/19

From: [Bustillo, Sandra](#)
To: [Dick, Lorraine](#)
Subject: FW: Responses to Parents Question 6A
Date: 13 December 2019 16:16:57
Attachments: [IMG_20191112_100307699.jpg](#)
[IMG_20191112_100316262.jpg](#)
[IMG_20191112_100433473.jpg](#)
[IMG_20191112_101426317.jpg](#)

In response to the issues raised we can confirm:

(a) Ventilation

Extensive testing of the ward environment found no link between infections and the ward. We have introduced HEPA filters to the bedrooms and en-suites; the bedrooms have a positive pressure reading which means that the generally filtered air flows out rather than into the rooms. In addition, it should be noted that the high specification general filtration system for the entire hospital means that we have high levels of air filtration (87%) in place on all general areas.

The infection rates in the ward – as Cab sec confirmed – have reduced and the rates in the ward are on a par with other Scottish units.

Prophylaxis line (Scott Davidson)

(b) Water

What have we said about S-J K? No other infections have been linked to the water supply, despite testing.

(c) Showers

We answered these questions based on the concerns that families had raised with the clinical teams. We were aware that questions had been raised about the drainage and our response made clear that there were no issues with regards to the drainage system.

We had however previously briefed parents about dampness in some of the showers which was a result of sealant coming away from the walls. We also issued a media statement confirming this situation. Parents were kept fully informed about the action taken to address this issue.

(d) Leak in kitchen

The leak in the ward kitchen was inspected on close examination there was no evidence of saturated wall boarding, or of water getting behind, or below the flooring. All works were undertaken under RA conditions in line with the conditions that CP has outlined.

(e) IMT

It is true that there were a number of different views and hypotheses examined as part of our investigations into potential links between a number of infections and the environment. We also drew on national expertise, HPS, and the ward was re-opened on this basis of the extensive investigations by both the IMT and HPS, the results of which led to the agreement that the ward was safe to re-open to new patient admissions.

Sandra Bustillo | Interim Director of Communications | NHS Greater Glasgow and Clyde
 JB Russell House | Gartnavel Royal Hospital | 1055 Great Western Road, G12 0XH

web: www.nhsggc.org.uk

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From: Steele, Tom

Sent: 13 December 2019 14:16

To: Bustillo, Sandra <Sandra.Bustillo@nhs.uk>

Subject: FW: Responses to Parents Question 6A

Once you've finished your darning, you can look over this???

Tom Steele | Director of Estates and Facilities

| NHS Greater Glasgow and Clyde | JB Russell House | Gartnavel Royal Hospital | 1055 Great Western Road | Glasgow | G12 0XH

From: Riddell, Mark

Sent: 13 December 2019 14:08

To: Steele, Tom <[Tom.Steele](#)>; Purdon, Colin <[Colin.Purdon](#)>
Cox, Gerry <[Gerry.Cox](#)> Conner, Darryl James
<[DarrylJames.Conner](#)>

Cc: Hirst, Allyson <[Allyson.Hirst](#)>

Subject: RE: Responses to Parents Question 6A

Tom

Have reused a previous statement along with supporting pictures that Ker had compiled, I think this tells the full story.

Ward 6A Entrance is -1pa to the lift hall with the doors closed, when the doors open the ward entrance becomes ambient as shown in Image 100307699 & 100316262.

Ward 6A Kitchen is -3 pa to the corridor with the door shut as it operationally should be as shown in image 1014266317 and does not fluctuate regardless of external door orientation, this is supported and expected by the evidence that the pressure cascade in the kitchen is under more negative pressure than the rest of the ward.

The narrative for the existing pressure regime in ward 6A is as follows :

All patient rooms are notionally positive to the corridor

The kitchen is negative to the corridor

The ward entrance to corridor is ambient to notionally negative depending on the door orientation which is extremely variable due to the traffic of people.

Regards

Mark

From: Steele, Tom

Sent: 13 December 2019 13:27

To: Riddell, Mark; Purdon, Colin; Cox, Gerry; Conner, Darryl James

Subject: RE: Responses to Parents Question 6A

Importance: High

Mark, I have changed a few bits, but I am sure that we can put up a robust response to the assertion about the leak in the ward kitchen. This was viewed and all works were undertaken under RA conditions and on closer examination there was no evidence of saturated wall boarding, or of water getting behind, or below the flooring. In addition, it would perhaps not be unusual to detect fungal spores form a floor that has very regular footfall over it?

Tom Steele | Director of Estates and Facilities

| NHS Greater Glasgow and Clyde | JB Russell House | Gartnavel Royal Hospital | 1055 Great Western Road | Glasgow | G12 0XH

From: Riddell, Mark

Sent: 13 December 2019 13:04

To: Steele, Tom <[Tom.Steele](#)> Purdon, Colin <[Colin.Purdon](#)>
Cox, Gerry <[Gerry.Cox](#)> Conner, Darryl James
<[DarrylJames.Conner](#)>

Subject: RE: Responses to Parents Question 6A

Tom

Please see comments below

Regards

Mark

From: Steele, Tom

Sent: 12 December 2019 08:30

To: Purdon, Colin; Cox, Gerry; Riddell, Mark; Conner, Darryl James

Subject: FW: Responses to Parents Question 6A

Importance: High

Colin, I need you to review the email below and edit your initial thoughts on the statements, most of which are known, but will gather significant momentum today, so I need all attention today, discuss with others as necessary, but keep discreet.

Regards Tom

Tom Steele | Director of Estates and Facilities

| NHS Greater Glasgow and Clyde | JB Russell House | Gartnavel Royal Hospital | 1055 Great Western Road | Glasgow | G12 0XH

From: Peters, Christine <[Christine.Peters](#)>

Sent: 11 December 2019 18:20

To: McQueen F (Fiona) <[Fiona.McQueen](#)>; White C (Craig) <[Craig.White](#)>

Cc: Inkster, Teresa (NHSmail) <[teresa.inkster](#)>

Subject: Responses to Parents Question 6A

Importance: High

Dear Prof McQueen and Prof White,

I hope you don't mind me writing to alert you to some objections I have to the answers that have been given to parents regarding 6A - which I saw on line today for the first time - as I consider them to contain inaccuracies based on my knowledge of the situation. In retrospect I think it would have been essential to discuss these answers with Dr Inkster who was Lead ICD and key microbiology Water expert in the hospital given her intimate knowledge of the history, results and expertise and experience in BMT environmental management over a decade at the Beatson.

Qus pertaining to ventilation

There is a difference between saying ventilation is "safe" (what does that mean?) and "meeting standards required for the patient cohort housed in the accommodation" . This is an important differential as it is only by meeting the standards /requirements that one can be assured that reasonable preventative measures are in place. Deviations from this are hard to compensate for – eg lack of positive pressure means unfiltered air readily accesses the room and is breathed by the patient posing a risk of fungal infection particularly (including Cryptococcus if it is in the air). This has been verified by air sampling results during Dr Hoods investigations.

The strain of Cryptococcus found in the patient that started the investigation has not been grown from the air. Confirmed at the Cryptococcus advisory group and John Hood

This ward is not designed to be a neutropenic facility, It was a clinical decision made by Infection Control to move to Ward 6A. however the interpretation of safe would be that this ward is safer than that of an equivalent standard general ward within the QEUH Campus, this is backed up by notional positive pressure barriers from rooms to corridor, mobile HEPPA scrubbers deployed throughout the ward corridors and bedrooms and standalone H13 air scrubbers installed in all en-suites which has evidentially reduced particulate rates.

It is a simple matter of fact that the rooms in 6A do NOT meet requirements for protective airborne isolation which is the infection threat to neutropenic high risk patients. Note , the same was true of 2A as evidenced by the external engineer reports and the requirement for a huge amount of remedial work that is required . This statement on 6A rooms is based on :

1. No positive pressure incorrect, notional positive pressure is established albeit is below the standard required for a Neutropenic cohort
2. 3 Ach instead of 10 correct
3. Chilled beams in situ Guidance does not stipulate that they should not be in situ, SHTM 03-01 gives specific guidance on the use of the chilled beams within Hospital and goes on to encourage the benefits they may bring (Section 2.38, SHTM 03-01 Part A, 2014). With regards to the internal air condition control, SHTM 03-01 states that humidity controls are not required within general wards in hospital areas (Section 1.24) but also suggests an air handling unit cooling coil control strategy which should be used when close control of

humidity is required of which has been implemented.

Guidance and legislation regarding the selection of active chilled beam HVAC system suitability for clinical environments will vary from country to country. Based on the Scottish Guidance (SHTM 03-01, 2014), it appears to be the case that Active Chilled beams are acceptable as the re-circulation is only present within the one space, and is not being transported across to different areas within the hospital as found in central plant re-circulation.

4. Air is not HEPA filtered at point of supply **Agreed this is the standard :**

Neutropenic patient ward temperature	10 ACH	+10 Pascals	H12 Filter	30 Noise rating	18-28
--------------------------------------	--------	-------------	------------	-----------------	-------

5. Air sampling has repeatedly found fungal counts above that expected for this patient cohort as well as bacterial counts

What is the Standard ? can she provide evidence of standards?

For this reason antifungal prophylaxis is the mainstay of risk mitigation at present.

Qus pertaining to water :

filters were put in place as a control measure due to a water supply that was contaminated **Who indicated that it was contaminated?** That is not made clear in the responses . The water that is describes as wholesome has high colony counts of Mycobacterium and fungi. This does not pose an issue to immune competent patients but certainly does for the cohort under discussion. At least one mycobacterial infection has clearly been linked to the hospital water by whole genome sequencing and my view is that it is not possible to state that the other 6A infections have no link to the hospital environment as has been stated in public statements, based on the epidemiology , environmental results and the nature of the organisms themselves. Teresa is best place to give a comprehensive review of the water risks. **Is there a separate standard for Neutropenic patient water supply out with Governments standards for hospital water supplies?** No other infections have been linked to the water supply, despite testing.

Qu 4 : re no problems with the showers

There was a problem with leakage of water under the floor with extensive mould under the flooring due to a poorly designed seal and the rigidity of the flooring material used . This required significant remedial work and a decant from the ward earlier this year. **Where welds in vinyl joints have broken the area has been inspected, repaired, or replaced under SCRIBE RA conditions.**

There was one incident in 4B of sewage effluent coming up a shower drain while a BMT patient was bathing . The patient went on to have an extremely rare environmental organism line infection. **Is there evidence that this infection is linked to the incident?** Unfortunately drains block, especially in Hospitals. Incidents such as this are quickly dealt with by the estates team as well as the domestic services staff in conjunction with infection control colleagues and clinical team.

QU 8 : Chilled Beams

chilled beam cleaning is in place to prevent build up of dust and particulate matter and organisms on the chilled beams. The fact that this is required as frequently as 6 weekly is an indication of a faulty system. **Guidance states that service intervals are 6 monthly to yearly and have only been shortened at the request of IC and estates endeavouring efforts to provide a high level service.** This level of service clean will be under review once regular surface testing is undertaken and reduced if possible to minimise disruption to the ward rooms.

These chilled beams should not be used in the immune compromised setting .**I agree in principle, but as previously stated this is not a guidance stipulation and as long as adequate control measures are implemented, dew point monitoring and source dehumidification of which now are, they meet the standard of the current guidance available.** And even when they are used in other settings the design is such that if they are installed correctly they should only be required to be cleaned 6

monthly to yearly. It is a major question of concern that these chilled beams accumulate dust and particulate matter at such a rate as to require 6 weekly cleaning. **Active chilled beams operate under induction therefore if they are requiring cleaning after 6 weeks then the cleaning process of the room must be called into question.**

Qu 30 : re leak into kitchen 27th September

Please find attached the SBAR I wrote regarding the leak and the results that Fungus was grown from a sample of the wet material. **This would not be unexpected given it is a floor that has regular footfall access by staff.** This was not a staff kitchen in the sense that it was where patient special feeds were stored and drinks prepared for parents and children. Please see photos of the water damage.

The risk from ANY water ingress into a BMT area is fungal propagation and spore dispersal followed by infections as well as collection of water borne organisms. Therefore the assurance given is incorrect. For the kitchen to have been made functional again all the wet material would need to have been removed with strict HAISCRIBE process in place . Was this carried out? **YES as standard SOP.** In addition, **no wall material was saturated, nor had any water permeated to the underside of the flooring, therefore all surfaces were intact.**

Qu Pertaining to IMT

There is no consideration given to the marked difference in opinions on the IMT or the fact that the chair of the IMT was replaced followed by her resignation linked to the way the IMT was handled. This is not an easy message to convey , however I think it is vital that there needs to be a level of acknowledgement regarding the fact that the main expert in infection control in the organisation had a view that was not taken on by the organisation, for this to be a truly transparent process. **Not for comment by me, any recommendations set by Terresa and her team were fully implemented to offset their original decision to move this patient group to a general ward.**

I am happy to discuss all of the above and while I do not doubt for a moment that every effort is being made to reduce infection risk, I believe that in order to build trust going forward a high level of accuracy in delineating risks is warranted.

Kind regards,

Christine

Dr Christine Peters

Consultant Microbiologist

Queen Elizabeth University Hospital,

GGC

Ex [REDACTED]

Mobile: [REDACTED]



Ward 6A



Welcome to the Ward
We are making a change to our visiting times. This means:

- 1. We have no set visiting times
- 2. Please discuss with the person you are visiting and staff what it would be good for you to be here
- 3. We will always welcome and encourage your presence and support
- 4. Sometimes we may need to ask you to leave the ward temporarily to ensure privacy, safety, space and to rest in bed
- 5. If you have any questions, please just ask

What matters to you?

Please Open
When Busy

Please Close
When Busy

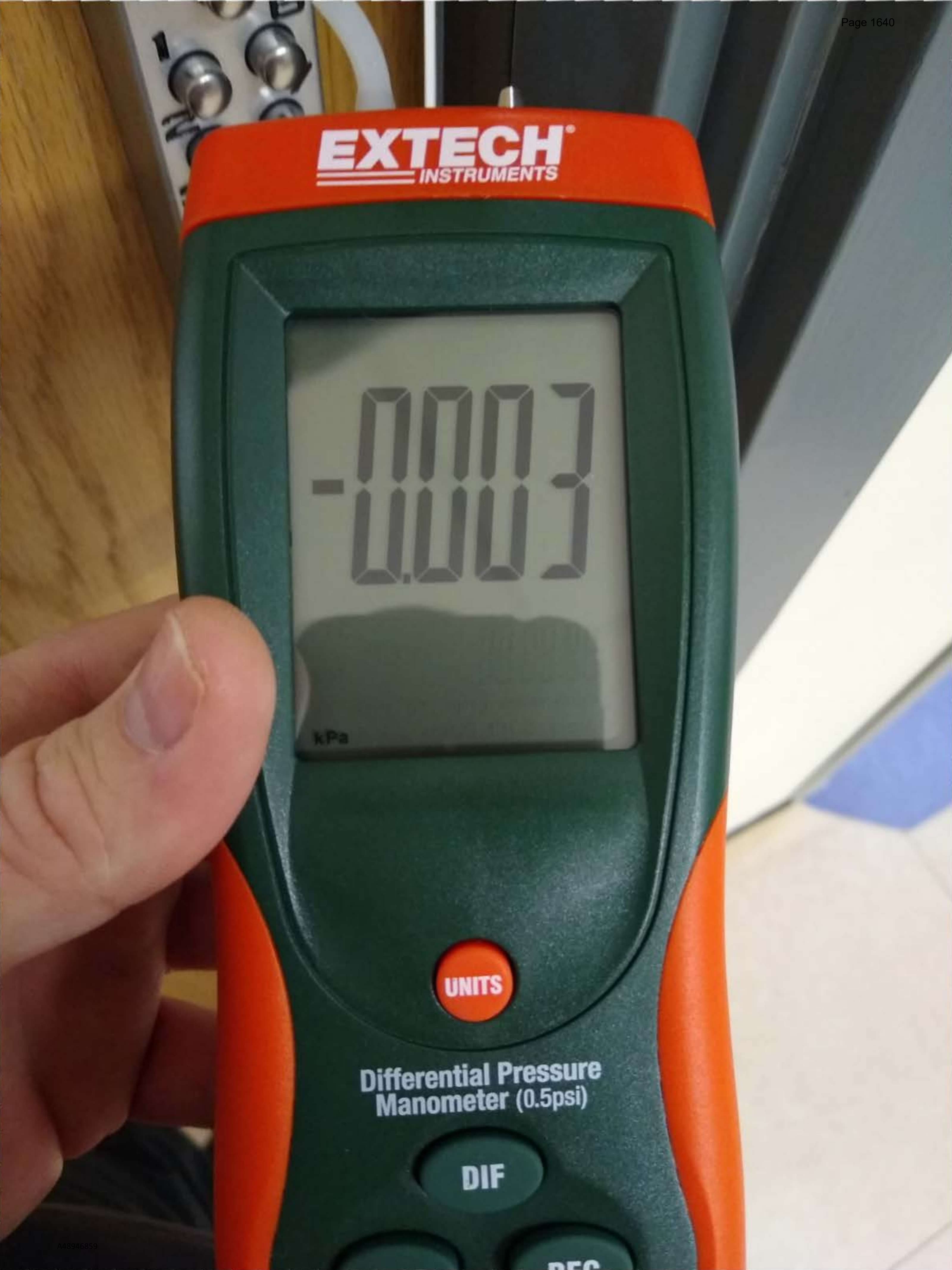


STRICTLY
NO
THOROUGHFARE TO
OTHER WARDS!!!

PLEASE WAIT TO BE
BUZZED INTO
WARD BEFORE
PULLING DOOR
HANDLE







EXTECH
INSTRUMENTS

-0.0003
-0.0003

kPa

UNITS

Differential Pressure
Manometer (0.5psi)

DIF

HOLD

Background

The adult haemopoietic stem cell transplant service moved to the QEUH in May 2015, because of concerns that the planned level of support for acutely unwell patients on the GGH site would be insufficient to support such a high intensity speciality and would not meet the JACIE accreditation standards. The level of high intensity support provided at GGH prior to May 2015 was already far from ideal and any reduction would make it extremely difficult to maintain a safe service for patients. It was known in May 2013, at the time of the decision to move the BMTU to the new unit at the QEUH, that the corridor would not be HEPA filtered, but it was expected that the rooms provided would be of an acceptable standard for highly immunocompromised patients with appropriate HEPA filtration, room pressures and air exchange rates. Given the frequent requirement for support from HDU, ICU and other acute specialities it was agreed by the clinical team that this need should be prioritised when balanced against the lack of HEPA filtration in the corridor. Unfortunately, the unit had to return to the Beatson, West of Scotland Cancer Centre in July 2015 because of the identification of extremely poor air quality in the new transplant unit. This return was predicated on it being short-term with remedial works to improve the air quality in ward 4B, QEUH to acceptable levels. The BMT team agreed to work closely with the BWOSCC high acuity and QEUH teams to minimise the risk to critically unwell patients whilst at the BWOSCC.

Remedial Works Required

The GGC Infection control lead, Dr T Inkster, sought advice from Health Protection Scotland (HPS) about the changes required to ward 4B to establish the current standards for highly immunocompromised patients and review how they could be met. HPS in their document (SBAR_BMT_NHSGGC_PDF_version 52) detail what these should be. Some work has already been done and plans have been drawn up to achieve virtually all the other requirements. A feasibility analysis has been carried out and remedial action outlined which will improve the air quality in ward 4B, QEUH. However, this is still below the specifications set out in the HPS document

The major issues are

- Frequency of air exchange is below the recommended 10/hour
- Positive pressure in the room is below the recommended +10PA
- The corridor is not directly HEPA filtered although all air entering will be

It should be noted that in the above document HPS state that *“Ideally the corridor should also be HEPA filter supplied, however, this is normally only achieved in a purpose built unit and is less important if the rooms are appropriately ventilated and achieve positive pressure in comparison to the corridor.”*

Risks of Suboptimal Air Handling

The main risk poor air quality poses to patients is significant invasive fungal infection. It is impossible to quantify if there will be an increased risk incurred by moving back to the QEUH compared with the current provision at BWOSCC once the planned upgrade in air handling provision has been completed, given that there will be suboptimal air exchanges and no direct HEPA filtration of the corridor. Until the proposed changes have been made we cannot do air sampling or particle counts to look for fungal colonies. However, we can reduce the risk of invasive fungal infection by using well tolerated and effective anti fungal prophylaxis such as posaconazole. With the measures that have been taken already, and further measures that are being planned, the air quality is almost certainly going to be adequate to protect patients, albeit the specification does not fully meet HPS standards.

Risks of Remaining at the BWOSCC

The failure to completely meet the HPS standards at QEUH needs to be balanced against the following which are incurred whilst the service remains at the QEUH

- Lack of HDU/ITU at BWOSCC

- Requirement for early transfer to QEUEH to reduce risk of critically unwell patient at BWOSCC site. This means patients are being transferred to the QEUEH who would normally be managed on the ward.
- Exposure to an unprotected environment during transfer
- Potential for significant compromise in outcome due to lack of rapid access to these staff and facilities.
- On-going concern about ensuring optimal care for patients who have been transferred from the BWOSCC transplant unit to the QEUEH due to lack of on site BMT nursing, pharmacy and AHP expertise.
- Significant psychological effects on patients moved to QEUEH, who require to remain there for long periods of time, due to concerns about general stability of condition, but who could be managed in the BMTU if onsite at the QEUEH
- Difficulty in obtaining prompt medical and surgical opinions at BWOSCC, particularly OOH. Patients require transfer to QEUEH.
- Lack of beds at the BWOSCC delaying admissions and increasing risk of disease progression
- Single air handling plant at the BWOSCC which cannot be serviced and has failed several times in the last few months.
- The level of support available on-site will be inadequate for the unit to achieve JACIE accreditation.

Monitoring Regime

On conclusion of the works outlined in the feasibility report, monitoring of the environment will take place as follows:

- Air particle Count
- Active air sampling

Acceptable levels would be:

- Air particle Count < 1000
- Active air sampling fungal colonies < 1CFU/m³

UK Benchmarking

Of the 7 centres who responded to a local survey (across the UK), all are operating within varying environments as follows:

Hospital	HEPA filtered Rooms Y / N	HEPA filtered Corridors Y / N	Room Air Changes 10/hour Y / N (if different, please specify)	Room Pressure Positive 10Pa Y / N (if different, please specify)	Sealed Rooms (fixed ceilings etc) Y / N	Air Lock Entrance to Ward Y / N	Is Air Pressure Monitoring System Alarmed Y / N	Is there a "Back-up" air handling plant for Wards Or Separate plant for each room	Rooms with anteroom at negative pressure for infectious BMT patients Y / N (Please state approx. Pa)	Do you operate a programme of Environmental Monitoring (Particle Counting / Microbial air sampling etc – please state acceptable limits)	HDU / ICU on-site	Comment
QEUH Proposal	Y	N (approx. 4 AC/hr with positive pressure to external corridors + wards)	N Approx. 6AC/hr	N (approx. 2.3-8 Pa)	Y	Y	Y Audible alarm outside each room	Y Independent (back-up) AHU unit available if primary unit fails	Y (Available via adjacent Renal Ward)	Y Monthly programme of Microbial Air Sampling and Particle Monitoring	Y	
UCLH	Y	N	Y	Y	Y	N	No, pressure gauge on wall	No	-10KPa on separate floor	Micro sampling of all wards (contact plates etc) led by infection control. HEPA qualified annually by external company.	ITU + HDU	

St Bartholomews (Barts Health)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Back up	Yes	Done by infection control. No SOP that I'm aware of.	ICU on-site for BMT patients. Other ICU'/HDU' for cardiac patients	Whole floor is HEPA filtered (Brand new facility – last year)
Nottingham University Hospital	Y	N	Y	Y Runs at <10	N Suspended ceilings	N	N But is checked every morning by ward staff and then alarm raised if out of range.	Y Back up generators Monitored by estates dept	N/Y Negative pressure can be achieved by leaving the bathroom door open. ?Pa	Y NUH Infection control dept coordinates this – air particle sampling and micro sampling done. Also water sampling showers and sinks. Throughout ward. Results go through to ward Manager.	Critical Care Unit on-site	
KCH	Y	Y	Y	Y	Y	Some	Y	N	Y	No. Rooms verified on opening. Regular HEPA filter replacement.	HDU + ICU	
ANON	Y	No. Each room positive to corridor	Y	Y	Y	Y	Yes, local and central	Separate AHU for each patient room. Main Ward on separate system.	Yes, 15Pa in anteroom and 10Pa in patient room.	No. Rooms verified on opening. Regular HEPA filter replacement.	ICU (ITU)	
Royal Devon & Exeter	Y	N	Y	Y	Y	N	N	N	Y	Y	ITU (+HDU)	
Leeds Adult	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	ICU + HDU	

N.B QEUH is based on the specification once the works outlined in the recent feasibility study are completed.

Conclusions

On this basis, it is our belief that the current proposals will ensure an adequate solution to providing a safe environment for patients and compare favourably to the physical environment available at BWoSCC:

	Current BWoSC C	Proposed QEUH
HEPA filtered Rooms Y / N	Y	Y
HEPA filtered Corridors Y / N	Y	N (HEPA filtered air supplied to rooms – cascaded to corridor then external corridor under positive pressure differential).
Room Air Changes 10/hour Y / N	Y	Approx 6 AC/hr
Room Pressure Positive 10Pa Y / N	Y	Approx 2.3 – 8 Pa
Sealed Rooms(fixed ceilings etc) Y / N	Y	Y
Air Lock Entrance to Ward Y / N	Y	Y
Is Air Pressure Monitoring System Alarmed Y / N	N	Y
Back-up plan Y / N	Y	Y
Rooms with anteroom at negative pressure for infectious BMT patients Y / N	Y	Y
Programme of Environmental Monitoring Y / N	Y	Y
ICU /HDU	N	Y

Queen Elizabeth University Hospital (NHSGGC) Bone Marrow Transplant Unit**Situation**

NHS Greater Glasgow and Clyde (NHSGGC) initially requested support from Health Protection Scotland (HPS) in 2015 in the review of their Bone Marrow Transplant Unit within Queen Elizabeth University Hospital (QEUEH) prior to transfer of patients from the Beatson Oncology Centre (WOSBOC). This review focussed mainly on the ventilation and provision of a safe environment for the care of these patients within the QEUEH. HPS liaised with HFS and support has continued since the initial request.

Background	The decision to transfer the care of bone marrow transplant patients from the Beatson Oncology Unit to the QEUH was made in June 2013. Construction of the QEUH was well established at this point and therefore the unit was not purpose built. When the new hospital opened patients transferred to ward 4b from the Beatson Oncology unit. Concern was raised following environmental and air sampling yielded high particulate counts and fungal spore growth. On identification of these results the patients were relocated back to the WOSBOC as a temporary measure whilst remedial work was undertaken in ward 4b. Currently the patients remain in the WOSBOC whilst works have been ongoing in ward 4B in an attempt to make the unit compliant. It is noted that there is no current UK guidance on BMT isolation rooms. General ventilation guidance is contained within SHTM 03-01 (Parts A and B) and SHPN 04-01 Supplement 01. Additionally, an SBAR was produced in May 2015 which provided GGC with recommendations to allow the provision of a protective environment for patients within the bone marrow transplant unit. The SBAR focussed primarily on the adult BMT transfer to ward 4B was produced by HPS/HFS in December 2015 (Appendix 1). Whilst NHSGGC has continued to work towards these recommendations it is noted that the solution proposed does not meet the guidance nor does it seek to address all the recommendations in the SBAR(2015). As a result HFS cannot comment on the effectiveness of the measures intended to be put in place. NHSGGC are working towards transfer of the patients from the BOSWOC to ward 4B by early 2018. A staged approach to repatriation of the BOSWOC BMT patients back to ward 4B has been proposed. This includes transfer of existing medical patients to other areas within the hospital, ventilation within the area turned back on once patients have vacated the area and external validation and commissioning of the unit will be undertaken. Once this has been completed and agreed with facilities, IPCT and management haemato-oncology patients from the South Glasgow are will occupy ward 4b for a period of 6 months will microbiological monitoring is undertaken. HPS have been requested to provide support relating to initial monitoring of the environment prior to transfer and during the first six months of the transfer to allow early identification of airborne fungal spore risks. A rapid literature review relating to microbiological risks was undertaken (Appendix 2) and support sought from Peter Hoffman (Public Health England)
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Assessment	The recommendations outlined in the SBAR (2015) relating to ventilation included: To allow the provision of a protective environment for patients within the bone marrow transplant unit (Ward 4B) • The rooms must be positively pressured at 10 pa • ALL air entering the room must be via the HEPA filter • The HEPA filter should as a minimum be E12 (H13) and located within the supply air diffuser • The rooms must be sealed and no air which has not passed via the HEPA filter should access the room • A strict protocol which minimises the length of time the door is opened and reduces air entry via an open door is required. • There must be a continuous pressure monitoring system for each room which alarms and gives an early indication of a pressure drop within the room • Bedroom Air changes of 10 ACH must be achieved • The walls and ceilings within the rooms and ensuite must be sealed. • All room services must be sealed • All service access hatches within the bedrooms/ensuite must be sealed NHSGGC have confirmed that the rooms meet 10Pa however fall short on air changes at 6 AC/hr instead of the recommended 10 AC/hr. Air changes dilute the microbial content of the room from what is already dispersed within the room. The main focus from protection of the immune-compromised patient is to ensure protection is provided from outdoor contamination via hepa filtration. The integrity of the hepa filter requires to be insitu checked with particles to ensure its efficiency and correct fitting. It is an engineering recommendation that the design philosophy as outlined in SHPN 04-01 Supplement 1 is followed as far as reasonably practicable and that the supply and extract branches to each suite are fitted with spring close gas tight dampers to allow individual suites to be closed for maintenance or cleaning. It should be noted that BSRIA are recommending that air permeability should be between 2.5-1.0m³/hr/m² at 50Pa and given the limitations of the existing solution, it may be prudent for NHS GGC to consider this. Extract ventilation ductwork should be separate and terminate as described in SHPN 04 Supplement 01.
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	<u>Ventilation rates:</u> Validation of the entire system should be as detailed in SHTM 03-01 part A and verification of the entire system should be as outlined in SHTM 03-01 part B. The frequency of verification should be at least annually, or more frequently if issues arise. <u>Sampling:</u> There are two ways of sampling: • Active air sampling • Passive air sampling Active air sampling involves using the air sampler and monitoring all patient rooms and corridor on the same day and sampling a high volume of air of at least 1 cubic metre of air from each room. There is no requirement for rooms to be empty during sampling as the testing is to identify fungi not bacteria Passive air sampling involves using settle plates in every room and allowed to remain in situ for a period of approximately 5-6 hours. Settle plates will sample fungal spores relatively inefficiently but can sample over a far longer time than active air samplers and so capture isolated contamination dispersion events that active sampling is likely to miss. The medium used should be selective medium which only allows the growth of fungi. (e.g Sabaraud's with appropriate selective supplements), Sampling should take place in an adjacent unprotected environment simultaneously to those within the rooms. Fungal levels in the outdoor environment (i.e. the challenge to any system of patient protection) will vary over time. A finding of low fungal counts in the protected may just be the result of a low challenge level. This sampling strategy allows the determination of a contamination ratio of the protected environment versus unprotected environment. A combined approach of both passive and active air sampling undertaken in parallel utilising media which selects fungi only , using the same medium, is the preferred method for commissioning and monitoring purposes, with both methods being undertaken simultaneously including an external unprotected control sample. Samples taken at weekly intervals for a period of 4-6 weeks at varying times should provide sufficient information on the integrity of the ventilation system with consideration being given to a follow up one month later. Thereafter sampling should return to the agreed boards protocol. Microbiological sampling is used as a validation of
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	engineering and engineering controls and should only be done after the engineering parameters have been assured as adequate. Annual validation of engineering is important and must be undertaken. Results: Fungal growth does not require to be speciated. If controls are in place the optimal level should be zero growth. The presence of any fungal spores on active sampling should prompt a review. The following strategy per cubic metre of air sampled is proposed • Zero growth = optimal • Single digit = review room air supply, confirm direction of outward air passage at multiple gaps in the room's integrity, examine room for areas of dampness or fungal growth. Investigate possible errors in sampling technique and resample • Double digits and above = indication of a serious problem. Urgent investigation and clinical consideration of fungal prophylaxis It is worth noting that a zero result, whilst optimal, does not always assure engineering efficacy as it may be reflective of no circulating fungal spores at the time of testing. <u>Lighting and power:</u> Luminaires to be recessed into a solid ceiling and be (minimum) IP44 with clear access strategy for maintenance including gear and lamp replacement. Any power, trunking or other services penetrations into the space must be sealed. <u>Water:</u> The water systems should be to SHTM 04-01 and free of any waterborne pathogens at the point of use. <u>Contingency:</u> As it is proposed that only one air handling unit serves the BMT isolation rooms, planned shut downs or unplanned events (such as motor failures or power failures) require to be addressed. The result of these shutdowns may mean that patients may need to be relocated. It is suggested that contingency plans include:- • AHU complete failure for prolonged period • AHU complete failure for short duration • AHU maintenance (air related – filters, fans, cleaning,
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	etc) • AHU maintenance (water related - cleaning, testing, inspecting) • Cleaning or deep cleaning of rooms following occupation. • If the AHU does not have a duty/standby arrangement, spare supply fans are sourced and stored locally to the AHU. • If ALL the ductwork is not fire rated, what happens in the event of a fire scenario. It may also be prudent to have contingency plans for local power failure and in the event of pathogens found in the local water supplies to the BMT isolation facilities
Microbiological monitoring Recommendation	• Both active and passive air sampling should be undertaken in parallel • Sampling should be undertaken weekly at varying times for a period of 4 -6 weeks and a follow up one month later • All patient rooms within 4b should be included in each sample period • An external adjacent unprotected area should be identified and passive sampling undertaken in parallel with protected (BMT unit rooms) sampling • Standard sample plates should be used which are selective for fungi and that inhibit bacterial growth • Any fungal colonies identified require to be counted but not speciated • As the medium used are selective for fungi and not bacteria, the rooms do not require to be vacated during the sampling period. • Passive sampling/settle plates should be left insitu for 4-6 hours approximately ensuring the plates do not dry out. • Active sampling volume should be approx 1,000 litres per room. • The air sampler should be placed on a clean trolley or stand • The medium for both passive and active sampling should be the same • Results should be interpreted: • Zero growth = optimal • Single digit = review room air supply, confirm direction of outward air passage at multiple gaps in the room's integrity, examine room for areas of dampness or fungal growth. Investigate possible errors in sampling technique and resample

	• Double digits and above = indication of a serious problem. Urgent investigation and clinical consideration of fungal prophylaxis • Annual validation of ventilation should be undertaken in line with the agreed protocol, based on selected components of SHTM 03-01 part B. • Once completion of commission monitoring as outlined above the normal monitoring protocol endorsed by NHSGGC should be resumed
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Appendix 1:

Insert SBAR

Appendix 2:
Research studies

Reference	Study type	Setting	Summary	Conclusions/recommendations
Alberti et al. Relationship between environmental fungal contamination and the incidence of invasive aspergillosis in haematology patients. <i>Journal of Hospital Infection</i> (2001) 48:198-206	Prospective surveillance	BMT unit and 2 haematology wards France	Bi-monthly air and surface fungal sampling of patient rooms (some with HEPA filters and LAF systems) as well as communal sites (corridors etc) carried out over a 4-year period. Invasive nosocomial aspergillosis infections were monitored over the same period. Patterns of fungal contamination were comparable in the three wards, with a gradient ranging from high levels in common sites and conventional rooms (up to 6 cfu/m ³) to a virtual absence in rooms equipped with HEPA filters and LAF systems. Using a regression model, a significant relationship was found between	This study emphasizes the utility of environmental surveillance. The authors recommend that pressure measurement should be regularly checked , as a decreased air pressure within the ward can result in a fungal contamination from adjacent sites. Monitoring of air fungal contamination is also recommended based on the significant relationship observed between incidence of invasive aspergillosis and air contamination with <i>Aspergillus</i> and non- <i>Aspergillus</i> species. The authors also recommend environmental surface monitoring based on the relationship they observed between fungal contamination of surfaces and invasive aspergillus infections.

Reference	Study type	Setting	Summary	Conclusions/recommendations
			the incidence of invasive nosocomial aspergillosis and the degree of fungal contamination of air and surfaces in conventional patient rooms (not equipped with HEPA) and common sites. The study found that peaks of air contamination by <i>Aspergillus</i> ≥ 2 cfu/m ³ had a determining role in the relationship between environment contamination and the occurrence of invasive aspergillosis.	
Bellanger et al. Fungal aerocontamination exposure risk for patients in 3 successive locations of a paediatric hematology unit department: influence of air equipment and building structure	Prospective surveillance	Paediatric haematology department France	Monthly air fungal sampling carried out of patient rooms and weekly air fungal sampling of corridors over a ten-year period, during which time the unit was relocated twice: from a building without a	Based on their results, the authors suggest a threshold alert of 8 CFU/m³ for unit corridor aerocontamination.

Reference	Study type	Setting	Summary	Conclusions/recommendations
on air quality. <i>American Journal of Infection Control</i> (2017) 45: e109-e113.			filtration system (B1) to a renovated building with low air pressure (B2) to a new building with high air pressure and HEPA filters. Multivariate statistical analysis showed that B2 was approximately 2.9 times more contaminated by mould than B3 ($P = .004$), whereas B1 was approximately 1.8 times more contaminated than B3 ($P = .32$). The study also found that contamination of air in corridors was important. Whenever opportunistic fungi are >8 CFU/m ³ in unit corridors, the risk of fungal aerocontamination in rooms is multiplied by 4.	
Reboux et al. A 10-year survey of fungal of	Prospective surveillance	Haematology units	Study retrospectively assessed the	A trigger threshold of 40 cfu/m ³ in main corridors is suggested – the authors state

Reference	Study type	Setting	Summary	Conclusions/recommendations
aerocontamination in hospital corridors: a reliable sentinel to predict fungal exposure risk? <i>Journal of Hospital Infection</i> (2014) 87: 34-40	e		contribution of fungal aerocontamination measurement in haematology corridors and main hospital corridors as a sentinel to assess fungal exposure and risk of invasive mould infections over a ten year period. Air samples were taken every week in the same locations in haematology corridors and main hospital corridors. All fungal species were identified. The Haematology and Hospital Hygiene Departments were alerted systematically whenever a peak of opportunistic species was detected and corrective action was planned. 12 peaks of <i>Aspergillus fumigatus</i> (>40 CFU/m³) were	that at this level it was possible to keep the staff alert without warning them too often. A trigger level of >1cfu/m³ was set in haematology corridors. While the study found that while monitoring did not prevent all invasive aspergillosis cases, the authors felt that the absence of surveillance could reduce staff vigilance and consequently increase the risk of invasive fungal infection.

Reference	Study type	Setting	Summary	Conclusions/recommendations
			observed in the main hospital corridors, and <i>A. fumigatus</i> contamination was detected up to six times per year in the haematology corridors. Peaks in the main corridors were thought to be associated with outdoor works (building, excavation and construction), indoor works (removal of false ceilings) and turning on the heating system. It was not possible to establish a link between invasive aspergillosis diagnosis and recent <i>A. fumigatus</i> peaks in the main or haematology corridors.	

Reviews and Other

Reference	Study type	Setting	Summary	Conclusions/recommendations
Gray and Ludman. The	Letter to the	BMT unit United Kingdom	Letter reporting microbial air counts	Authors introduced three-monthly air

Reference	Study type	Setting	Summary	Conclusions/recommendations
protected environment for high-risk haematology patients: as safe as we think? <i>Journal of Hospital Infection</i> (2016) 92: 295	Editor		in HEPA filtered BMT unit found to be unexpectedly high in two subsequent years following yearly planned maintenance. Increases attributed to deficiencies in the vicinity of ceiling air-supply vents: damage to the paintwork on the ceilings, and to the seals around light fittings which led to dust collecting directly in the path of laminar airflow supply; dust on the ceiling air-supply vents themselves, which had not been cleaned by the contractors. Cleaning and fixing defects returned samples to expected levels.	sampling of BMT isolation cubicles in order to obtain greater ongoing assurance of the safety of the air on the unit.
Kennedy et al. A novel application of statistical process control charts- monitoring air quality in a paediatric haematology/oncology unitcategory: lesson in	Conference abstract	Paediatric Haematology/Oncology unit United Kingdom	This study sought to determine whether statistical process control charts were useful in environmental air monitoring of high risk healthcare units. Results of air sampling at several sites within the paediatric	Statistical process control charts are a useful addition to environmental control measures to provide optimal air quality within clinical areas housing immunocompromised patients at risk of invasive fungal infection. This has now

Reference	Study type	Setting	Summary	Conclusions/recommendations
microbiology and infection control. <i>Journal of Infection</i> (2011) 63(6): e75-e76			haematology/oncology/BMT unit (in addition to external sites within the hospital grounds) collected over a 2 year period were used to produce SPC charts. The SPC charts provided mean fungal spore counts, upper control limits and trigger alert lines for (a) total fungi, (b) <i>Aspergillus</i> spp. and (c) <i>Aspergillus fumigatus</i> at each site sampled within the unit, thus providing information on the state of control for each area. For areas with high efficiency air filtration, the upper control limits and trigger alert lines are set at very low levels of spore counts. Subsequently, if fungal counts in any area approach the trigger alert category, action will be taken e.g. checking efficiency of air filters, particle counting, monitoring of cleaning procedures etc.	become a continuous process with results from routine monthly air sampling being incorporated into the SPC charts.

Reference	Study type	Setting	Summary	Conclusions/recommendations
Gonçalves Meneguetti et al. Assessment of microbiological air quality in hemato-oncology units and its relationship with the occurrence of invasive fungal infections: an integrative review. <i>Revista da Sociedade Brasileira de Medicina Tropical</i> (2013) 46(4):391-396	Review	Haematology/Oncology units	Integrative review that included 13 primary studies. The results of the studies suggest that suggesting that HEPA filtering of the ambient air in hemato-oncology units can prevent the incidence of invasive fungal infections. Currently, there is no consensus about the maximum allowable count of fungi in the air, which complicates filtration monitoring, including filter maintenance and replacement.	There is a requirement for consensus on maximum allowable count of fungi in air.
Morris et al. Sampling of <i>Aspergillus</i> spores in air. <i>Journal of Hospital Infection</i> (2000) 44: 81-92	Review	General healthcare	The review outlines many of the physical and environmental parameters that influence meaningful air sampling for <i>Aspergillus</i> and recommends a simple procedure that has been tried and tested in many aspergillosis outbreaks.	Interpretation of air sampling data and recommendations A single air sample will often underestimate the fungal contamination in the air: multiple air sampling has to be performed No strict numerical guidelines are available which are appropriate for assessing whether the contamination in a particular location is acceptable or not but the following threshold

Reference	Study type	Setting	Summary	Conclusions/recommendations
				levels have been recorded: • Outdoor air: total fungal count: 10^3 to 10^5 CFU/m³ • Aspergillus: 0.2–3.5 conidia/m³ Note: seasonal variation recognised • HEPA filtered air (> 95% efficiency and > 10 air changes per hour): <0.1 CFU/m³ • No air filtration: 5.0 conidia/m³ • Construction/defective ventilation: 2.3–5.9 conidia/m³ If total fungal count exceeds 1.0 CFU/m³ on several occasions the air systems or procedural practice in patient areas requires intensive evaluation.
Rupp et al, Routine sampling of air for fungi does not predict risk of invasive aspergillosis in immunocompromised patients. <i>Journal of Hospital Infection</i> (2008) 68: 270–282	Letter to the editor	Haematopoietic stem cell transplant Unit	In response to an outbreak of invasive aspergillosis, the authors implemented weekly fungal sampling in the unit, which continued for a 7 year period. <i>Aspergillus</i> spp. were recovered from 163 (16.7%) of the air samples. Of air cultures yielding <i>Aspergillus</i> spp., the quantitative results	Due to the fact that air sampling did not appear to be helpful in predicting the risk of invasive aspergillosis, as well as the fact that it takes 5–7 days for results of air samples making it too late to intervene to prevent exposure, the authors discontinued routine air sampling for mould. Instead, emphasis is now placed on

Reference	Study type	Setting	Summary	Conclusions/recommendations
			ranged from 1.8 cfu/m³ to 28.3 cfu/m³. Other non-<i>Aspergillus</i> spp. of fungi, predominantly <i>Penicillium</i> spp., <i>Cladosporium</i> spp. and <i>Alternaria</i> spp., were detected in 567 of the air cultures (58%). Analysis revealed that routine weekly quantitative air cultures did not appear to be helpful in predicting the risk of development of invasive aspergillosis in the subsequent 14-day and 28-day time periods.	maintenance of the ventilation system and the physical integrity of the HSCT unit, as well as environmental cleanliness.

Guidance

Reference	Key recommendations /information
Chang et al. Consensus guidelines for implementation of quality processes to prevent invasive fungal disease and enhanced surveillance measures during hospital building works. <i>Internal Medicine Journal</i> (2014) 44: 1389-1397	• Employ targeted air sampling prior to the commissioning of a new ward or air-handing system • Consider using targeted environmental sampling as a measure of enhanced surveillance during any hospital building works. • Consider using targeted environmental sampling to facilitate outbreak investigations. Air sampling: A written, defined, standardised, multidisciplinary protocol for sample collection and culturing is required in institutions where targeted air sampling is performed. Analysis and interpretation of results should use scientifically determined or anticipatory baseline values for comparison. Expected actions, based on the results obtained, should also be defined. Unfortunately, the

Reference	Key recommendations /information
	sensitivity, specificity and threshold values are unclear, and there are no uniform air quality standards. Microbiological sampling of air, water and inanimate surfaces is hampered by the variability in collection protocols, analysis and interpretation. Settle plates (sedimentation or depositional methods) are not recommended for sampling fungal spores as spores can remain suspended in the air indefinitely. There are no universally accepted standards or guidelines for the interpretation of fungal spore or colony counts collected in response to an outbreak. Fungal spore levels vary over time and with other factors, such as ambient light and humidity. An exposure level of <5 CFU/m³ of <i>Aspergillus</i> spp. in protective isolation areas and <0.1 CFU/m³ in HEPA-filtered environments, with limits of 15 CFU/m³ for gross colony counts of all fungal organisms, is recommended.
Dykewicz. Hospital infection control in hematopoietic stem cell transplant recipients. <i>Emerging Infectious Diseases</i> (2001) 7(2): 263-267	• Some experts suggest that hospitals routinely sample air, ceiling tiles, ventilation ducts and filters to test for molds, especially when construction or renovation occurs near or around the rooms of immunocompromised patients or when clinical surveillance demonstrates a possible increase in mold (e.g. aspergillosis) cases [CIII: This is an optional intervention because evidence is insufficient to support a recommendation or evidence for efficacy might not outweigh adverse effects/This is evidence from authorities' opinions based on clinical experience, descriptive studies, or reports of expert committees]. • In the absence of a nosocomial outbreak, HSCT units need not perform routine fungal cultures of devices and dust in the rooms of HSCT recipients and candidates undergoing conditioning therapy [DIII: Indicates that moderate evidence for lack of efficacy or adverse outcome supports against the intervention/ This is evidence from authorities' opinions based on clinical experience, descriptive studies, or reports of expert committees]
Sehulster LM et al.Guidelines for environmental infection control in health-care facilities.	Microbiologic sampling of air in health-care facilities remains controversial because of currently unresolved technical limitations and the need for substantial laboratory support.

Reference	Key recommendations /information
Recommendations from CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC). Chicago IL; American Society for Healthcare Engineering/American Hospital Association; 2004	Infection-control professionals, laboratorians, and engineers should determine if microbiologic and/or particle sampling is warranted and assess proposed methods for sampling. The most significant technical limitation of air sampling for airborne fungal agents is the lack of standards linking fungal spore levels with infection rates. Despite this limitation, several health-care institutions have opted to use microbiologic sampling when construction projects are anticipated and/or underway in efforts to assess the safety of the environment for immunocompromised patients. Microbiologic air sampling should be limited to assays for airborne fungi; of those, the thermotolerant fungi (i.e., those capable of growing at 35°C–37°C) are of particular concern because of their pathogenicity in immunocompromised hosts. Use of selective media (e.g., Sabouraud dextrose agar and inhibitory mold agar) helps with the initial identification of recovered organisms. Box 6. Unresolved issues associated with microbiologic air sampling • Lack of standards linking fungal spore levels with infection rates (i.e., no safe level of exposure) • Lack of standard protocols for testing (e.g., sampling intervals, number of samples, sampling locations) • Need for substantial laboratory support • Culture issues (e.g., false negatives, insensitivity, lag time between sampling and recording the results) • New, complex polymerase chain reaction (PCR) analytical methods • Unknown incubation period for <i>Aspergillus</i> spp. infection • Variability of sampler readings • Sensitivity of the sampler used (i.e., the volumes of air sampled) • Lack of details in the literature about describing sampling circumstances (e.g., unoccupied rooms vs. ongoing activities in rooms, expected fungal concentrations, and rate of outdoor air penetration) • Lack of correlation between fungal species and strains from the environment and clinical specimens • Confounding variables with high-risk patients (e.g., visitors and time spent outside of protective

Reference	Key recommendations /information
	environment [PE] without respiratory protection) • Need for determination of ideal temperature for incubating fungal cultures (95°F [35°C] is the most commonly used temperature) Settle plates, because they rely on gravity during sampling, tend to select for larger particles and lack sensitivity for respirable particles (e.g., individual fungal spores), especially in highly-filtered environments. Therefore, they are considered impractical for general use. Settle plates, however, may detect fungi aerosolized during medical procedures (e.g., during wound dressing changes). The use of slit or sieve impactor samplers capable of collecting large volumes of air in short periods of time are needed to detect low numbers of fungal spores in highly filtered areas. In some outbreaks, aspergillosis cases have occurred when fungal spore concentrations in PE ambient air ranged as low as 0.9–2.2 colony-forming units per cubic meter (CFU/m³) of air. On the basis of the expected spore counts in the ambient air and the performance parameters of various types of volumetric air samplers, investigators of a recent aspergillosis outbreak have suggested that an air volume of at least 1000 L (1 m³) should be considered when sampling highly filtered areas. Investigators have also suggested limits of 15 CFU/m³ for gross colony counts of fungal organisms and <0.1 CFU/m³ for <i>Aspergillus fumigatus</i> and other potentially opportunistic fungi in heavily filtered areas (≥12 ACH and filtration of ≥99.97% efficiency). No correlation of these values with the incidence of health-care– associated fungal infection rates has been reported.
National Guidelines for the Prevention of Nosocomial Invasive Aspergillosis During Construction/Renovation Work. National Disease Surveillance Centre, Dublin 2002	Contains an Appendix outlining a recommended air sampling method, drawn from Morris et al's 2000 review. No strict numerical guidelines are available, which are appropriate for assessing whether the contamination in a particular location is acceptable or not but the following threshold levels have been recorded: • Outdoor air (Note: seasonal variation recognised): • Total fungal count: 10³ to 10⁵ CFU/m³, • <i>Aspergillus</i>: 0.2-3.5 conidia/m³

Reference	Key recommendations /information
	• HEPA filtered air (>95% efficiency and >10 air changes per hour): < 0.1 CFU/m³ • No air filtration: 5.0 conidia/m³ • Construction/defective ventilation: 2.3-5.9 conidia/m³ If total fungal count exceeds 1.0 CFU/m³ on several occasions the air systems or procedural practice in patent areas requires intensive evaluation.
Ruiz-Camps et al. Guidelines for the prevention of invasive mould diseases caused by filamentous fungi by the Spanish Society of Infectious Diseases and Clinical Microbiology (SEIMIC). Clinical Microbiology and Infection (2011) 17(supplement 2): 1-24	• What is the usual spore concentration in hospital air? Studies must be carried out in each centre [unprotected hospital air] to determine the normal concentration and detect significant increases. Counts above 25 CFU/m³ can be considered to be very high. (Level II) • When should microbiological determinations of air be performed? It is advisable to carry out environmental cultures when required by current legislation and when there are cases of IFI [invasive fungal infection] caused by aerial fungi or when refurbishment and maintenance works are being carried out. However, some experts recommend carrying out cultures on a regular basis to verify the proper operation of the facility, both in operating theatres and in protected rooms. (Level IA) • What is the acceptable concentration of fungi (CFU) in protected air? The limit of CFU/m³ of air is 0.5, which means, as a maximum, it is possible to detect one colony of filamentous fungi in a sample of 2 m³ of air. (Level IC) • What is the acceptable concentration of fungi (CFU) in unprotected hospital air? Figures vary according to the study consulted. Under normal conditions, this should be below 25 CFU/m³. (Level II) • Do routine microbiological surveillance cultures have any additional value? They may be useful to determine the integrity of the filters of protected areas, although filter maintenance is more important. They may be helpful to determine the presence of unexpected contamination foci in centres that do not have adequate installations. They make it possible to have historical measurements to use for comparison purposes. (Level II)
Tomblyn et al. Guidelines for preventing infectious complications among hematopoietic cell transplantation recipients: a global	• Routine microbiologic air sampling for fungal spores in HCT units is not recommended, as its role has not been established (DIII). However, during a suspected outbreak, there may be a role for microbiologic air

Reference	Key recommendations /information
perspective. <i>Biol Blood Marrow Transplant</i> (2009) 15: 1143-1238 Yokoe et al. Infection prevention and control in health-care facilities in which hematopoietic cell transplant patients are treated. <i>Bone Marrow Transplantation</i> (2009) 44: 495-507	sampling in patient care areas (CIII). If microbiologic air sampling is performed as part of an outbreak investigation, sample volumes of at least 1000L may achieve a higher degree of sensitivity than smaller samples.



Ventilation Review Appendix K information discussed at meeting of 10/11/10

Noted that the review was on the preliminary design of 5 departments produced for GMP costing purposes and that flexibility in design is possible moving into the detail design phase. **Issues having wider implications and major effect on the energy consumption are highlighted.**

1.	Ventilation review	ZBP issues	Nightingale issues	Relevant drawing	Response/ discussion points	Action
2.	General and information requests					
2.1.	Resend as file corrupt	ZBP-XX--PL-534-301_02 ZBP-XX--PL-534-302_02 ZBP-XX--PL-524-304_02				
2.2.		ZBP-XX--PL-524-050_03				
2.3.		ZBP-XX--PL-524-023_01				
2.4.		ZBP-XX--PL-524-004_03				
2.5.		ZBP-XX--PL-524-005_02				
2.6.		ZBP-XX--PL-524-015_04				
2.7.		ZBP-XX--PL-524-007_02				
2.8.		ZBP-XX--PL-524-028_02				
3.	Zoning comments generally					
3.1.	AHUs serving ward areas A and C	Where there are areas within wards which are unlikely to be used at night , can ventilation be reduced to these areas- e.g. dayrooms, treatment rooms offices, school rooms etc?		ZBP-XX-03-PL-524-303_02		
3.2.	41 AHU 22 2 nd floor NCH admin areas	This only serves office and daytime use area – is there any potential for mixed mode here or for air flow related to internal temperature only? Is it full fresh air or can recirc be introduced here?			Minimal fresh air therefore no point in recirculation. Openable windows not possible at this stage	
3.3.	Isolation AHUs	Is there any form of control			Discussed and to be referred to	BE/ZBP

		so that when these areas are not in use, they shut down or go onto low volume and uncontrolled temperatures (indications and local control to bring areas up to "room ready" may be required)			Board – operational policy needed - note that room ready indication would be needed in any case for +ve,-ve operation and in case unit has a fault or is shut down for maintenance.		
3.4.	Circulation and storage	How are these heated/ventilated?			(please confirm response)	BE/ZBP	
3.5.	31AHU26 Endoscopy	Configuration for this unit? Is all extract through PHX?			Please confirm – this unit was either not on schematic or on a drawing we could not open	BE/ZBP	
3.6.	IT hubs	Do these have supplementary cooling and if so, how is this achieved?			Confirmed that this is from central chilled water. Further development needed here as 1. Chillers may be required all year to serve these distributed areas – free cooling via air only to be considered for majority of year 2. Need to combine with IT meeting to discuss target PUE and means of air distribution plus potential for natural cooling (possibly with chiller back up)	BE/ZBP/EL/NHSGGC	
3.7.	Control generally	Where AHUS serve rooms with varying heat gain, how is individual room temperature control achieved?			Needs further discussion – to be reviewed with controls	BE/ZBP/EL	
3.8.	33AHU01 renal? area		Staff base and store			BE/NA	

			if reversed would give staff view out				
3.9.	As above		Planning around the reception/plant/waiting / changing creates large internal office – could any re-planning here for example relocating the staff change create a better staff environment and reduced lighting energy consumption?			BE/NA	
3.10.	31AHU29 staff areas	There appears to be a mix of 24 hour and 12 hour areas here – how is the unit sub zoned?	The staff change areas have access to daylight via the atrium, whereas various offices and 4 person workstation area do not - could any re-planning here for example relocating the staff change create a better staff environment and reduced lighting energy consumption?		Consider sub zoning – need to develop with board more accurate and detailed occupancy patterns to establish the most efficient way of serving this and the remainder of the theatre areas.	BE/ZBP	
3.11.		Local override controls could be useful to overnight room			General issue where there are isolated 24 hour areas within	BE/ZBP	

		– to top up heating when rest of unit is on setback for example which time out automatically			zones which are otherwise 24 hour – to be considered on full review of detailed design	
3.12.	31AHU17 and all other theatre plant and recovery areas	How are these controlled and is there a setback facility to each?			Set back facility confirmed to all theatres but noted that extended hours and 24 operation to emergency theatre likely. Recovery – 2 areas – detailed discussion on usage patterns needed to establish if one area can be set back.	
3.13.	31AHU27	Is this a day case areas – it incorporates the lift lobby areas - is it 12 hour only or 24 hour and again what if any are set back arrangements ?			Please confirm – need to review lobbies generally.	BE/ZBP/EL/NHSGGC
3.14.	31AHU30	This appears to be a general clean area ancillary to theatres – presumably positive pressure area. – is there set back/ variable volume to this area and how is it controlled? Is there heat recovery to the extract?			Heat recovery confirmed in schematics. Set back confirmed as possible – see 3.12 above	
3.15.	41AHU25 and wards generally with regen kitchens	What is likely heat gain to the area, what happens to the extract and is there opportunity here for heat reclaim?		ZBP-XX-03-PL-524-305_02	Regeneration kitchens need further consideration and detail design. To be reviewed once equipment type more developed. Confirmed that heat reclaim from extract is planned. Consider serving regeneration	BE/ZBP/EL/NHSGGC

					kitchens from dedicated plant with no cooling	
3.16.	41AHU25 – children’s wards generally	There are quite large daytime only areas from grid R13.1 west – these could be mixed mode.			Sealed building decision now taken. Sub zoning of daytime only areas to be considered – where these are at the end of distribution, dampers would be possible to VSDs. Detailed patterns of use to be discussed,	BE/ZBP/EL/NHSGGC
3.17.	All Adult ward plant	Public core areas are served from ward plant – is it necessary for this area to have cooled air and would simple vent plant with heat recovery be more economical?		ZBP-XX-03-PL-524-306,7_02	These areas are circulation and waiting only. Extract and simple local vent to waiting rooms would appear to be sufficient. BE/ZBP to confirm	BE/ZBP/EL/NHSGGC
3.18.		As comment 3.1				
3.19.	121AHU07 122AHU07 CORE AREAS PLANT	What is confirmation of units and can these be simple vent without cooling?			As 3.17 above	BE/ZBP
3.20.	Kitchen 31AHU61	How is heat recovered from chilled areas – opportunity to preheat supply air – need to discuss refrigerant heat reclaim options for this area		ZBP-XX-03-PL-524-300_02	This area is understood to be under development. The chilled production areas would be capable of heat recovery and the heat used for adjacent areas	BE/ZBP
3.21.			I assume main kitchen layout still in production?		The kitchen layout is still in development. The schematics show full conditioned air to the kitchen. It was suggested that the canopies should be untempered filtered air only and conditioned air used for background ventilation to kitchen only	BE/ZBP

3.22.	22AHU25	Is this a basic vent unit as serving storage only? I would suggest demand based time out control to maintenance area heating as this is likely to be intermittent and entire area can then be heated to say 16C only with no cooling			To be confirmed	BE/ZBP
4.	Ventilation schematics					
4.1.	General comments based on 21AHU01	Is carbon filtration to be fitted and permanently active? This will significantly increase energy use and maintenance cost of plant even when there is no need of carbon filtration. Could a bypass be arranged so that carbon filter is only used when necessary?		ZBP XX XX SC 524 701_02	This needs discussion at main design meeting – it was acknowledged by all that the carbon filtration will have a high pressure drop and therefore high impact on the fan energy consumption. It was agreed that a whole life cost should be developed for a sample AHU looking at the life cost in energy, maintenance and capital cost terms for a range of options including carbon filtration – options for this include omission of carbon filtration or a bypass arrangement. The results to be contained in brief report for presentation to board.	BE/ZBP by next meeting
4.2.		I assume heat recovery device is a thermal wheel – please confirm, is there a control mode such that that when free cooling is possible, heat is not			To be developed further in controls discussion	BE/ZBP

		recovered from exhaust?				
4.3.		Motor drive - belt or direct? Belted and running to both motors or one – what is relative motor frame size for these options? Have integrated variable speed motors been considered?			The options for direct and belt driven to be considered in WLC terms as 4.1 above.	
4.4.		What are filter ratings and clean/dirty settings?			To be confirmed and reviewed.	BE/ZBP/EL
4.5.		How is VSD configured?			To be confirmed and reviewed.	BE/ZBP/EL
4.6.		Are MD1 and 2 for maintenance only? If so are these necessary as motorised – isolation plates decrease airstream resistance – for discussion			To be confirmed and reviewed.	BE/ZBP/EL
4.7.		VSDs- performance spec to consider efficiency and losses – what is best and worst on market and suppliers to be chosen on WLC			VSD choice and effect of best and worst to be part of WLC review	BE/ZBP/EL
4.8.		Have we now confirmed that the motors and fans are not to be oversized?			Discussion took place on the means of achieving the ER's requirement for 25% spare capacity. Option A Over sizing fans and motors is least favoured option as the fan efficiency is likely to be poor for the life of the plant. Option B Space for additional plant and	BE/ZBP by next meeting

					ductwork is possible but the additional plant and riser space is significant and the cost and complication of retrofitting additional plant is substantial Option C A further option which is favoured on carbon saving grounds is providing plant sized at 25% lower face velocity – i.e 2.0m/s as opposed to 2.5m/s. This is a modest increase in plant room and riser size compared to option B and has the further advantage of saving in fan power for the life of the plant until any upgrading is required. When upgrading is required, the fans would be changed to the higher duty which is a relatively simple and low cost operation. Option C is therefore recommended – to be confirmed by WLC cost exercise and to wider design team	
4.9.		Are all motors HEMs			Confirmed – to be checked through detail design.	
4.10.		What is face velocity? (payback 2.5 to 2.0 is <3 years typically)			See discussion in 4.8 above – to be part of WLC exercise	
4.11.		Fan efficiency- see design guide			Choice of DD or belt drive and the motor in or out of airstream	

Comment [SCL final1]: The choice of drive mechanism and motor type will also yield considerable energy-savings potential. Additional energy savings of 2 to 5 W/ft² (21.6 to 54 W/m²) may be achieved with the substitution of high-efficiency motors for standard-efficiency motors. The choice to use fans with motors outside the primary air stream will save 1.0 to 1.5 w/ft². (10.7 to 16.15 W/m²) due to motor inefficiency, but removal of the motor from the air stream by using belt-driven fans with lower mechanical efficiencies will reduce the energy savings. High-efficiency motors have an inefficiency of 6% to 8%, whereas belt-drive systems have inefficiencies of 4% to 6%. The use of special direct-drive fans with motors outside the air stream (bifurcated fan housings) may result in higher system effects and lower total efficiency.

		Discussion needed on whether proximity of HR will allow fan to develop full performance			to be considered as part of WLC exercise as above		
4.12.		Coli design – compare pressure drops between manufacturers which can vary considerably for the same performance			To be further developed in detail design.	BE/ZBP/EL	
4.13.		Overall what is target SFP _v ?			Calculate typical for WLC exercise – discussed that SFP overall would need to be calculated for Building Warrant but that this is likely to be an average value as AHU SFP likely to be higher than extract.	BE/ZBP by next meeting	
4.14.		See comments above re zoning- is clinical staff office 12 or 24 hour?			All zoning to be re-reviewed as detail design progressed	BE/ZBP	
4.15.		Reheat arrangements – can room temp sensors reschedule off coil to prevent wasteful reheat?			To be further considered during controls review	BE/ZBP/EL	
4.16.		Are cooling and main reheat coils in ahu interlocked to prevent simultaneous operation?			To be further considered during controls review	BE/ZBP/EL	
4.17.		What are economics for heat reclaim from dirty extract?			This required further discussion at wider team level. There are considerable economies to be gained both in space, capital cost, carbon and running cost terms by omitting separate dirty extract provision. HTM03-01	BE/ZBP	

					states that "Extract ventilation is required in sanitary facilities, dirty utilities and rooms where odorous but non-toxic fumes are likely; this is to ensure air movement into the space. A single fan/motor unit should be provided to meet this need. There is no healthcare requirement to provide a separate foul/dirty extract system." Whilst it is appreciated that the equivalent SHTM does not have this provision, it was agreed that as an update in the near future of the Scottish standard may follow the precedent set by the English standard, it is worth seeking derogation of the requirement for separate twin dirty extract. This will enable all heat from extract to be recovered	
4.18.		Is supplementary heating or cooling proposed in spaces served?			It was agreed that this was hard to follow across the various drawings issued to date. A marked up set of drawings is to be prepared which demonstrates the control	BE/ZBP by next meeting

					heating cooling and ventilation strategy to each space – this can be colour coded and initially cover the 5 designed departments		
4.19.	21AHU08-17 critical care isolation	As comments above 4.1 4.3 4.4-4.13 4.16 4.18	ZBP XX XX SC 524 707_02		See comments above		
4.20.		What are economics for heat reclaim from extract?			See comments above		
4.21.		Is fan to be sized for future HEPA – if so, how does this affect efficiency and would it be better to accept a future fan change if very inefficient selection likely?			Fan change suggested as a strategy – to be agreed with wider design team	BE/ZBP/EL	
4.22.		See also zoning comments re set back – room ready could be added to nurse panel			See comments in 3.3 above	BE/ZBP	
4.23.	Acute assessment ward 21 AHU24	As comments above 4.1 4.3 4.4-4.13 4.15-18 (single motor noted)		ZBP XX XX SC 524 714_02	See comments above	BE/ZBP	
4.24.		Are DE and CE volumes reversed?			To be confirmed and clarified	BE/ZBP	
4.25.	Adult A&E 21AHU28 and 29	What is the criteria for thermal wheel versus PHX and what is the impact in loss/gain of efficiency?			To be part of the WLC exercise	BE/ZBP by next meeting	

Comment [SCL final2]: Synchronous belts are stretch-free and can achieve higher efficiency than V-belts due to lower hysteresis, lower friction losses, and truly synchronous operation (no slip; no creep). The lower flexing losses result from the small thickness of the belt between the teeth. The absence of speed losses (slip and creep) is due to the positive mating of the teeth of the belt with the teeth of the sprockets. Because of these lower losses the synchronous belts have not only higher peak efficiency than V-belts, but also the efficiency curve is flatter. Synchronous belts require toothed pulleys (sprockets), which are more expensive than V-belt pulleys. In a retrofit application, the additional investment required is the cost of the sprockets, plus the extra cost of the belts and of the installation. In the cost-effectiveness calculations it is assumed that those extra costs fall in the range \$8-16/hp. This price variation is strongly dependent on the rating of the belt drive, with the large drives requiring a smaller price premium per horsepower. The sprockets typically cost 1.5-2 times the cost of belts (the second and third purchased at future times and thus discounted) and one set of sprockets. Additionally, it is assumed that there is an average 5% efficiency improvement and that the belt will last 24,000 operating hours. Synchronous belts provide slip-free synchronous operation, have a long lifetime, and can operate in wet and oily environments. Their operation can be noisy at high speed and their main weakness is the lack of capability to absorb shock loads.

4.26.		Is single temperature detection sufficient within spaces ?			Needs further discussion – to be reviewed with controls	BE/ZBP/EL
4.27.		As comments above 4.1 4.3 4.4-4.13 4.15-18			See comments above	
4.28.	Theatres 22AHU11-13 ultraclean	As comments above 4.1 4.3 4.4-4.13 4.15-18		ZBP XX XX SC 524- 747_01	See comments above	
4.29.	Theatres 22AHU14-17	As above		ZBP XX XX SC 524 748_01	See comments above	
4.30.		What is function of humidistat? Is this to control high limit only?			Confirmed as high limit as no humidification.	
4.31.	Theatres 22AHU01/02/09/10-20	As above		ZBP XX XX SC 524 801_02	See comments above	
4.32.	Theatres 22AHU03-08 ultraclean	As above		ZBP XX XX SC 524 802_02	See comments above	
4.33.	Theatres Recovery 31AHU21/22	As above		ZBP XX XX SC 524 803_02	See comments above	
4.34.		Zone control not shown as yet			Needs further discussion – to be reviewed with controls	BE/ZBP/EL

4.35.	X ray 31 AHU52 Adult radiology etc 31AHU55	What is the criteria for thermal wheel versus PHX and what is the impact in loss/gain of efficiency?		ZBP XX XX SC 524 833_03 ZBP XX XX SC 524 836_02	Needs further discussion – to be reviewed with controls	BE/ZBP/EL
4.36.		Is single temperature detection sufficient within spaces ?			To be further considered during controls review	BE/ZBP/EL
4.37.		As comments above 4.1 4.3 4.4-4.13 4.15-18			See comments above	
4.38.	MRI unit	As X ray above plus		ZBP XX XX SC 524 834_01	See comments above	
4.39.		What is ethos for reheats? Is heat gain here likely to be less or greater than ancillary and anaesthetic areas or do these areas have supplementary heating?			Needs further discussion – to be reviewed with controls	BE/ZBP/EL
4.40.		What is function of humidity detector – is this to control high limit in space?			Confirmed as high limit as no humidification.	
4.41.	Restaurant and kitchen 32 AHU 02	The riser runs for the extracts are very long – I assume there is no other possible discharge locations? What are velocities in ducts	Location of kitchen problematic – need to consider intermediate plant area	ZBP XX XX SC 524 852_02	Acknowledged that location undesirable due to fire risk and maintenance difficulty as well as energy considerations.	BE/ZBP/EL/NHSGGC

		and likely SFPs?				
4.42.		It seems wasteful to supply canopy with conditioned air – have untreated canopy supply been considered ?			See comments in 3.20 above	
4.43.		As comments 4.1 4.3-13 4.16 4.18			See comments above	
4.44.		What is the function of the reheat to the restaurant?			To be further considered during controls review	BE/ZBP/EL
4.45.		Are extracts interlocked to equipment operation and can supply volume reduce when major extracts are not operating?			To be further considered during controls review	BE/ZBP/EL
4.46.	Renal dialysis 33AHU01	As comments 4.1-4.13, 4.15-18		ZBP XX XX SC 524 861_03	See comments above	
4.47.		Is there an opportunity to recover heat from renal RO plant?			To be further considered during detail design review	BE/ZBP/EL
4.48.		Is this a daytime only plant ?			To be confirmed	BE/ZBP
4.49.	NSH OPD 41AHU 05	As comments 4.1-4.13, 4.15-18		ZBP XX XX SC 524 874_02	See comments above	
4.50.		Is this a daytime only plant ?			To be confirmed	BE/ZBP
4.51.	NCH atrium 41 AHU09	As comments 4.1-4.13, 4.15-18		ZBP XX XX SC 524 878_02	See comments above	
4.52.		Full conditioning of this			Needs further consideration	BE/ZBP

		space which is primarily circulation seems uneconomical – can summer temps be moderated by opening vents and winter by exhaust from adjacent heated areas?			and discussion	
4.53.		Is this a daytime only plant?			To be confirmed	BE/ZBP
4.54.	Perimeter bedrooms 121 AHU 01, 2 and internal; areas plant, ward central core plant 121AHU07	As comments 4.1-4.13, 4.15-18		ZBP XX XX SC 524 901_02 ZBP XX XX SC 524 902_02 ZBP XX XX SC 524 903_03 ZBP XX XX SC 524 907_02	See comments above	
4.55.		How are temperatures scheduled – is it room control to terminal units only and plant at set off coil temperature? If so is there allowance for seasonal shift?			To be further considered during controls review	BE/ZBP/EL
4.56.		Internal spaces plant – I assume no supplementary heating to these areas?			To be further considered during controls review	BE/ZBP/EL

4.57.		Is cooling necessary to core plant?				
4.58.		Why thermal wheel to core plant?			Philosophy of thermal wheel versus PHX to be considered in WLC exercised	BE/ZBP by next meeting
5.	Ventilation layouts					
5.1.	Second floor adult theatres	Noted- terminal velocities <2.5m/s - is this the same for all terminals ?		ZBP-XX-- PL-524-024_03 ZBP-XX-- PL-524-025_02	Confirmed	
5.2.						
5.3.	First floor restaurant and NSC theatres	Electric heater battery – avoid if possible – are there any more of these?		ZBP-XX-- PL-524-016_04	Error – to be amended in detail design	
5.4.	Isolation/CCU	No comment		ZBP-XX-- PL-524-017_03		
5.5.	Renal dialysis and dermatology OPD	No comment		ZBP-XX-- PL-524-029_02		

Proposal to Relocate Adult haemopoietic Stem Cell Transplant Service From Beatson West of Scotland Cancer Centre to Queen Elizabeth University Hospital

1. Introduction

This paper outlines the background to the current situation within BMT services. The paper details the enabling works and monitoring processes that have been undertaken since the last paper to the Acute Services Committee in March 2017.

The paper recommends that the service relocates from the Beatson West of Scotland Cancer Centre to Ward 4B at the Queen Elizabeth Hospital as originally intended.

The Acute Services Committee is asked to endorse this recommendation.

2. Background

NHS Greater Glasgow and Clyde is commissioned by National Services Division to provide all adult allogeneic donor stem cell transplantation for the population of Scotland. The national service covers both stem cell donation from family members and unrelated donors. The SLA value in 2016/17 was £7,904,092 for 70 transplants. This is proposed to increase to £8,114,359 for 73 in 2017/18, with on-going increases in activity predicted.

In 2013, a decision was taken to move the BMT service from wards B8/B9 at the BWoSCC to the new QEUH. This was to address concerns that the planned level of support for acutely unwell patients on the Gartnavel General Hospital (GGH) site would be insufficient for such a high intensity speciality as BMT and would not meet the JACIE accreditation standards. The move also allowed for an increase of beds from 19 to 24 to support the agreed increase in the national transplant programme.

Capital funding of £1million was invested to support enabling works to 4B, such as upgrade air filtration plant, and the BMT service moved to the QEUH in May 2015.

Following the identification of air quality issues in the new transplant unit, the service was, however, returned to B8/9, BWoSCC in July 2015. This return was predicated on it being short-term, with further remedial works to be undertaken to improve the air quality in ward 4B QEUH to acceptable levels. Remedial works were completed by October 2015 and at this time the service began to make plans to move back to QEUH.

The Infection Control Team raised concerns regarding the specification of works that had been completed and requested input from Health Protection Scotland (HPS) at this time. Following the receipt of recommendations from HPS with regard to the required specification, the Infection Control Team advised that the specification did not meet the required environmental standards for a BMT Unit and therefore, they were unable to support return to the QEUH. The BMT service has remained at BWoSCC since this time. The

clinical team have on-going concern about delivering a safe and sustainable service from the BWoSCC site, given high demand for critical care support and support from other medical and surgical specialties for transplant patients.

In the autumn of 2016, a further feasibility study commenced into potential options utilising retained estate on the QEUH site. A report was produced in January 2017 and a multi professional option appraisal was undertaken. From this, the conclusion drawn was that further options on the QEUH site at this stage were neither technically, clinically nor financially viable.

The two options that remained for consideration were remaining in the existing location on B8/9 in BWoSCC or relocation to 4B at QEUH as per the current specification. Following a detailed option appraisal process, involving clinical teams, infection control and Health Protection Scotland the Acute Services Committee at their meeting in March, 2017 approved a monitoring period of the ward 4B environment be undertaken to reassess the environmental suitability of transferring the BMT service to QEUH.

3. Process

Enabling works were performed from October to December 2017 to include new solid ceilings in the en-suite areas, replacement of filters, HEPA filtration unit installed in drug preparation area, heating controls rewired to eliminate control issues and door control devices fitted to improve the pressure differentials. Validations and permeability testing were performed and confirmed as satisfactory.

In October 2017, a robust process for assessing the effectiveness of this work to provide an appropriate protective environment for patients undergoing transplantation was developed in consultation with Health Protection Scotland, Health Facilities Scotland and expert external advice. An SBAR was produced and the subsequent monitoring and validation has been completed according to these recommendations.

4. Air Monitoring

Weekly monitoring started in January 2018 for an agreed period of 6 weeks, with non-transplant haemato-oncology patients in the ward to ensure testing in real-world conditions. The air sampling results were as expected with counts generally <1000 given the unit specification and are deemed satisfactory for the intended purpose of the unit.

Active air sampling has revealed low fungal counts including *Aspergillus* and *Mucor* – this is to be expected given the lack of a HEPA filtered corridor. These counts were mainly in the corridor area rather than the HEPA filtered rooms. In view of this, keeping doors closed to rooms is essential.

Moving forward we would plan to institute monthly air sampling with the same parameters as those used in the Beatson BMT unit i.e. particle counts <1000. Fungal colonies would trigger a review by the infection control doctor.

5. Water Monitoring

Water testing for *Legionella* and *Pseudomonas* is negative. Regular testing will be undertaken. There is a water contamination incident in QEUH and RHC with several different

Gram negative environmental bacteria and fungi. There have been no patient cases in ward 4B linked to water contamination. The source has been traced to the taps and showerheads and possibly contaminated pipework. The same taps and showerheads are in 4B therefore, the same control measures will be employed. Shower heads will be changed to disposable. All outlets in 4B have filters which is a short term control measure. Expert opinion is being sought with regards to long term control measures which will likely include different taps and chemical dosing. Fungi can be difficult to eradicate from water therefore the likely recommendation will be point of use filters in the long term.

6. Meeting to Review Monitoring Results

All relevant parties including representation from HPS, HFS, NSS met in March 2018 and agreed that testing to date was satisfactory and if confirmed in a final round of testing, the group would recommend the transplant unit to return to the QEUH. This has now been completed with recent results consistent with previous monitoring results.

7. Contingency Planning

There is an agreed contingency plan utilising mobile HEPA filter units in the event of a ventilation failure.

The costs associated with this are £100,000 to include 25 mobile units, 2 industrial supply units and critical spares.

8. Summary and Recommendation

The enabling works and subsequent validation and monitoring have been completed according to the SBAR recommendations and confirms the environment in ward 4B is appropriate for transplant patients. It is therefore recommended that the BMT unit return to the QEUH as soon as practicable with proposed date of 16th June 2018.

The Acute Services Committee is asked to endorse the recommendation that the BMT service moves back to QEUH in June 2018.

Gram Negative Bacteraemia (GNB) and Mycobacterium *chelonae* Incident Management Team

Date Agreed Action	Action	Responsible Person/s	Completion Date	Status/Update
23/08/19	John Mallon will get new stickers to be made up which will easily identify water samples requiring testing in relation to this incident.	John Mallon	Ongoing	
23/08/19	IPCT to see if any surveillance has been carried out in the past regarding paediatrics which the IPCT can pick up on	IPCT	Ongoing	
23/08/19	Standard Operating Procedure is to be written to outline requirements if a patient is moved out with Ward 6A.	IPCT	Ongoing	
23/08/19	Biocide is to be introduced to the chilled beams water.	Estates	Ongoing	
23/08/19	Revised SOP regarding the cleaning of chilled beams is to be sent to Dr Inkster	Estates	Ongoing	
23/08/19	Public toilets out with ward 6A including the disabled toilet are to be closed.	Estates	Ongoing	
23/08/19	Increase the dosing of chlorine dioxide to 0.7 PPM	Estates	Ongoing	
23/08/19	HEPA filtration units are to be fitted to en-suite bathrooms in Ward 6A.	Estates	Ongoing	
23/08/19	Timeline of when the boiler lost pressure and increased condensation is being compiled by Estates and will be mapped against patient timeline	Estates	Ongoing	
23/08/19	Unfiltered water from Ward 6A DSR is to be tested along with water from DSR in PICU	Estates	Ongoing	
23/08/19	Point of use filter to be fitted to DSR within PICU	Estates	Ongoing	
23/08/19	Briefing communication for staff and patients/family are to be created	Lorraine Dick Jenn Rodger	Ongoing	
23/08/19	A holding statement for the press is to be written up	Lorraine Dick	Ongoing	
23/08/19	Peer review of ward 6A by someone from Great Ormond Street or Leeds Children Hospital is to be arranged	Dr Emilia Crighton	Ongoing	

Date Agreed Action	Action	Responsible Person/s	Completion Date	Status/Update
23/08/19	Walk round to Ward 6A by HPS is to be organised.	Annette Rankin	Ongoing	
23/08/19	Air testing is to be carried out within the Room 6 en-suite as new HEPA filter unit has been installed.	Estates	Ongoing	
23/08/2019	William Hunter is to investigate the details of the new scrubbing machine that Emma Somerville reported on being used within Ward 6A.	William Hunter	Ongoing	
23/08/2019	Replace sink and IPS panel within Ward 6A DSR to enable a different tap to be fitted so a point of use filter can be installed.	Colin Purdon	Ongoing	
23/08/19	Access to filtered water domestics can use while the sink in Ward 6A DSR is not being used.	Estates	Ongoing	
23/08/2019	Check that Ward 2A/2B RHC refurbishment are not installing similar sinks within the DSR where point of use filters cannot be used.	Colin Purdon	Ongoing	
14/08/19	Stefan Morton is to carry out hand hygiene training for staff within Ward 6A.	Stefan Morton	Ongoing	Extra teaching has been planned for the next few weeks
14/08/19	Push fittings are to be replaced with mechanical fittings for the chilled beams.(4 replacement connectors in each room) This will be carried out as soon as possible.	Colin Purdon	Ongoing	
08/08/19	Environmental samples of the chilled beams are to be taken within Ward 6A and compared with samples taken of chilled beams in a spate area out with ward 6A.	Teresa Inkster	Ongoing	
08/08/19	Clinicians have requested 2 additional beds be made available within Ward 4B, BMT, QEUH to accommodate immunocompromised patients.	Dr Emelia Crighton	Ongoing	Dr Crighton will see if there is two additional beds for patients within Ward 4B, QEUH
08/08/19	An option appraisal meeting is to be held to set out possible solutions if Ward 6A is to relocate.	Kevin Hill	Ongoing	
08/08/19	Point of use filters to be fitted to taps within Clinic 2, RHC. Some sensor taps may need replaced in order to fit filters.	Colin Purdon	Ongoing	Estates haven't identified a suitable tap to replace sensor taps which are unable to be fitted with point of use filters. An alternative tap is to be procured.

Date Agreed Action	Action	Responsible Person/s	Completion Date	Status/Update
03/07/19	Alan Gallagher is to create a detailed plan on what measures will be taken to minimise disruption to patients and clinical service when shock dosing treatment is implemented.	Alan Gallagher Teresa Inkster	Ongoing	Water experts were contacted on 13th August. They have requested for more extensive testing around the campus to ascertain how extensive mycobacteria is throughout the hospital. Dr Inkster has asked to see a report on what has been done regarding the water dosing, including water samples that have been taken. Water group are meeting on Friday 16th August to discuss further. Estates have concerns regarding the problems which occur when carrying our shock dosing to Ward 6A as a whole tower will need shut down to implement this. Increase of dosing has been carried out from 0.2 to 0.5 PPM on 5th July 2019
25/06/19	Annette Rankin is to obtain a list of all positive M.Chelonae cases in Scotland. She will also do a report of all gram negative bacteramias and compare them between hospitals. About the nature of the organisms	Annette Rankin	Ongoing	Annette will send an SBAR relating to this to Dr Inkster tomorrow morning. Last two cases will be added onto her report. AR will send out next week w/b 19/8

Date Agreed Action	Action	Responsible Person/s	Completion Date	Status
COMPLETED				
08/08/19	Estates to explore if it is possible to add in Chlorine Dioxide to the sealed water supply within the chilled beams.	Tom Steele	Complete	Estates have spoken to the chilled beams service provider who have experienced dosing the system with biocides. They require to know what has been found in the system so they know what biocides are required but will need to make sure there is no chemical reaction. Adding more chemicals to the chilled beams may cause other problems if there are any future leaks from them.
08/08/19	Lorraine Dick is to set up a meeting to discuss how future correspondence can be given to patients/staff.	Lorraine Dick	Ongoing	Lorraine is meeting with Kevin Hill at the end of this week to discuss. Patients/parents are given a weekly update with staff given written communication so they can refer to if questioned.
08/08/19	John Mallon and facilities are to meet to discuss future labelling of samples.	John Mallon	Ongoing	Colin spoke to DMA not enough room on bottles to put location on it so they put codes on bottle and create a sheet with a list of codes. They will now send the list of codes. Getting lot of water samples through find easy way what to test water for. Look for a sticker or an analysis so that they know what the lab have to test for/target. DMA to have specific form or have a specific sticker for water testing regarding this incident. John Mallon will get office staff to come up with new stickers in which DMA can use for future water testing.
08/08/19	Sink within Nuclear medicine used to dispose of isotopes is to be investigated.	Colin Purdon	Ongoing	A partition has been placed between the two sinks. Colin Purdon will try and procure a tap that a point of use filter can be fitted to this sink. Been some resistant from department but this has since been resolved.
08/08/19	Updated timeline of all patients involved regarding this incident is to be sent out to the group. Dr Inkster will send Gillian Bowskill of a 2 nd possible case to be added onto the time	Gillian Bowskill	Complete	GB to send updated timeline electronically to clinicians. Sent out this morning.

Date Agreed Action	Action	Responsible Person/s	Completion Date	Status
14/08/19	William Hunter is to find out if the scrubbing machines used in Ward 6A use Actichlor solution within them	William Hunter	Ongoing	William looked at scrubbing machine there was a slight residue of water after. Solution has been changed to Actichlor after finding out it was filled with unfiltered water with a neutral detergent solution. Emma Sommerville reported that there now seems to be different scrubbing machine being used within the ward which William Hunter will investigate.
14/08/19	Tom Steele is to send Dr Inkster the Data sheet regarding the a sample HEPA filtration unit which can be deployed within patients en-suites.	Tom Steele	Ongoing	This has been installed into Room 6, Ward 6A.
14/08/19	Toilet seat covers are to be fitted to patient en-suites	Colin Purdon	23/08/19	Complete
03/07/19	ARJO bath is to be removed from Ward 6A and cap the water outlet to the bath once approval has come from Anne Harkness	Darryl Connor	14/08/19	It was agreed that the water pipes will be capped so minimal disruption to ward. Scribe has been prepared and awaiting the go ahead for the decommission for this.
08/08/19	Look into a device that could gather all the condensation from chilled beams and be collected centrally within the ward	Colin Purdon	N/A	This has been taken off the action plan as there should be no condensation coming from the chilled beams.
08/08/19	Mechanical lock to be fitted to public toilet at the entrance of Ward 6A.	Colin Purdon	14/08/19	Complete
08/08/19	Alan Gallagher is to circulate his action plan regarding how estate/facilities issues are managed within Ward 6A.	Alan Gallagher	14/08/19	Complete
08/08/19	List of patient that are planned to come into Ward 6A is to be obtained.	Brenda Gibson	14/08/19	Complete
01/08/19	Water samples from the chilled beams are to be taken	Darryl Conner	08/08/19	Complete
01/08/19	The new algorithm regarding the functionality of the chilled beams is to be implemented	Colin Purdon	08/08/19	Complete
01/08/19	Chilled beams are to be cleaned every 6 weeks instead of 3 months. Estates will link in with SCN to ascertain availability of patient rooms	Darryl Conner	08/08/19	Complete

Date Agreed Action	Action	Responsible Person/s	Completion Date	Status
01/08/19	Dr Inkster will send the en-suite room numbers from where the positive air samples originated room so estates can look into possible sources.	Teresa Inkster	08/08/19	Complete – no obvious source
01/08/19	The introduction of Ciprofloxacin is to be given to patients if clinicians are in agreement?	Brenda Gibson	08/08/19	Complete
01/08/19	Peer audit of patient central line care is to be carried out by the practice development educator in conjunction with the Infection Control Team.	Jenn Rodgers	08/08/19	Complete
01/08/19	Gillian Bowskill and Sandra Devine will complete HIORT to be sent to Dr Inkster then onto HPS	Gillian Bowskill Sandra Devine	08/08/19	Complete
01/08/19	Agreement on general communication that can be shared between patient's/parents and NHS staff.	Teresa Inkster Kevin Hill Lorraine Dick	08/08/19	Complete
01/08/19	Dr Kennedy will send out his epidemiology findings comparing infection rates from the old Yorkhill site to the new RHC site.	Iain Kennedy	08/0/819	Complete – this will be added to the agenda for the next IMT as Dr Kennedy was not present.
03/07/19	Sink within DSR may be getting a retrofitted filter attached to it. Currently speak to manufacturer	Darryl Conner	N/A	This was taken off action list as no Point of Use filter can be found that would fit this sink. Ongoing struggling to find a filter that is suitable to fit. This is not do able take off action plan.

Date Agreed Action	Action	Responsible Person/s	Completion Date	Status
03/07/19	Drain cleaning is to be carried out in Nuclear Medicine and MRI where ward 6A patients have been visiting.	Darryl Conner	08/08/19	Complete - Work in progress, sink used in Nuclear medicine radioactive waste is put down the sink. Darryl will need to check drainage. Complete.
03/07/19	All point of use filters removed for routine replacement are to be labelled and kept until water results have been returned	Darryl Conner	01/8/19	Complete
03/07/19	Every 2 weeks water testing is to be carried out for half of Ward 6A then carried out for the other half	Darryl Conner	01/08/19	Complete - for water testing for all cold taps every 2 weeks
03/07/19	Karen Connelly will contact Anne Harkness to seek approval for the removal of the ARJO bath.	Karen Connelly	01/08/19	Complete
03/07/19	Tap within unused prep room in ward 6A is to be replaced as no point of use filter can be fitted.	Darryl Conner	01/08/19	Tap has been replaced but water is now hitting the back of the sink. The sink has been put out of use.
03/07/19	Dr Inkster & Prof Gibson are to meet up with Steve Russell to discuss the current development of ward 2A/2B, RHC	Teresa Inkster Brenda Gibson	01/08/19	Dr Inkster & Prof Gibson have met with Steve Russell and Hazel McIntyre from Capitol planning and signed off the design for Ward 2A/2B.
25/06/19	Patient recently transferred to Edinburgh Children's Hospital is to be included in the Gram Negative patient timeline	Susie Dodd	25/06/19	Complete
25/06/19	Dr Iain Kennedy is to contact Scottish water to obtain samples of water being sent to QEUH campus to be tested within our own labs. Samples have been obtained from properties beside the QEUH and also from the Gartnavel site.	Dr Iain Kennedy	01/07/19	Complete
25/06/19	Darryl and Gael to meet up to confirm when the best time to fit point of use filters to areas where Ward 6A patients are likely to attend i.e. Theatres	Darryl Conner Gael Rolls	01/07/19	Complete

Date Agreed Action	Action	Responsible Person/s	Completion Date	Status
25/06/19	Modification to the aluminium sphigots within CHWB in Theatres & CDU will be undertaken. Unable to carry out due to technicalities so it was agreed that bottle brushing the drains will be carried out instead.	Darryl Conner	01/07/2019	Complete
25/06/19	Increase dosing of chlorine dioxide is to be undertaken to the water supply	Colin Purdon	01/07/19	Complete
25/06/19	Additional hand hygiene step involving gelling of hands after being washed is to be introduced.	Gael Roll	01/07/19	Complete
25/06/19	Water samples are to be taken from chilled beams from Ward 6A	Darryl Conner	01/07/19	Complete
25/06/19	A log of when and where water leaks have happened due to the chilled beams is to be completed.	Darryl Conner	01/07/19	Complete
25/06/19	Air sampling for bacteria within Ward 6A is to be carried out while water is running into a CHWB to see if aerolisation is present	Dr Teresa Inkster	01/07/19	Complete
25/06/19	Kevin Hill & Dr Chris Deighan will take forward at Executive level regarding incidence of similar cases of Gram Negative Bacteraemia within similar units in with the rest of the UK.	Kevin Hill Dr Chris Deighan	01/07/19	Complete
25/06/19	Sandra Devine spoke to Dr Jennifer Armstrong about informing Edinburgh Royal Infirmary about testing their water supply before opening. She has requested that this should be carried out in a national forum and asked HPS for clarity. HPS informed the group that ventilation and water issues have been discussed at length between HPS and HFS	Sandra Devine	01/07/19	Complete
19/6/19	Compile Timeline of M.chelonae case (SJK)	Susie Dodd	20/06/19	Complete
19/6/19	Apply POUFs to theatre outlets	Colin Purdon	21/06/19	Complete
19/6/19	Check water cooler removed from 6A staff room	Colin Purdon	20/06/19	Complete
19/6/19	Carry out water testing in ward 6A pre and post POUFs (incl showers) and in theatres pre POUF application.	Colin Purdon	24/06/19	Complete

Date Agreed	Action	Responsible Person/s	Completion Date	Status
19/6/19	Water testing to be undertaken on outlets identified from timeline which currently have no filters.	Colin Purdon	24/06/19	Complete
19/06/19	Obtain Information from PAL to ensure that POUF are effective against Mycobacteria.	Colin Puirdon	24/06/19	Complete
19/6/19	Compile report of water sampling results across RHC site to establish extent of M.chelonae within water supply.	Colin Purdon	24/06/19	Complete
19/6/19	Situation update report for clinical staff	Dr Chaudhury	20/06/19	Complete
19/6/19	Prepare holding press statement	Mark Dell/Dr Inkster	20/06/19	Complete
19/6/19	Provide email update to senior management teams	Dr Teresa Inkster	19/06/19	Complete



New Southern General Hospitals

Project Manager Instruction #659

Status: Accepted

Notification

Raised By

GGC01.NSGLP.sfrew on 21 Nov 2011 11:44AM

Raised To

BCL01

Response Required By

5 Dec 2011 12:00AM

Title

PMI/General/126 - A&C Hospitals - Omission of Carbon Filters

Description

The Board advise that they do not want carbon filters installed to the A&C Hospitals. (Cross reference EW 036). The Board wish to understand the cost saving of a) not fitting carbon filters to Air Handling Units which allow for the Carbon Filters to be retro-fitted and b) omission of carbon filters completely and fitting of air handling units which do not require carbon filters nor have the infrastructure for retro-fitting carbon filters.

Instruction

The Board advise that they do not want carbon filters installed to the A&C Hospitals. (Cross reference EW 036). The Board wish to understand the cost saving of a) not fitting carbon filters to Air Handling Units which allow for the Carbon Filters to be retro-fitted and b) omission of carbon filters completely and fitting of air handling units which do not require carbon filters nor have the infrastructure for retro-fitting carbon filters.

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Efficacy of High-Efficiency Particulate Air Filtration in Preventing Aspergillosis in Immunocompromised Patients With Hematologic Malignancies

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EFFICACY OF HIGH-EFFICIENCY PARTICULATE AIR FILTRATION IN PREVENTING ASPERGILLOSIS IN IMMUNOCOMPROMISED PATIENTS WITH HEMATOLOGIC MALIGNANCIES

Theresa Hahn, PhD; K. Michael Cummings, PhD; Arthur M. Michalek, PhD; Brian J. Lipman, MD; Brahm H. Segal, MD; Philip L. McCarthy, Jr., MD

ABSTRACT

OBJECTIVES: To describe and investigate the cause of an outbreak of 10 cases of nosocomial invasive infection with *Aspergillus flavus* in a hematologic oncology patient care unit.

DESIGN: A retrospective cohort study.

SETTING: The hematologic oncology unit of a comprehensive cancer center.

PATIENTS: Ninety-one patients admitted to the hematologic oncology service between January 1 and December 31, 1992, for 4 or more consecutive days were included in the study.

RESULTS: Ten (18%) of 55 patients admitted from July to December 1992 were diagnosed as having invasive aspergillosis compared with 0 (0%) of 36 patients admitted from January to June 1992 to the same patient care units. Patient characteristics, mortality rate, autopsy rate, and admitting location did not change significantly during the course of the year to result in a sudden

increase in the number of aspergillosis cases. The source of the outbreak was the high counts of *Aspergillus* conidia determined from air sampling in the non-bone marrow transplant wing during the outbreak. After high-efficiency particulate air (HEPA) filters were installed as an infection control measure, there were only two additional cases of nosocomial aspergillosis in the 2 years following the outbreak.

CONCLUSIONS: This outbreak occurred among hematologic oncology patients with prolonged granulocytopenia housed in an environment with neither HEPA filters nor laminar air flow units. Our data demonstrate that in the setting of an outbreak of aspergillosis, HEPA filters are protective for highly immunocompromised patients with hematologic malignancies and are effective at controlling outbreaks due to air contamination with *Aspergillus* conidia (*Infect Control Hosp Epidemiol* 2002;23:525-531).

Fungal infections are a significant determinant of the morbidity and mortality of selected patients undergoing immunosuppressive therapy for hematologic malignancies.^{1,3} Early stage fungal infections are difficult to diagnose and treat, resulting in a high mortality rate.^{3,5} *Aspergillus* species are common organisms that cause fungal infections in patients with leukemia and lymphoma, second only to infections with *Candida* species.^{6,7} Aspergilli have a ubiquitous distribution in the environment and their conidia are easily transported to distant sites.⁸ In invasive pulmonary aspergillosis, the main route of entry of *Aspergillus* is by inhalation of conidia.^{9,10} Air concentration of conidia and duration of exposure are important factors in the pathogenesis of pulmonary aspergillosis.¹⁰⁻¹²

During the past two decades, invasive pulmonary aspergillosis has been encountered with increasing frequency in patients with hematologic malignancies.^{13,14} The principal host defenses against invasive *Aspergillus* infection are alveolar macrophages, which target inhaled conidia, and neutrophils, which target the hyphal stage. Impairment of these cellular defenses and mucosal immu-

nity by cytotoxic chemotherapy, corticosteroids, and other immunosuppressive agents predispose patients with hematologic malignancies, hematopoietic stem cell transplants, or both to invasive filamentous fungal infections. A major obstacle to successful treatment is the difficulty establishing an early diagnosis. Many *Aspergillus* infections are not diagnosed until late in the course of infection or until post-mortem examination.¹⁵ Thus, aspergillosis outbreaks are underestimated or unnoticed because of the low rate of positive cultures of tissue and sputum samples.

Reported outbreaks of nosocomial invasive pulmonary aspergillosis have been caused by concentration of conidia in hospital ventilation systems,¹⁶ air contamination from construction,^{12,17-24} contaminated fireproofing materials,²⁵ and other sources.^{26,27} Cancer and transplant centers are at high risk for aspergillosis outbreaks. Reported aspergillosis outbreaks have occurred mainly among patients with acute or chronic myeloid leukemia and prolonged neutropenia. Some patients also received cytotoxic chemotherapy, corticosteroids, an allogeneic bone marrow transplant (BMT), or all three. The duration of granulocy-

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The authors thank the staff of the Department of Occupational and Environmental Safety at Roswell Park Cancer Institute for their management of the air and contact sampling and Nachimuthu Natarajan, MS, for assisting with data management.

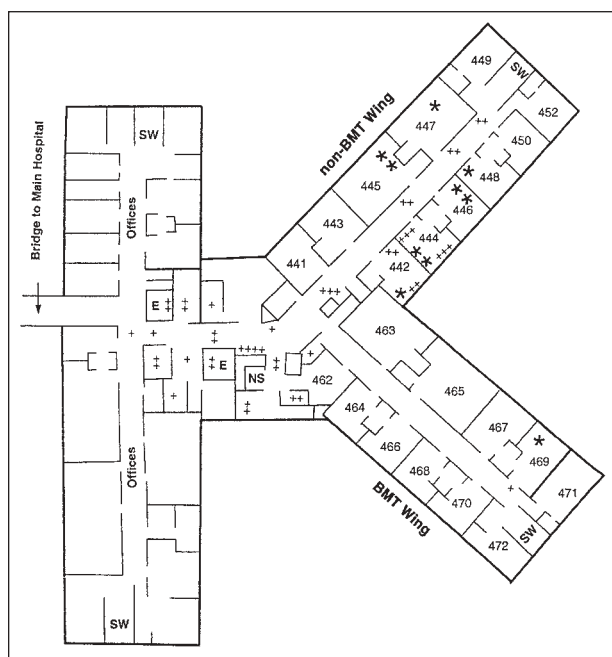


FIGURE 1. Floor plan of the fourth floor of the satellite building depicting the location of the patients with aspergillosis and air sampling. Rooms 462 to 471 were in the high-efficiency particulate air filtration environment. There is a set of double doors outside rooms 462 and 463 that separate the bone marrow transplant (BMT) wing from the nurses' station (not reflected on this diagram). SW = stairwell; E = elevator; NS = nurses' station; +: > 0 to 1 colony-forming units (CFU)/m³; ++: > 1 to 10 CFU/m³; +++: > 10 to 100 CFU/m³; ++++: > 100 CFU/m³; bold stars: location of each patient at the time of diagnosis of aspergillosis.

topenia is a consistently important risk factor for invasive aspergillosis.²⁸

METHODS

Study Design

Because of the availability of detailed medical records and air sampling, a retrospective cohort design was used to study an outbreak of nosocomial aspergillosis among the patients who were treated on the hematologic oncology unit. All 91 patients admitted to this unit for 4 or more consecutive days between January 1 and December 31, 1992, were included in the study. Patients who were admitted for less than 4 days were excluded because their length of stay was not long enough for them to develop a nosocomial infection and have it detected. All data were analyzed using SPSS software (SPSS Inc., Chicago, IL).

Definition of Aspergillosis

Because this was an outbreak investigation, we used stringent criteria and included only documented proven cases of aspergillosis in this analysis, although definitions of possible and probable cases are available.²⁹ A case of aspergillosis was defined as any patient who had a species of *Aspergillus* isolated from a sinopulmonary culture, from a tissue biopsy specimen, or at autopsy, and who had radiographic evidence of invasive disease, had invasive disease

determined at autopsy, or both. The first positive culture had to have been taken more than 72 hours after the patient was admitted to be considered indicative of nosocomially acquired infection. Because this was a population with neutropenic leukemia, any patient with at least one positive sputum culture and radiographic evidence consistent with invasive fungal infection was assumed to have invasive disease based on prior research.³⁰ Seven of the eight patients who died had an autopsy performed that confirmed the diagnosis of invasive aspergillosis. All patients had *A. flavus* (two also had *A. niger*) isolated from their specimens. Patients suspected of having aspergillosis had clinical symptoms (eg, cough, dyspnea, or neutropenic fever unresponsive to antibiotics) and radiographic findings compatible with invasive fungal infection without confirmatory culture or histopathology. They were treated for invasive fungal infection but were not included in this analysis.

Description of Facilities

In 1992, Roswell Park Cancer Institute facilities included an 8-story main hospital building connected by an aboveground pedestrian walkway to a 4-story satellite building. The satellite building's fourth floor consisted of an office wing and two patient care wings with a shared nurses' station (Fig. 1). The BMT wing had high-efficiency particulate air (HEPA) filtration and four rooms with laminar air flow units (LAFUs). The non-BMT wing housed patients with hematologic disorders who were usually admitted for high-dose chemotherapy without stem cell support. Most of these patients (> 70%) had leukemia. Each unit served as the overflow wing for the other, but all allogeneic BMT patients stayed in the HEPA-filtered environment (BMT wing). All of the rooms in these two units were private. Procedures of staff, cleaning personnel, and maintenance personnel did not differ between the two units.

Air Sampling

Routine surveillance air samples were collected weekly using Mattson Garvin Slit Air samplers (Fred Baker Scientific, Cheshire, United Kingdom). All samples were collected during 60 minutes at a flow rate of 1 cu ft/min, yielding a total volume of air sampled of 1.7 m³. The growth medium was Sabouraud Dextrose Agar, Emmons Formulation pH 7.0 (Remel, Lenexa, KS). Air samples were incubated at 27°C. Air samples were taken in each patient room, office, elevator, and storage room, at the nurses' station, and at intervals in each hallway.

Air Quality or Filtering

The air handling systems for the BMT and the non-BMT units established two different environments. The air intake on the ground floor brought in ambient air that went through two filtering processes, one with 30% efficiency and one with 95% efficiency. The filtered air was delivered to the fourth floor through a single ventilation shaft that split at the fourth floor to supply the two wings. The filtered air was delivered to each room on the non-BMT unit so that there was a positive pressure gradient in each room.

The same filtered air was delivered to the BMT unit. However, four patient rooms in the BMT wing had LAFUs with HEPA filtration (99.7% efficiency) mounted in the wall over the patient's bed. The LAFUs continually provided a uni-directional airflow of 90 linear feet per minute toward the door leading to the hallway. There were also freestanding HEPA filters at intervals in the hallway of the BMT unit. Each patient room on both the BMT unit and the non-BMT unit was filtered with 10 to 12 air exchanges per hour establishing positive pressure of clean to dirty air. Self-closing or air-lock doors were not installed in any patient rooms. No windows were operable and there were no air conditioners installed in individual patient rooms or elsewhere on either unit. The additional air filtering provided by the HEPA filters and LAFUs resulted in fewer *Aspergillus* conidia in the BMT unit compared with the non-BMT unit. This was confirmed with weekly air sampling (Fig. 1) during the outbreak.

RESULTS

There were 10 cases of invasive aspergillosis during 1992, all of which were diagnosed between August and December (Fig. 2). Table 1 summarizes the information on these patients. The incidence of acquiring aspergillosis during the second half of 1992 was 18%, yielding a relative risk estimate of 13.9 ($P = .004$) when compared with the first half of 1992. The presence of immunocompromised patients on two patient care units with different environments (HEPA filtration vs no HEPA filtration) established an unintentional, natural experiment testing the efficacy of HEPA filters.

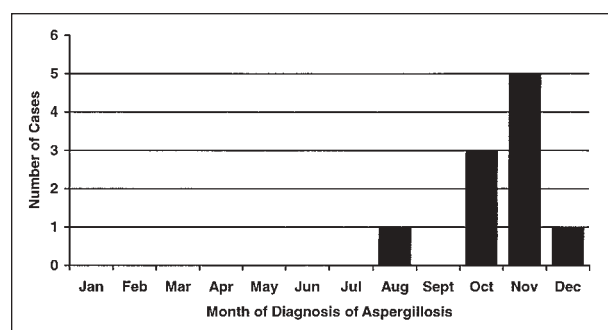


FIGURE 2. The number of cases of aspergillosis during 1992 by month of diagnosis.

Timing of the Outbreak

The patients admitted during the first half of 1992 were compared with the patients admitted during the second half of 1992 to determine whether there were more high-risk patients during the second half of 1992. As detailed in Table 2, most of the patient characteristics remained unchanged. The median number of febrile days increased significantly ($P = .03$), whereas the median length of stay and duration of neutropenia increased marginally. The proportion of patients with myeloid leukemia increased from 47% to 58%, although this was not statistically significant. The duration of antifungal medication use increased significantly, although this was a result of prolonged antifungal therapy in the cases of aspergillosis.

The mortality rate (31% vs 33%) and the autopsy rate

TABLE 1
CHARACTERISTICS OF THE PATIENTS WITH ASPERGILLOSIS*

Patient No.	Age (y)	Gender	Diagnosis	Sino-pulmonary Culture [†]	Biopsy Specimen [†]	Chest X-ray or CT Consistent With IA [‡]	Sinus X-ray or CT Consistent With IA [§]	ANC < 500/m ³ (d)	Body Temperature $\geq 38^{\circ}\text{C}$ (d)	Corticosteroids	Died	Autopsy
1	71	M	AML	+	+	+	–	17	9	Yes	Yes	Yes
2	58	M	AML	+	+	+	–	17	18	No	Yes	Yes
3	57	M	AML	+	+	+	+	20	19	No	Yes	Yes
4	77	M	AML	–	+	+	–	29	27	Yes	Yes	Yes
5	40	M	AML	+	NP	+	–	20	20	No	No	No
6	45	M	AML	+	+	+	–	56	56	Yes	Yes	Yes
7	54	M	CML	+	NP	+	+	26	18	No	Yes	No
8	79	F	AML	–	+	+	–	30	13	Yes	Yes	Yes
9	31	F	ALL	+	+	–	+	26	16	No	No	No
10	59	F	NHL	+	+	+	–	15	11	No	Yes	Yes

CT = computerized tomography; IA = invasive aspergillosis; ANC = absolute neutrophil count; AML = acute myeloid leukemia; NP = not performed; CML = chronic myeloid leukemia; ALL = acute lymphoid leukemia; NHL = non-Hodgkin's lymphoma.

*None of these patients had received bone marrow transplants.

[†]Positive or negative cultures for *Aspergillus* species.

[‡]Presence or absence of persistent or progressive infiltrates despite appropriate antimicrobial therapy, or the presence of a halo sign or cavitation.

[§]Presence or absence of sinusitis.

^{||}Corticosteroids (prednisone, methylprednisolone, or cyclosporine) were used for coexisting medical conditions (eg, temporal arteritis or suspected adult respiratory distress syndrome or interstitial pneumonitis) that necessitated them.

TABLE 2

COMPARISON OF CHARACTERISTICS OF PATIENTS ADMITTED BETWEEN JANUARY AND JUNE 1992 VERSUS PATIENTS ADMITTED BETWEEN JULY AND DECEMBER 1992

Characteristic	Jan.–June (N = 36)	July–Dec. (N = 55)	P
Median age, y (range)	44.5 (16–79)	46 (16–80)	NS*
Median LOS, d (range)	31 (4–64)	33 (4–146)	.06
Median no. of days with temperature $\geq 38^{\circ}\text{C}$ (range)	8.5 (0–42)	13 (0–76)	.03
Median no. of days with ANC $< 500/\text{mm}^3$ (range)	18.5 (0–43)	20 (0–75)	.07
Median duration of antifungal medication use, d (range)	10 (0–41)	19 (0–76)	.01
Median BMI, kg/m^2 (range)	24.5 (15.8–43.7)	25.5 (16–40.7)	NS*
Male (%)	19 (53)	30 (55)	NS*
AML or CML (%)	17 (47)	32 (58)	NS*
Current or former smoker (%)	20 (56)	29 (53)	NS*
Non-BMT wing (%)	22 (61)	35 (64)	NS*
BMT during current admission (%)	10 (28)	17 (31)	NS*
Current or prior BMT (%)	15 (42)	21 (38)	NS*
Steroids [†] (%)	14 (39)	25 (45)	NS*
Any antifungal medications (%)	28 (78)	50 (91)	NS*
Other fungal infection [‡] (%)	5 (14)	9 (16)	NS*
Aspergillosis (%)	0 (0)	10 (18)	.005
Died (%)	11 (31)	18 (33)	NS*
Autopsy (%)	5 (14)	10 (18)	NS*

NS = not significant; LOS = length of hospital stay; ANC = absolute neutrophil count; BMI = body mass index; AML = acute myeloid leukemia; CML = chronic myeloid leukemia; BMT = bone marrow transplant.

* $P > .10$.[†]Methylprednisolone or cyclosporine use for any indication.[‡]Fungal infection due to an organism other than *Aspergillus*.

(14% vs 18%) did not differ significantly between the two time periods. Although eight patients with aspergillosis died during the second half of 1992, the mortality rate did not increase significantly. We therefore believe that the increased number of cases of aspergillosis during the second half of 1992 was not biased by methods of detection.

Location of the Outbreak

The analysis of the location of the outbreak compared the patients admitted to the non-BMT wing with those admitted to the BMT wing during the second half of 1992, when 9 of the 10 patients with aspergillosis were admitted to the non-BMT wing.

The results given in Table 3 indicate that the patients in the BMT wing exhibited more of the risk factors for aspergillosis and would have been considered at high risk for fungal infection. The length of hospital stay (37 vs 30 days; $P = .02$) and the rate of BMT (65% vs 11%; $P < .001$) were significantly greater for patients in the BMT wing compared with patients in the non-BMT wing. The patients in the BMT wing also had trends toward a higher rate of steroid use and a longer duration of neutropenia. Despite these risk factors for aspergillosis, only one case occurred in this group. The outbreak occurred in the patient population considered to be at lower risk for aspergillosis due to high *Aspergillus* conidia counts (> 150 colony-forming units

[CFU]/ m^3) in the non-BMT wing compared with low counts (< 4 CFU/ m^3) in the BMT wing (Fig. 1). The difference in air quality was attributed to the lack of HEPA filtration and LAFUs in the non-BMT wing.

Comparison Between Patients With Aspergillosis and Patients Without Aspergillosis

Table 4 details the analysis of the patients with aspergillosis versus the patients without aspergillosis admitted to the non-BMT wing during the second half of 1992. Nine of 35 patients developed aspergillosis, 7 of whom died. The patients with aspergillosis had a significantly longer duration of fever and antifungal medication use, both of which are measures but not causes of the infection. The only other statistically significant differences between the two groups of patients were in the mortality and autopsy rates. More of the patients with aspergillosis had acute myeloid leukemia or chronic myeloid leukemia, but this difference was not significant. None of the patients with aspergillosis and 31% of the patients without aspergillosis had been admitted for or had had a prior BMT, although this difference also was not significant.

Source of the Outbreak

The source of the outbreak was determined to be the high *Aspergillus* conidia counts found in the non-BMT unit by

TABLE 3

COMPARISON OF PATIENTS ADMITTED TO THE NON-BONE MARROW TRANSPLANT WING WITH PATIENTS ADMITTED TO THE BONE MARROW TRANSPLANT WING DURING JULY THROUGH DECEMBER 1992

Characteristic	Non-BMT Wing (N = 35)	BMT Wing (N = 20)	P
Median age, y (range)	52 (21–80)	40.5 (16–79)	NS*
Median LOS, d (range)	30 (4–59)	37 (20–146)	.02
Median no. of days with temperature $\geq 38^{\circ}\text{C}$ (range)	13 (0–56)	12 (2–76)	NS*
Median no. of days ANC $< 500/\text{mm}^3$ (range)	20 (0–56)	22 (9–75)	NS*
Median duration of antifungal medication use, d (range)	19 (0–76)	16.5 (0–63)	NS*
Median BMI, kg/m^2 (range)	25.6 (16–41)	24.9 (18–38)	NS*
Male (%)	26 (74)	4 (20)	$< .001$
AML or CML (%)	21 (60)	11 (55)	NS*
Current or former smoker (%)	21 (60)	8 (40)	NS*
BMT during current admission (%)	4 (11)	13 (65)	$< .001$
Current or prior BMT (%)	8 (23)	13 (65)	.004
Steroids [†] (%)	12 (34)	13 (65)	.05
Any antifungal medications (%)	31 (89)	19 (95)	NS*
Other fungal infection [‡] (%)	8 (23)	1 (5)	NS*
Aspergillosis (%)	9 (26)	1 (5)	.08
Died (%)	10 (29)	8 (40)	NS*
Autopsy (%)	5 (14)	5 (25)	NS*

BMT = bone marrow transplant; LOS = length of hospital stay; ANC = absolute neutrophil count; BMI = body mass index; AML = acute myeloid leukemia; CML = chronic myeloid leukemia; NS = not significant.

* $P > .10$.[†]Methylprednisolone or cyclosporine use for any indication.[‡]Fungal infection due to an organism other than *Aspergillus*.

routine air sampling during the outbreak. The source of the high conidia counts was investigated and determined to be contaminated insulation in the wall of the fourth floor near the nurses' station, which was the point of the highest conidia counts. Another investigated source was the third floor office wing renovations, which were stopped on October 22, 1992, due to the possibility of contamination of the fourth floor. Although contact samples showed contamination of the work site with *A. flavus* and *A. niger*, the third floor had a separate air handling system. Thus, it was unlikely that the conidia were transported to the hematologic oncology units. Other sources that were investigated included the attic space above the fourth floor, the air handling system, and the outside ambient air, all of which had no conidia counts or counts that were lower than those from the BMT wing.

Air sampling data from the fourth floor taken between October 1 and November 15, 1992, showed the highest conidia counts ($> 150 \text{ CFU}/\text{m}^3$) around the shared nurses' station (Fig. 1). The BMT wing had relatively low conidia counts ($< 4 \text{ CFU}/\text{m}^3$), whereas the non-BMT wing had high conidia counts ($> 100 \text{ CFU}/\text{m}^3$) just inside the double doors separating the hallway from the nurses' station and a progressively declining gradient with low conidia counts ($< 5 \text{ CFU}/\text{m}^3$) at the end of the hallway farthest from the nurses' station. The HEPA filters in the BMT wing removed most of the conidia from the ambient air and the

absence of these filters in the non-BMT wing allowed the gradient to become established.

Infection Control Measures

The increased fungal conidia burden detected by environmental air sampling and the increased number of cases of aspergillosis led to the following infection control measures. On November 9, 1992, HEPA filters were placed at intervals in the non-BMT wing and at the nurses' station. Itraconazole was added to the antifungal prophylactic regimen, the wall insulation was decontaminated, and the third floor construction site was sealed with airtight barriers. Only two additional cases of invasive nosocomial aspergillosis were diagnosed in May 1993 after the initiation of these infection control measures. As of December 1994, 2 years after the outbreak, these were the only cases of nosocomial aspergillosis on the fourth floor. In December 1994, the patients on both wings were moved to two renovated floors of the main hospital with HEPA filtration. The fourth floor of the satellite building was converted to an outpatient clinic in 1995.

It is difficult to assess the efficacy of each infection control measure individually. In retrospect, the itraconazole fungal prophylaxis had little or no effect as a preventive measure due to its limited oral absorption. It is likely that the addition of HEPA filters to the non-BMT

TABLE 4

COMPARISON OF CHARACTERISTICS OF PATIENTS WITH ASPERGILLOSIS VERSUS PATIENTS WITHOUT ASPERGILLOSIS ADMITTED TO THE NON-BONE MARROW TRANSPLANT WING DURING JULY THROUGH DECEMBER 1992

Characteristic	Patients With Aspergillosis (N = 9)	Patients Without Aspergillosis (N = 26)	P
Median age, y (range)	57 (31–77)	51 (21–80)	NS*
Median LOS, d (range)	32 (21–59)	28.5 (4–53)	NS*
Median no. of days with temperature ≥ 38°C (range)	18 (9–56)	8.5 (0–26)	.05
Median no. of days ANC < 500/mm ³ (range)	20 (15–56)	20 (0–45)	NS*
Median duration of antifungal medication use, d (range)	24 (19–76)	16.5 (0–31)	.02
Median BMI, kg/m ² (range)	25.3 (20–31)	25.7 (16–41)	NS*
Male (%)	7 (78)	19 (73)	NS*
AML or CML (%)	7 (78)	14 (54)	NS*
Current or former smoker (%)	6 (67)	15 (58)	NS*
BMT during current admission (%)	0 (0)	4 (15)	NS*
Current or prior BMT (%)	0 (0)	8 (31)	.08
Steroids [†] (%)	3 (33)	9 (35)	NS*
Any antifungal medications (%)	9 (100)	22 (85)	NS*
Other fungal infection [‡] (%)	2 (22)	6 (23)	NS*
Died (%)	7 (78)	3 (12)	.001
Autopsy (%)	5 (56)	0 (0)	< .001

BMT = bone marrow transplant; LOS = length of hospital stay; ANC = absolute neutrophil count; BMI = body mass index; AML = acute myeloid leukemia; CML = chronic myeloid leukemia; NS = not significant.

* $P > .10$.[†]Methylprednisolone or cyclosporine use for any indication.[‡]Fungal infection due to an organism other than *Aspergillus*.

wing led to the reduction in *Aspergillus* conidia and, consequently, to the reduction in the number of cases of aspergillosis.

DISCUSSION

A previous report from our institution of an outbreak of aspergillosis among BMT recipients demonstrated the need for HEPA filtration on BMT units.²⁶ This report demonstrates the efficacy of HEPA filters that have since been installed in our BMT unit and the additional need of this protective environment for patients with hematologic malignancies who are immunocompromised from therapies other than BMT. This study provides evidence-based information regarding the necessity and efficacy of HEPA filtration in hematologic malignancy units.

The main limitations of this study are the underestimation of cases, the unavailability of DNA analysis techniques, and the limited applicability and generalizability of this study to other institutions. Nine of the 35 patients admitted to the non-BMT wing were confirmed cases of aspergillosis. An additional 5 patients were suspected of having aspergillosis but were not included as cases because their sputum cultures were negative for *Aspergillus* and no biopsies or autopsies had been performed. The comparison between patients with aspergillosis and patients without aspergillosis on the non-BMT wing during

the second half of 1992 probably failed to yield any statistically significant differences because of the underestimation of cases and the small sizes of the groups.

Circumstantial evidence points to the wall insulation at the nurses' station as the source of the gradient of *Aspergillus* conidia in the non-BMT wing because it was located where the highest *Aspergillus* conidia counts were recovered. The moldy insulation we believe was the source of the outbreak was not suddenly disturbed by construction or other movement that would have contributed to a sudden increase in conidia concentrations. We speculate that the contamination of the insulation occurred concurrent to the sudden spike in *Aspergillus* conidia.

This outbreak occurred before the recent advances in the diagnosis of aspergillosis^{31,32} and the development of molecular techniques to determine point sources.^{33,34} These diagnostic tests may have detected additional cases; however, when molecular techniques became available, the samples either were not sufficient for adequate DNA analysis or had already been discarded. Random amplification of polymorphic DNA analysis could have helped identify the source of the outbreak or determine whether the patients with aspergillosis were infected from one or multiple sources. However, the identification of *A. flavus* from all cases is unusual and suggests a true outbreak from a single

source rather than multiple sporadic cases. On the basis of this study's results, we recommend that HEPA filters be used routinely in hospital units housing patients with hematologic malignancies and prolonged neutropenia. This study confirms previous findings of the efficacy of HEPA filters in controlling aspergillosis outbreaks.^{20,23,24,35,36}

REFERENCES

1. Bodey GP, Vartivarian S. Aspergillosis. *Eur J Clin Microbiol Infect Dis* 1989;8:413-437.
2. Meyers J. Fungal infections in bone marrow transplant patients. *Semin Oncol* 1990;17:10-13.
3. Lin S, Schranz J, Teutsch S. Aspergillosis case-fatality rate: systematic review of the literature. *Clin Infect Dis* 2001;32:358-366.
4. Aisner J, Wiernik PH, Schimpff SC. Treatment of invasive aspergillosis: relation of early diagnosis and treatment to response. *Ann Intern Med* 1977;86:539-543.
5. Pannuti CS, Gingrich RD, Pfaller MA, Wenzel RP. Nosocomial pneumonia in adult patients undergoing bone marrow transplantation: a 9-year study. *J Clin Oncol* 1991;9:77-84.
6. Fridkin SK, Jarvis WR. Epidemiology of nosocomial fungal infections. *Clin Microbiol Rev* 1996;9:499-511.
7. Iwen PC, Reed EC, Armitage JO, et al. Nosocomial invasive aspergillosis in lymphoma patients treated with bone marrow or peripheral blood stem cell transplants. *Infect Control Hosp Epidemiol* 1993;14:131-139.
8. Walsh TJ, Dixon DM. Nosocomial aspergillosis: environmental microbiology, hospital epidemiology, diagnosis and treatment. *Eur J Epidemiol* 1989;5:131-142.
9. Rhame FS. Prevention of nosocomial aspergillosis. *J Hosp Infect* 1991;18:466-472.
10. Alberti C, Bouakline A, Ribaud P, et al. Relationship between environmental fungal contamination and the incidence of aspergillosis in haematology patients. *J Hosp Infect* 2001;48:198-206.
11. Leenders AC, van Belkum A, Behrendt M, Luijendijk A, Verbrugh HA. Density and molecular epidemiology of *Aspergillus* in air and the relationship to outbreaks of *Aspergillus* infection. *J Clin Microbiol* 1999;37:1752-1757.
12. Iwen PC, Davis JC, Reed EC, Winfield BA, Hinrichs SH. Airborne fungal spore monitoring in a protective environment during hospital construction, and correlation with an outbreak of invasive aspergillosis. *Infect Control Hosp Epidemiol* 1994;15:303-306.
13. Beck-Sague CM, Jarvis WR. Secular trends in the epidemiology of nosocomial fungal infections in the United States, 1980-1990. *J Infect Dis* 1993;167:1247-1251.
14. Klimowski LL, Rotstein C, Cummings KM. Incidence of nosocomial aspergillosis in patients with leukemia over a twenty-year period. *Infect Control Hosp Epidemiol* 1989;10:299-305.
15. Groll AH, Shah PM, Mentzel C, Schneider M, Just-Nuebling G, Hebner K. Trends in the postmortem epidemiology of invasive fungal infections in a university hospital. *J Infect* 1996;33:23-32.
16. Lentino JR, Rosenkranz MA, Michaels JA, Kurup VP, Rose HD, Rytel MW. Nosocomial aspergillosis: a retrospective review of airborne disease secondary to road construction and contaminated air conditioners. *Am J Epidemiol* 1982;116:430-437.
17. Sarubbi FA, Kopf HB, Wilson MB, et al. Increased recovery of *Aspergillus flavus* from respiratory specimens during hospital construction. *Rev Respir Dis* 1982;125:33-38.
18. Arnou PA, Andersen RL, Mainous PD, Smith EJ. Pulmonary aspergillosis during hospital renovation. *Rev Respir Dis* 1978;118:49-53.
19. Thio CL, Smith D, Merz WG, et al. Refinements of environmental assessment during an outbreak investigation of invasive aspergillosis in a leukemia and bone marrow transplant unit. *Infect Control Hosp Epidemiol* 2000;21:18-23.
20. Cornet M, Levy V, Fleury L, et al. Efficacy of prevention by high-efficiency particulate air filtration or laminar airflow against *Aspergillus* air-borne contamination during hospital renovation. *Infect Control Hosp Epidemiol* 1999;20:508-513.
21. Loo VG, Bertrand C, Dixon C, et al. Control of construction-associated nosocomial aspergillosis in an antiquated hematology unit. *Infect Control Hosp Epidemiol* 1996;17:360-364.
22. Opal SM, Asp AA, Cannady PB, Morse PL, Burton LJ, Hammer PG 2nd. Efficacy of infection control measures during a nosocomial outbreak of disseminated aspergillosis associated with hospital construction. *J Infect Dis* 1986;153:634-637.
23. Peters WP, Thomann W, Hunt D, et al. Nosocomial *Aspergillus flavus* in a bone marrow transplant unit (BMTU): importance of air surveillance and HEPA filtration. *Proceedings of the American Society of Clinical Oncology* 1988;7:288.
24. Oren I, Haddad N, Finkelstein R, Rowe JM. Invasive pulmonary aspergillosis in neutropenic patients during hospital construction: before and after chemoprophylaxis and institution of HEPA filters. *Am J Hematol* 2001;66:257-262.
25. Aisner J, Schimpff SC, Bennett JE, Young VM, Wiernik PH. *Aspergillus* infections in cancer patients: association with fireproofing materials in a new hospital. *JAMA* 1976;235:411-412.
26. Rotstein C, Cummings KM, Tidings J, et al. An outbreak of invasive aspergillosis among allogeneic bone marrow transplants: a case-control study. *Infect Control* 1985;6:347-355.
27. Gerson SL, Parker P, Jacobs MR, Creger R, Lazarus HM. Aspergillosis due to carpet contamination. *Infect Control Hosp Epidemiol* 1994;15:221-223.
28. Gerson SL, Talbot GH, Hurwitz S, Lusk EJ, Cassileth PA. Prolonged granulocytopenia: the major risk factor for invasive pulmonary aspergillosis in patients with acute leukemia. *Ann Intern Med* 1984;100:345-351.
29. Ascioglu S, Rex JH, de Pauw B, et al. Defining opportunistic invasive fungal infections in immunocompromised patients with cancer and hematopoietic stem cell transplants: an international consensus. *Clin Infect Dis* 2002;34:7-14.
30. Yu VL, Muder RR, Poorsattar A. Significance of isolation of *Aspergillus* from the respiratory tract in diagnosis of invasive pulmonary aspergillosis: results from a three-year prospective study. *Am J Med* 1986;81:249-254.
31. Buchheidt D, Baust C, Skladny H, et al. Detection of aspergillus species in blood and bronchoalveolar lavage samples from immunocompromised patients by means of 2-step polymerase chain reaction: clinical results. *Clin Infect Dis* 2001;33:428-435.
32. Lass-Flörl C, Aigner J, Gunsilius E, et al. Screening for *Aspergillus* spp. using polymerase chain reaction of whole blood samples from patients with haematological malignancies. *Br J Haematol* 2001;113:180-184.
33. Khan ZK, Chowdhary L, Gyanchandani A, Goswami M, Farooqui N, Ranade SA. *Aspergillus fumigatus* strains recovered from immunocompromised patients (ICP): subtyping of strains by RAPD analysis. *Biochemistry and Molecular Biology International* 1998;46:537-548.
34. Brandt ME, Padhye AA, Mayer LW, Holloway BP. Utility of random amplified polymorphic DNA PCR and TaqMan automated detection in molecular identification of *Aspergillus fumigatus*. *J Clin Microbiol* 1998;36:2057-2062.
35. Sheretz RJ, Belani A, Kramer BS, et al. Impact of air filtration on nosocomial *Aspergillus* infections: unique risk of bone marrow transplant recipients. *Am J Med* 1987;83:709-718.
36. Rose HD, Hirsch SR. Filtering hospital air decreases *Aspergillus* spore counts. *Am Rev Respir Dis* 1979;119:511-513.

The effect of pressure differential and care provider movement on airborne infectious isolation room containment effectiveness

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Background: Airborne infectious isolation rooms (AIIRs) are maintained at a negative pressure relative to surrounding areas to prevent migration of potentially infectious droplet nuclei. Current US design standards require a pressure differential of only 2.5 Pascals (Pa), compared with 15 Pa in some other countries. The purpose of this work was to compare containment efficiency in a properly designed anteroom-equipped hospital AIIR at differential pressures ranging from 2.5 to 20 Pa under conditions of no provider traffic and simulated high provider traffic.

Methods: Fluorescent microspheres were released into the AIIR to simulate infectious droplet nuclei. Airborne concentrations were measured inside the AIIR, in the anteroom, and at the corridor-anteroom door both with and without care provider movement through the AIIR under differential pressure conditions of 2.5, 11, and 20 Pa. Particles were collected by air sampling onto filters, with enumeration via fluorescent microscopy.

Results: Reduced containment effectiveness during provider traffic was observed, consistent with previous studies. Containment increased with increasingly negative pressure differential and decreased with increasing provider traffic.

Conclusions: Provider traffic adversely affected containment. Containment improved with an increasing pressure differential. The anteroom plays an important role in limiting net particle escape, especially during provider movement through the space.

Key Words: AIIR; droplet nuclei; anteroom; air volume migration.

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The Centers for Disease Control and Prevention (CDC) identifies two measures for controlling airborne disease in health care facilities: (1) the use of administrative measures to reduce the risk of exposing uninfected persons to persons who have disease that is infectious by the airborne route, and (2) the use of engineering controls to prevent the spread and reduce the concentration of infectious droplet nuclei.¹ The use of hospital airborne infectious isolation rooms (AIIRs) involves both of these strategies.^{2,3} AIIR ventilation systems maintain a negative air pressure inside the room relative to the surrounding areas by mechanically removing (exhausting) more air than is supplied,

causing the room to be at slightly negative atmospheric pressure relative to surrounding areas. This is intended to cause air to flow into rather than out of the room through open doors, cracks, or other penetrations and thereby prevent airborne droplet nuclei from escaping the space.³ Numerous factors can interfere with proper AIIR performance, and although a negative pressure differential is necessary for correct air flow direction, it does not guarantee it.³

AIIR DESIGN STANDARDS

The *Guidelines for Design and Construction of Hospital and Health Care Facilities*⁴ has been accepted as the primary standard governing AIIR design in the United States.⁵ The American Society of Heating, Refrigerating, and Air-Conditioning Engineers and the CDC have provided additional information and recommendations on ventilation design performance.^{5,6} These US standards require a minimum pressure differential of only 2.5 Pa,⁴⁻⁶ whereas international standards require a minimum differential of as much as 15 Pa.^{7,8} US and international standards are in agreement regarding a required exhaust rate of 12 air changes per

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hour (ACH) in the AIIR, with at least 2 ACH of fresh air brought in from the outside. An anteroom is recommended as a transition from the potentially contaminated AIIR to the adjacent health care facility;⁶ health care providers typically use this space to don and doff personal protective equipment, such as respirators, gloves, and gowns.

EFFECT OF PROVIDER MOVEMENT ON AIIR CONTAINMENT

The literature contains little information regarding the airborne pathogen containment efficiency of AIIRs during provider movement into and out of the space at various ventilation conditions, but air volume migration (AVM), the escape of a parcel of air from the AIIR, has been demonstrated. Holding AIIR rooms at negative differential pressure relative to surrounding areas is essential. Beggs⁹ reported that the most common reason for loss of pressure differential in isolation rooms is the opening of doors. Several studies have demonstrated the adverse effects of door opening and provider movement on AIIR containment effectiveness,¹⁰⁻¹² including a tracer gas study by Rydock and Eian¹² that evaluated 4 “state-of-the-art” AIIR rooms in Norway with pressure differentials of 15 Pa between the corridor and anteroom and 30 Pa between the corridor and patient room, both of which greatly exceed US requirements. Sulfur hexafluoride (SF₆) was released at the patient bed position and allowed to mix in the room for 2 minutes before the release technician exited the room into the anteroom. The technician waited an additional 3 minutes in the anteroom before entering the adjacent corridor. Subsequently, SF₆ was readily detected in both the anteroom and the corridor, indicating that the AIIR did not contain all of the gas during provider movement even at this high pressure differential. Recent work by Johnson et al¹³ also demonstrated greatly reduced containment efficiency during simulated provider traffic into and out of an expedient isolation enclosure, such as might be used during a surge in demand for isolation capacity. We found no study that evaluated the effect of provider movement in a single facility over the range of recommended pressure differentials, however. The purpose of the present study was to compare containment efficiency in a properly designed, anteroom-equipped hospital AIIR at differential pressures ranging from 2.5 to 20 Pa under conditions of no provider traffic and simulated high provider traffic.

MATERIALS AND METHODS

This study evaluated the containment effectiveness of an AIIR with an anteroom under 3 different negative

pressure conditions with and without health care provider movement through the space. Uniformly sized 2- μ m-diameter green fluorescent polystyrene latex (PSL) microspheres (Duke Scientific, Palo Alto, CA), which simulate airborne pathogens, were distributed into an AIIR from water suspension using a medical air jet nebulizer. PSL microspheres were used because they are nonpathogenic, are the same size as many airborne pathogens, and fluoresce to make their identification more specific. Because the PSL microspheres are aerodynamically similar to airborne bacterial pathogens, they have the same transport behavior in air and thus have a similar potential to escape the AIIR. Once aerosolized, the particles were collected on preloaded 25-mm diameter, 0.8- μ m pore size mixed cellulose ester filters in conductive cowed cassettes (model 225-321; SKC, Eighty-Four, PA). The air sampling rate was 1.5 L/min. Each filter was transferred from the cassette to an oversized microscope slide (75 $\times$ 38 mm) and covered with a 35 $\times$ 50 mm slip tacked down with drops of clear fingernail polish. The sample was labeled with a unique identification number. To distinguish fluorescent particles from background particles, the filters were viewed using a Nikon Eclipse 80i top-illuminated fluorescence microscope fitted with a Prior Optiscan 29 motorized stage, Nikon DXM 1200 digital camera, and NIS Elements image analysis software (AR 2.10, Build 215) (all from Nikon Instruments, Melville, NY). Slides with dense particle deposition were counted at 40 $\times$ magnification using a random field technique, whereas the total surface of slides with light particle deposition was manually counted according to the method of Johnson and Lynch.¹⁴ The low (40 $\times$) magnification could be used because the fluorescent image of the deposited particle was much larger than its 2- μ m physical diameter. The time-weighted average airborne particle concentration estimate for each filter sample was calculated from the filter count, the average pump flow rate during the sample, and the sampling time.

The study took place in a major medical center in Oklahoma City, Oklahoma. The particular AIIR studied was selected because it had an anteroom, adjustable return air ventilation that enabled adjustment of the exhaust airflow and resulting negative pressure, and a high exhaust flow capable of achieving differential pressures exceeding 20 Pa. Swing-in type doors joined the corridor and the anteroom and the anteroom and the AIIR. Because this research project involved one human subject to simulate provider movement, Institutional Review Board approval was secured. The human subject wore surgical scrubs, rubber gloves, safety goggles, and an N95 respirator and played the role of a health care provider moving into and out of the space. Personal protective equipment was worn primarily to simulate a “real world” scenario.

The following protocol was followed during the trials that involved health care provider movement. The nebulizer was started remotely and allowed to operate for 15 minutes before the subject entered the room. After these 15 minutes, the subject opened the outer anteroom door, entered the anteroom, closed the door and waited 5 minutes, opened the inner anteroom door, moved into the patient area, closed the door and waited 5 minutes, opened the inner anteroom door and moved back into the anteroom, closed the door and waited 5 minutes, opened the outer anteroom door and exited the anteroom to the outside, and then closed the door and waited 5 minutes. The subject repeated these steps for a total of 3 cycles. The experiment involving the human subject was repeated 3 times for each of 3 pressure differentials, for a total of 9 trials. Each trial required 90 minutes of air sampling.

During the no-movement trials, the sampling pumps and the nebulizer were started remotely as in the movement trials, and after 90 minutes the cassette from each sampling pump was collected and labeled. No human subject moved to and from the rooms during the 90-minute no-traffic trials.

The initial 15-minute nebulization time before entry of the subject into the room was chosen to allow the room particle concentration to come to equilibrium after starting the nebulizer, and was based on the experimentally determined effective ventilation rate of the central area of the AIIR. The effective ventilation rate, Q'_{ACH} , expressed in air changes per hour (ACH), is the total fresh air ventilation rate, Q (eg, ft³/hour), divided by the room volume V (ft³/air change) and a dimensionless factor K that takes into account the reduction in dilution efficiency caused by less than perfect air mixing in the room, that is, $Q'_{ACH} = \frac{Q}{KV}$.¹⁵ Because K is generally unknown for a space, experimental determination of Q'_{ACH} is useful in estimating the nebulization time required to reach an equilibrium concentration. We estimated Q'_{ACH} for the AIIR using an approach similar to that of Pavelchak et al.¹⁶ In brief, air current tracing “smoke” (airflow indicator tubes model 810-500; SKC) was released into the AIIR in puffs as the investigator walked 3 times around the room. The multipoint release and motion of the investigator were intended to promote good particle distribution in the space. The ventilation system was operating at a 20-Pa pressure differential, with a supply flow rate of 185 cfm and an exhaust flow rate of 820 cfm. The subsequent “decay” in the smoke concentration was measured over time as it was diluted by the ventilation system. Theory predicts that once particle generation is stopped, the airborne particle concentration will decrease in an exponential fashion according to the equation $C' = e^{-\frac{Q}{KV}t}$ or $C' = e^{-Q'_{ACH}t}$, where C' is the normalized concentration (ie, the fraction of the initial concentration

remaining at time t). The $\frac{Q}{KV}$ or Q'_{ACH} exponential decay constant physically represents the effective ventilation rate of the AIIR expressed in air changes per unit time. The logarithmic form of the exponential decay equation is $\ln(C') = -Q'_{ACH}t$, and from this relationship we easily estimated the decay constant by linear regression with the line constrained to pass through a zero intercept. We took this value to be representative of the decay constant in the central area of the room in which the samplers were located. This estimate, which was 0.4745 air changes per minute or 28.47 ACH ($R^2 > 0.96$), then allowed us to calculate the time required to reach 90% of the equilibrium particle concentration C_{eq} during aerosol generation. Assuming exponential concentration buildup following the relation $C = C_{eq}(1 - e^{-Q'_{ACH}t})$,¹⁵ the nebulization time, in minutes required to reach 90% of C_{eq} , was calculated as

$$t = -\frac{1}{Q'_{ACH}} \ln\left(1 - \frac{C}{C_o}\right) = -\frac{1}{0.4745 \text{ min}^{-1}} \ln\left(1 - \frac{.9C_{eq}}{C_{eq}}\right) \\ = 2.303/0.4745 = 4.85 \text{ min.}$$

Measurement of exhaust ventilation rates at 20 Pa (185 cfm supply, 820 cfm exhaust), 11 Pa (175 cfm supply, 632 cfm exhaust), and 2.5 Pa (163 cfm supply, 295 cfm exhaust) indicated that the 15-minute nebulization period allowed before the start of sampling would be adequate to reach 90% of the equilibrium under all pressure (and exhaust flow rate) conditions used provided that no large differences in room air mixing characteristics occurred over this range of pressure differentials and air flow rates.

The nebulizer simulated a patient continually producing airborne particles through coughing, sneezing, and talking. A modified device was used that provided continuous replenishment of PSL particle source suspension via an injection pump (Figs 1 and 2). A dual-syringe infusion pump (model 200; KD Scientific, Boston, MA) fitted with two 30-mm-diameter, 60-mL syringes supplied the nebulizer with a constant suspension feed rate of 1 mL/min over a 90-minute period. An exit port that directed overflow to a 500-mL Erlenmeyer flask ensured a constant volume of suspension in the reservoir. A medical nebulizer compressor (ProNeb Ultra model 85B0000, Pari Innovative Manufacturers, Midlothian, VA) operating at 20 psi pressure provided a consistent air flow rate of 4.41 L/min, as measured with an air flow calibrator (DryCal model DC Lite, BIOS International, Butler, NJ).

AIIR containment was assessed by measuring PSL concentrations inside and outside the AIIR in the presence and absence of provider traffic. Particle concentrations were measured at 4 locations inside the AIIR, 2 locations in the anteroom, and 4 locations outside the corridor-anteroom door (10 total) at each of

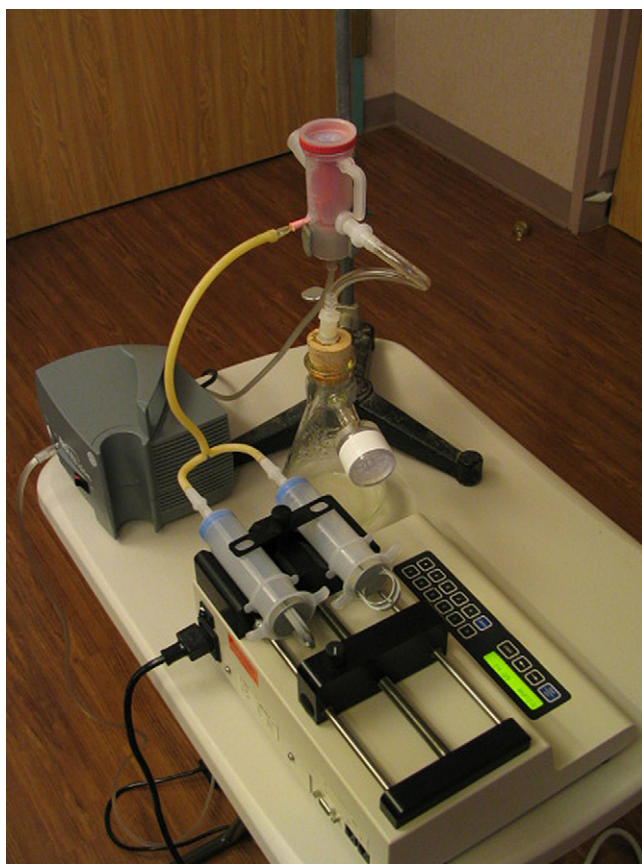


Fig 1. Nebulization system. The nebulization system comprised a medical air jet nebulizer modified to allow the continuously replenishment of the reservoir with particle source suspension via an infusion pump.

3 pressure differential conditions (2.5 Pa, 11 Pa, and 20 Pa) for each of two traffic conditions (no traffic or 3 provider passes through the AIIR), with 3 replicates of each trial. This resulted in 10 filter samples $\times$ 3 pressure differentials $\times$ 2 traffic conditions $\times$ 3 replicates = 180 samples.

Pressure differentials for each experimental condition were measured between the corridor and patient room and between the anteroom and patient room using a digital micromanometer pressure meter (model DM-4; Infiltec, Waynesboro, MA). Pressure differential readings were taken by placing one of the two micromanometer sensing hoses inside the room and running the second hose under the doorway into the corridor. The instrument displayed the resulting pressure differential between the spaces. Visual smoke tests to trace air current direction also were performed throughout the study to ensure maintenance of appropriate pressure gradients. An Alnor standard balometer “flow hood” (TSI, St Paul, MN) was used to measure the exhaust air flow rates.

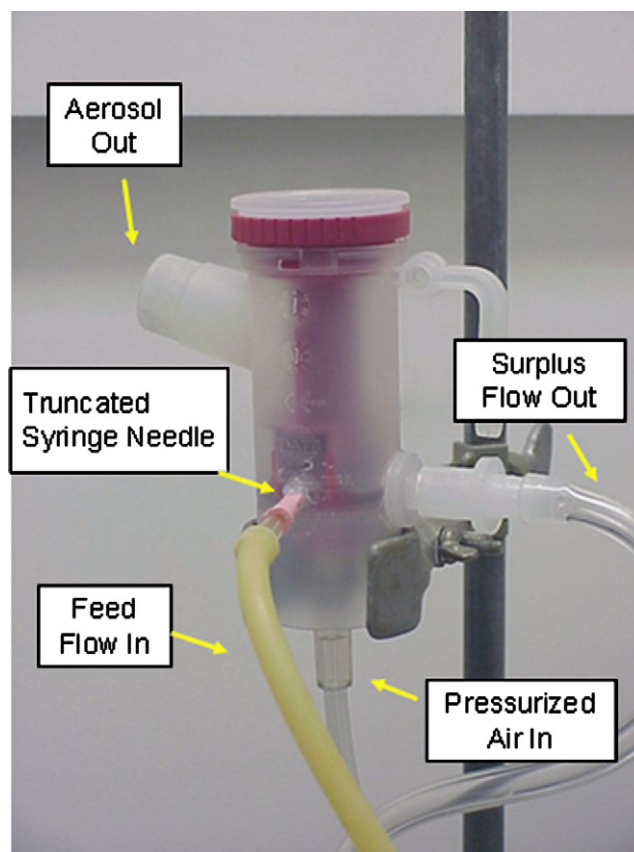


Fig 2. Modified nebulizer. Continuous replenishment with an excess of particle suspension prevented depletion of the suspension during the 1.5-hour nebulization periods.

During each trial, 4 air-sampling pumps (SKC 224-PCXR4 or MSA Escort ELF [Mine Safety Appliances, Pittsburgh, PA]) were placed in the 4 quadrants of the patient care area. Before sampling, the pumps were calibrated to a flow rate of 1.50 ± 0.03 L/min using the air flow calibrator, and the values were recorded. The flow was measured again after sampling to verify consistent operation and determine the average flow rate for the trial. The pumps were placed on tabletops approximately 30 inches above the floor. Each pump was fitted with a preloaded 25-mm-diameter mixed cellulose ester filter. Two pumps with filters were also placed on a countertop in the anteroom, and 4 additional pumps with filters were placed outside of the anteroom door in the corridor. The pumps in the corridor were placed on stands on each side of the door at elevations of 3 feet and 6 feet, with two on each side of the door. These pumps were positioned within 1 foot of each side of the doorway.

Conditions for the experiment were as follows. An extension cord was run from the nebulizer compressor

Table 1. Corridor-to-room and anteroom-to-room particle concentration ratios

	Mean measured differential pressure					
	Anteroom to patient care area			Corridor to patient care area		
	1.5 Pa	7.3 Pa	12.5 Pa	2.1 Pa	10.7 Pa	20.7 Pa
Without provider traffic	7.00×10^{-4}	2.38×10^{-4}	1.62×10^{-4}	3.55×10^{-4}	1.20×10^{-4}	0
	2.06×10^{-3}	2.72×10^{-4}	1.23×10^{-4}	3.07×10^{-4}	6.98×10^{-5}	0
	1.59×10^{-4}	0	0	1.05×10^{-4}	1.45×10^{-4}	3.90×10^{-4}
With provider traffic	5.12×10^{-2}	1.55×10^{-2}	1.10×10^{-2}	3.84×10^{-4}	6.04×10^{-4}	2.04×10^{-4}
	5.60×10^{-2}	1.79×10^{-2}	1.13×10^{-2}	5.03×10^{-4}	5.40×10^{-4}	2.86×10^{-4}
	4.25×10^{-2}	1.57×10^{-2}	1.08×10^{-2}	7.99×10^{-4}	1.21×10^{-4}	0

NOTE. Values represent the ratio of the mean particle concentration in either the corridor or the anteroom to the mean particle concentration inside the room for each sampling event.

into the hallway so that the nebulizer could be started without having to enter the room. The room's ventilation system was adjusted to provide a nominal differential pressure of 2.5, 11, or 20 Pa by controlling the amount of exhausted air. The AIIR chosen for this study had a normal operating differential pressure exceeding 20 Pa, so the target differentials were achieved by physically obstructing a portion of the exhaust air grill to "choke" the exhaust flow. At each pressure differential condition, smoke tests were conducted between the AIIR and anteroom and anteroom and corridor to visually verify the correct air flow direction, ensuring an appropriate pressure gradient. Corridor-AIIR and anteroom-AIIR pressure differentials were measured with a digital micromanometer for each pressure condition. Pump air flow rates were remeasured after each trial and recorded.

RESULTS AND DISCUSSION

Of the 180 filter samples obtained, 4 were discarded due to either pump failure during the trial or unacceptable variation in the before-and-after pump flow rate measurements ($>10\%$ or 0.15 L/min). Three of the discarded samples were from inside the AIIR and the other was from inside the anteroom, and no more than one sample was lost in any one trial. Owing to intermittent operation of the building's heating, ventilation, and air-conditioning (HVAC) system, pressure differentials were seen to vary somewhat from the target levels of 2.5, 11, and 20 Pa. The mean measured differentials were 2.1 Pa (range, 1.2-2.5 Pa), 10.7 Pa (range, 9.4-12.0 Pa), and 20.7 Pa (range, 20-21.3 Pa). These differentials were measured at one point in time before each trial, and due to the intermittent operation of the building's HVAC system might not represent the mean pressure differential for the entire 90-minute trial. Mean patient care area exhaust air flow rates were 208 cfm (range, 198-218 cfm), 434 cfm (range, 413-445 cfm), and 660 cfm (no variation). Mean

pressure differentials between the patient care area and the anteroom were 1.5 Pa (range, 0.9-3.1 Pa), 7.3 Pa (range, 6.6-7.5 Pa), and 12.5 Pa (range, 12.2-13.9 Pa). The anteroom did not have its own supply or exhaust; air was drawn into the anteroom from the corridor via a gap under the door and passed through to the patient care area of the AIIR.

The maximum particle count for any sample collected outside the corridor door was 5, compared with filter counts of approximately 2500-4500 inside the AIIR for the same period. The mean counts for the 2.5-, 11-, and 20-Pa pressure conditions were 1.08, 0.42, and 0.25 in the absence of provider traffic and 1.83, 1.50, and 0.42 with provider traffic. The corresponding mean corridor particle concentrations were approximately 8.1, 3.1, and 1.9 particles/ m^3 in the absence of provider traffic and 13.6, 11.2, and 3.1 particles/ m^3 with provider traffic.

The maximum particle count for any sample collected in the anteroom was 242. The mean counts for the 1.3, 7.5, and 12.5 Pa pressure conditions were 5.17, 0.60, and 0.33 in the absence of provider traffic and 156.5, 52.8, and 29.0 with provider traffic. The corresponding mean anteroom particle concentrations were approximately 38.2, 4.5, and 2.5 particles/ m^3 in the absence of provider traffic and 1149, 393, and 215 particles/ m^3 with provider traffic.

Table 1 presents the ratio of mean particle concentrations in the corridor to those in the AIIR patient care area, as well as the ratio of mean anteroom concentrations to mean patient care area concentrations, for each of the 9 trials. As noted by Johnson et al,¹³ the particle concentration measured in the corridor immediately outside the room entrance is only a relative measure of the degree of particle escape from the room. This is due to the inability to contain all of the air in the vicinity of the door during sampling, with subsequent particle dispersion by room currents. Thus, absolute containment efficiencies that might be calculated from the "escape fraction" estimates

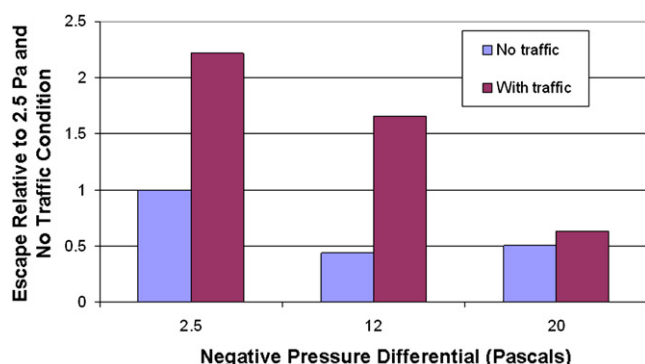


Fig 3. Relative particle escape from the patient area to the corridor. Net particle escape to the corridor from the patient care area at different pressure differentials with and without provider traffic is shown relative to the observed particle escape under the 2.5-Pa, no-traffic condition.

represented by Table 1 would be overestimates of the true containment. However, the measures are illustrative of the *relative* containment under the various conditions when one of the conditions is taken as the baseline.

Figure 3 graphically presents corridor-to-room concentration ratios at the three pressure differential conditions with and without provider movement, relative to the ratio observed at the 2.5-Pa, no-traffic condition. That condition was chosen because it represents the US design standard. The figure reflects a decrease in particle escape as the negative pressure differential increases from 2.5 Pa to 20 Pa for both the no-traffic and with-traffic conditions. It also reflects much greater particle escape during provider traffic compared with the no-traffic condition at 2.5 Pa, but with a diminishing traffic effect at 11 Pa and little or no difference in escape at 20 Pa.

Figure 3 appears to indicate improved containment at pressure differentials above 2.5 Pa, especially in the presence of provider movement. However, although a two-way analysis of variance (ANOVA) of the data in Table 1 (data not shown) indicated a statistically significant difference ($P < .03$) in containment across the traffic conditions, it did not show a significant difference due to the pressure differential ($P = .09$); the traffic–pressure interaction term was also not statistically significant ($P = .36$). Whether this result is due to an actual lack of effect, to the small sample size, or to variations in differential pressure during trials or other sources of imprecision, with subsequently low statistical power to detect the real differences, is unclear. A larger-scale study is needed to improve statistical power and resolve this question.

Figure 4 illustrates the substantial contribution of the anteroom in limiting the net escape of particles

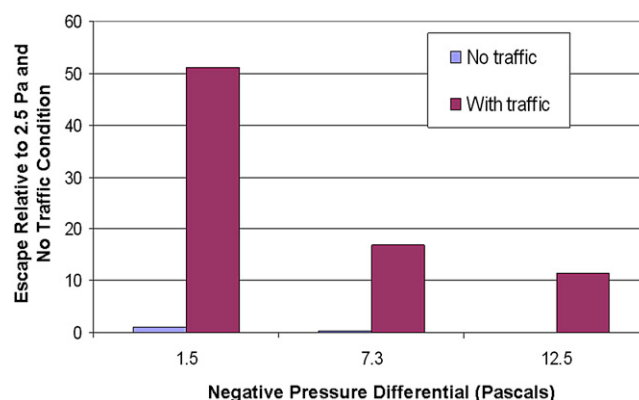


Fig 4. Relative particle escape from the patient area to the anteroom. Particle escape to the anteroom from the patient care area at different pressure differentials with and without provider traffic is shown relative to the observed particle escape under the 2.5-Pa, no-traffic condition.

from the patient care area to the corridor. Whereas a 50-fold increase in particle escape occurred during provider traffic relative to no traffic at the lowest differential pressure, this translated to only a roughly 2-fold increase in net particle escape to the corridor from the patient care area. There again appeared to be a decrease in particle escape with increasing pressure differential for both traffic conditions, as supported by a two-way ANOVA in which traffic condition, differential pressure, and their interaction were all statistically significant ($P < 10^{-6}$). The anteroom was clearly effective in limiting the migration of particles out of the AIIR, even though its only ventilation was by pass-through air.

Interpreting our results is complicated somewhat by the question of air flow rate into the AIIR through the door undercut and other leakage points while the door is closed, and through the door opening while the door is in operation. These flows were not measured in the present study. Gill^{17,18} and Streifel¹⁹ have suggested that a makeup air flow rate in the range of 100–130 cfm through one door to a well-sealed AIIR can effectively minimize air volume migration. Gill¹⁸ reported that a 130-cfm flow through the undercut of a closed AIIR door resulted in a pressure differential of about 12.5 Pa. Wiseman²⁰ recommended a differential air flow rate of 400 cfm that can be “throttled down” to a lower flow adequate to maintain a 2.5 Pa pressure differential when the AIIR door is closed. In an extremely well-sealed AIIR, a pressure differential of perhaps 11 Pa might be achieved with a much lower differential air flow rate than would be required in a less well-sealed AIIR. However, in that case the well-sealed AIIR might then have less effective containment when the door is open due to the lower differential

flow. Apparently, the most effective design approach would include a minimum pressure differential during door-closed conditions and a minimum differential air flow during door-operating conditions.

CONCLUSIONS

The reduced containment effectiveness during provider traffic observed in this study is consistent with previous studies that demonstrated substantial air volume migration during AIIR door operation and provider movement into and out of a space. Although the specific quantitative results presented here are particular to the conditions used in this study, they appear to indicate that AIIR containment effectiveness in the presence or absence of provider traffic may increase with increasing pressure differential. It may be that pressure differentials greater than the current 2.5 Pa US design standard (say, on the order of the 15 Pa standard used in other countries) would be more protective in controlling the escape of airborne droplet nuclei from an AIIR during care provider movement into and out of the room. The limited scope of the present study does not allow us to draw a firm conclusion in this regard, and additional work is needed to explore this question. As shown by Rydock and Eian,¹² even differential pressures in the 15 Pa range might not be sufficient to completely prevent air volume migration during provider movement, and it must be recognized that whether or not a particular pressure differential would be adequately protective in a specific circumstance is a complex question. "Adequate" protectivity depends on a variety of factors, including the infectivity and potential health effects of the threat organism, the frequency and pattern of provider traffic into and out of the AIIR, and the degree of droplet nuclei dilution provided in the interior of the AIIR by the HVAC system and perhaps supplemental free-standing HEPA filtration devices. In this study, the anteroom was found to play an important role in controlling net particle migration from the AIIR patient care area to the corridor, especially in the presence of provider traffic. Additional studies of AIIR containment effectiveness under real-world patient care conditions, in the presence and absence of an anteroom, would provide the more detailed information needed to consider further refinements to AIIR design standards.

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References

1. Centers for Disease Control and Prevention. Guidelines for preventing the transmission of *Mycobacterium tuberculosis* in health care facilities. *Morb Mortal Recomm Rep* 2005;54(RR-17):6-7.
2. Lidwell OM. The control by ventilation of airborne bacterial transfer between hospital patients, and its assessment by means of a particle tracer. *J Hygiene* 1972;70:287-97.
3. Pavelchak N, Ronald PD, London M, Stircof R, Oxtoby M, Diferdinando G, et al. Identification of factors that disrupt negative pressurization of respiratory isolation rooms. *Infect Control Hosp Epidemiol* 2000;21:191-5.
4. Facility Guidelines Institute. Guidelines for design and construction of hospital and health care facilities. Dallas (TX): Facility Guidelines Institute; 2010.
5. Centers for Disease Control and Prevention and the Healthcare Infection Control Practices Advisory Committee (HICPAC). Guidelines for environmental infection control in health-care facilities. *Morb Mortal Recomm Rep* 2003;52(RR-10):34-8.
6. American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE). HVAC design manual for hospitals and clinics. Atlanta (GA): American Society of Heating, Refrigerating and Air-Conditioning Engineers; 2003.
7. Department of Human Services Standing Committee on Infection Control. Guidelines for the classification and design of isolation rooms in health care facilities. Victoria, Australia: Department of Human Services Standing Committee on Infection Control; 1999.
8. Regional Advisory Committee on Communicable Disease Control. Isolation rooms (including mechanically ventilated rooms): best practice standards for capital planning. Belfast, Northern Ireland: Regional Advisory Committee on Communicable Disease Control; 2004.
9. Beggs CB. The use of engineering measures to control airborne pathogens in hospital buildings. Available from: <http://www.efm.leeds.ac.uk/CIVE/MTB/CBB-Nov8.pdf>. Accessed April 26, 2006.
10. Hayden CS, Johnston OE, Hughes RT, Jensen PA. Air volume migration from negative pressure isolation rooms during entry/exit. *Appl Occup Environ Hygiene* 1998;13:518-27.
11. Decker J. Evaluation of isolation rooms in health care settings using tracer gas analysis. *Appl Occup Environ Hygiene* 1995;10:887-91.
12. Rydock JP, Eian PK. Containment testing of isolation rooms. *J Hosp Infect* 2004;57:228-32.
13. Johnson DL, Lynch RA, Mead KR. Containment effectiveness of expedient patient isolation units. *Am J Infect Control* 2009;37:94-100.
14. Johnson DL, Lynch RA. An efficient analytical method for evaluating airborne infectious isolation containment using fluorescent microspheres. *J Occup Environ Hygiene* 2008;5:271-7.
15. American Conference of Governmental Industrial Hygienists. Industrial ventilation: a manual for recommended practice. 26th ed. Cincinnati (OH): American Conference of Governmental Industrial Hygienists; 2007. p. 4.4.
16. Pavelchak N, Palmer W, DePersis RP, London MA. A simple and inexpensive method for determining the effective ventilation rate in a negatively pressurized room using airborne particles as a tracer. *Appl Occup Environ Hygiene* 2002;17:704-10.
17. Gill KE. HVAC design for isolation rooms. *HPAC* 1994;66:45-52.
18. Gill KE. Tuberculosis isolation room design using CDC guidelines. *HPAC* 1997;69:69-73.
19. Streifel AJ. Health-care IAQ: Guidance for infection control. *HPAC* 2000;72:28-36.
20. Wiseman B. Room pressure for critical environments. *ASHRAE J* 2003;45:34-9.

A Nosocomial Outbreak of Multidrug-Resistant Tuberculosis

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Background: An outbreak of seven cases (in six patients and one health care worker, all of whom had AIDS) of multidrug-resistant tuberculosis occurred in a hospital in Chicago. The hospital had a respirator-fit testing program but no acid-fast bacilli isolation rooms.

Objective: To identify risk factors for transmission of *Mycobacterium tuberculosis*.

Design: Retrospective cohort study.

Setting: Private hospital.

Participants: Patients and health care workers exposed to *M. tuberculosis*.

Measurements: Analysis of *M. tuberculosis* isolates, tuberculin skin testing, assessment of exposure, and assessment of participant characteristics.

Results: All seven *M. tuberculosis* isolates had matching DNA fingerprints. Of patients exposed to *M. tuberculosis*, those who developed tuberculosis had lower CD4⁺ T-lymphocyte counts ($P = 0.02$) and were more likely to be ambulatory ($P = 0.03$) than those who did not. Of 74 exposed health care workers, the 11 (15%) who had conversion on tuberculin skin testing were no more likely than those who did not have conversion to report that they always wore a respirator with a high-efficiency particulate air filter.

Conclusions: Transmission of *M. tuberculosis* occurred in a hospital that did not have recommended isolation rooms. A respirator-fit testing program did not protect health care workers in this setting.

Nosocomial outbreaks of tuberculosis have affected recommendations for infection control practices in hospitals in the United States (1–8). Administrative and environmental measures and respiratory protection for health care workers have been recommended (9, 10). Evidence suggests that adherence to these guidelines may be effective in preventing nosocomial transmission of *Mycobacterium tuberculosis* (11–13).

Of the 34 cases of multidrug-resistant tuberculosis (resistant to at least isoniazid and rifampin) that were reported to the Chicago Department of Health from January 1994 through April 1995, 6 occurred in patients with AIDS who had been admitted to one floor of one hospital. Because nosocomial transmission of multidrug-resistant tuberculosis was suspected, an investigation was initiated.

Methods

Potential outbreak cases—cases of tuberculosis in persons whose isolates were resistant to at least isoniazid and rifampin—were identified by matching the names of patients and health care workers at the hospital to state and local tuberculosis registries and by reviewing laboratory records and death certificates. We performed DNA fingerprinting of *M. tuberculosis* isolates using IS6110 and pTBN12 probes (14, 15).

Medical records were reviewed for patients who were admitted to the outbreak floor when a patient whose sputum smears were positive for acid-fast bacilli was present. Patients who died within 30 days of exposure were excluded.

Private providers of patients who may have been exposed to *M. tuberculosis* were contacted by telephone or by mail. All were advised to screen their patients for tuberculous disease and infection by tuberculin skin tests and symptom checks. A positive result on a tuberculin skin test was defined as induration of 5 mm or more, and an increase in induration of at least 5 mm was considered a skin test conversion. Severely immunocompromised patients (CD4⁺ T-lymphocyte count < 50 cells/mL) who did not receive skin testing were assumed to be anergic (16).

To assess exposure of health care workers to *M. tuberculosis*, we reviewed work schedules, chart signatures, and patient assignments. Results of testing for fit of respirators with high-efficiency particulate air (HEPA) filters and results of annual tuberculin skin tests were obtained from employee records. Health care workers also completed a form about infection control practices and exposure to *M. tuberculosis*.

Acid-fast bacilli isolation rooms (that is, rooms in

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From the Centers for Disease Control and Prevention, Atlanta, Georgia; and St. Joseph Hospital and the Chicago Department of Public Health, Chicago, Illinois. For current author addresses, see end of text.

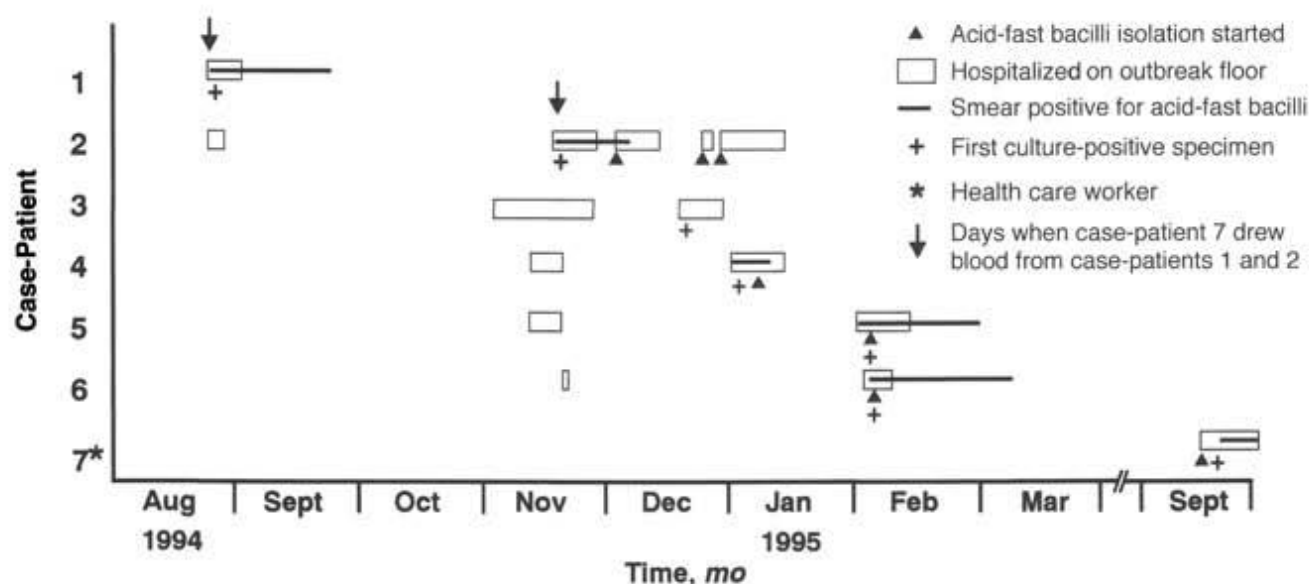


Figure. Timeline demonstrating two chains of nosocomial transmission of tuberculous organisms between August 1994 and September 1995 in a hospital in Chicago.

which the air pressure is negative in relation to the hallway and that have ≥ 6 air changes per hour) were installed in December 1994. The design of the ventilation system on the outbreak floor was reviewed, and smoke tube testing was done to assess the direction of air flow.

Data analysis was conducted using Epi Info, version 6 (17). Categorical variables were compared using the chi-square test, and relative risks with 95% CIs were derived. Continuous variables were compared using the Wilcoxon rank-sum test.

Results

Seven persons had outbreak cases of tuberculosis: six patients already known and one health care worker identified during the investigation. All of these persons had AIDS. All of their *M. tuberculosis* isolates were resistant to isoniazid and rifampin and had identical DNA fingerprints. Two generations of nosocomial transmission were identified (**Figure**). Case-patient 1 was admitted to the hospital with a diagnosis of tuberculosis; was placed in a private room; and began receiving therapy with isoniazid, rifampin, pyrazinamide, and ethambutol. From the time this patient was admitted, persons entering the patient's room were required to use HEPA-filter respirators. Case-patient 1 refused to remain in the room and was the source of infection for case-patient 2, who was hospitalized at the same time across the hallway.

Case-patient 2 was readmitted to the hospital 10 weeks later with fever, sinus pressure, and cough. Because the chest radiograph at admission was normal, tuberculosis was not initially suspected. A spu-

tum smear obtained 3 days after admission was positive (3+) for acid-fast bacilli. Treatment with isoniazid, rifampin, and ethambutol was started, and persons entering the patient's room were required to use HEPA-filter respirators. It was reported that the door to the patient's room was malfunctioning and failed to remain closed. Case-patient 2 remained in his room and yet was the source of infection for case-patients 3, 4, 5, and 6, who were hospitalized on the same ward. Transmission to case-patient 6, who was restricted to bed rest, occurred during this patient's short 23-hour hospitalization. Case-patient 7, the health care worker, drew blood from case-patient 2 before case-patient 2 received a diagnosis of tuberculosis and occasionally worked on the outbreak floor while case-patients 1 and 2 were present. For case-patients 2, 3, 4, 5, 6, and 7, no exposure to *M. tuberculosis* other than that which occurred in the hospital was identified. Case-patients 1 and 2 were never in an acid-fast bacilli isolation room while they were infectious because no such rooms were available until December 1994. Case-patients 4, 5, 6, and 7 were all placed in acid-fast bacilli isolation rooms when tuberculosis was suspected; case-patient 3 did not have sputum samples smear-positive for acid-fast bacilli. Smoke tube testing done in April 1995 revealed that the rooms occupied by case-patients 1 and 2 while these patients were infectious had air pressure that was positive in relation to the hallway. The acid-fast bacilli isolation rooms had air pressure that was negative in relation to the hallway. Ultraviolet germicidal irradiation was not used in the hospital.

The outbreak floor was composed of two separate wings with a central nursing station. Of the 169 patients on the floor, 5 had tuberculosis (case-

patients 2, 3, 4, 5, and 6). Of the 164 patients who did not have tuberculosis, 71 (43%) had AIDS. Fifty-three of the 164 patients died before completing screening; none (including 37 patients with AIDS) received a diagnosis of tuberculosis. Of the remaining 111 patients, 5 had positive results on tuberculin skin testing, 34 had negative results, 5 had previously had positive results, 27 were anergic, and 40 had unknown test results. All 5 patients with positive test results had other risk factors for *M. tuberculosis* infection (for example, foreign birth).

All 5 patients were on the same ward as case-patients 1 or 2 while these patients were infectious. No evidence of transmission among patients who did not have AIDS or patients exposed only to case-patients 3, 4, 5, or 6 was identified. Twenty-six patients with AIDS (all of whom were known or presumed to be anergic) were exposed to case-patients 1 or 2. At the time of exposure, case-patients had lower CD4⁺ T-lymphocyte counts than non-case-patients and were more likely to be ambulatory (Table).

Of the 104 exposed health care workers, 17 who had previously had positive results on skin tests and 13 who had resigned from the hospital were excluded from analysis. Of the remaining 74, 11 (15%) had tuberculin skin test conversions (6 nurses, 4 housestaff physicians, and 1 ward secretary) and 4 had positive skin test results, but no baseline test results. None had any other identified exposure to tuberculosis. The remaining 59 (80%) had negative results on skin testing at least 12 weeks after exposure. Except for case-patient 7, no health care worker developed tuberculosis.

Case-patient 2 was the source of most of the episodes of transmission to health care workers. While case-patient 2 was hospitalized with infectious tuberculosis, health care workers with skin test con-

versions worked more days on the floor than did health care workers with negative test results. Health care workers who had conversion were no more likely to have provided direct care to a case-patient, including case-patient 2, than were workers with negative test results (Table).

Forty-two (57%) of 74 exposed health care workers responded to questions about infection control practices. Those with negative test results were no more likely than those with skin test conversion to report always wearing a HEPA-filter respirator when entering the room of a patient with tuberculosis (25 of 29 workers compared with 4 of 5 workers; 8 workers did not recall whether they used HEPA-filter respirators). The results of respirator-fit testing before exposure were available for 68 health care workers; 62, including 80% of those with skin test conversions, passed this testing.

Discussion

This investigation provides evidence of nosocomial transmission of multidrug-resistant *M. tuberculosis*, including 1) exposure of case-patients who had secondary cases of tuberculosis to a source case-patient on the same floor of the hospital; 2) consistency of incubation periods with those of previous nosocomial outbreaks among patients with AIDS (1–3); 3) isolates with matching patterns of drug susceptibility and DNA fingerprints; 4) lack of any other identified exposure to tuberculosis; and 5) exposure of all health care workers with skin test conversion to a case-patient who was not in an acid-fast bacilli isolation room.

Several factors may have contributed to the transmission of *M. tuberculosis*, but the evidence for the role of insufficient environmental controls is

Table. Risk Factors for Nosocomial Transmission of *Mycobacterium tuberculosis* among Patients and Staff

Risk Factor	Persons with Tuberculosis (n = 5)	Persons without Tuberculosis (n = 21)	Rate Ratio (95% CI)	P Value	Persons with Conversion on Tuberculin Skin Testing (n = 11)	Persons Negative on Tuberculin Skin Testing (n = 59)	Rate Ratio (95% CI)	P Value
Risk factors for active tuberculosis among patients admitted to the hospital								
Mean CD4 ⁺ T-lymphocyte count (range), cells/mL	15 (0–61)	157 (0–559)	–	0.02				
Being ambulatory, n*	3	2	6.3 (1.4–28.2)	0.03				
Risk factors for tuberculin skin test conversion among health care workers								
Providing direct care to a case-patient, nt					7	30	1.3 (0.8–2.1)	>0.2
Exposure to case-patient 2, nt					8	21	3.8 (1.0–13.0)	0.04
Duration of exposure to case-patient 2 (range), d					3 (0–9)	1 (0–9)	–	0.03

* Values given are numbers of patients.

† Values given are numbers of health care workers.

most compelling. Case-patients 1 and 2 were both infectious, and the flow of contaminated air from their rooms (which had air pressure that was positive in relation to the hallway) facilitated the spread of infectious droplet nuclei throughout the outbreak floor. Organisms were transmitted to health care workers who did not directly care for a patient with infectious tuberculosis and to one secretary who did not have patient care responsibilities. In this situation, a respiratory protection program did not prevent transmission to health care workers; these findings are consistent with previous evidence that inadequate environmental controls were an important factor in nosocomial transmission (8). Case-patients 1 and 2 were both placed on antituberculous medication either at admission or within 3 days of admission, but the delayed recognition of and inadequate therapy for multidrug-resistant tuberculosis could have contributed to transmission. In many other reports (2-7), delayed recognition was a common reason for transmission of tuberculous organisms.

Case-patient 2 shows that a patient with AIDS can have infectious tuberculosis despite a normal chest radiograph. Active pulmonary tuberculosis should be suspected in patients who have AIDS, fever, and cough, regardless of radiographic findings (10). The evidence of transmission to a patient exposed for only 23 hours underscores the urgency with which patients who have signs and symptoms compatible with tuberculosis should be immediately isolated and evaluated.

Limitations of this investigation include the possible underestimation of transmission to exposed patients as a result of a high patient mortality rate. In addition, immunosuppression among patients may have made tuberculin skin testing unreliable. Skin test results were not available for 40 of the patients who may have been exposed; however, most of these patients were not known to have HIV infection, and their private physicians did not consider them to be at high risk for tuberculous infection or disease. The number of exposed health care workers who became infected without directly caring for a patient with tuberculosis may have been overestimated because chart signatures and assignment sheets may have been incomplete. Information is lacking for health care workers who resigned from the hospital or did not complete the questionnaire. Use of respirators may have been overestimated as a result of self-reporting.

As of 1993, 38% of hospitals in the United States reported not having acid-fast bacilli isolation rooms consistent with guidelines from the Centers for Disease Control and Prevention (18). Inadequate isolation facilities and delayed diagnosis of tuberculosis may contribute to the airborne spread and nosoco-

mial transmission of *M. tuberculosis*. Germicidal ultraviolet irradiation may be used as a supplemental environmental control measure to reduce the concentration of infectious droplet nuclei in the environment (10). The excellent skin testing program in this hospital facilitated the detection of new infections. A respiratory protection program alone cannot protect all health care workers from infection with *M. tuberculosis*, especially those who work on the wards but do not enter patient rooms. Hospital infection control programs should emphasize the prompt identification of patients with tuberculosis and isolation consistent with the recommendations of the Centers for Disease Control and Prevention. Although all cases of active tuberculosis in this outbreak were seen in persons with AIDS, inadequate administrative and environmental controls put all patients and hospital staff at risk for tuberculous infection and disease.

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References

1. Dooley SW, Villarino ME, Lawrence M, Salinas L, Amil S, Rullan JV, et al. Nosocomial transmission of tuberculosis in a hospital unit for HIV-infected patients. *JAMA*. 1992;267:2632-4.
2. Edlin BR, Tokars JI, Grieco MH, Crawford JT, Williams J, Sordillo EM, et al. An outbreak of multidrug-resistant tuberculosis among hospitalized patients with the acquired immunodeficiency syndrome. *N Engl J Med*. 1992;326:1514-21.
3. Fischl MA, Uttamchandani RB, Daikos GL, Poblete RB, Moreno JN, Reyes RR, et al. An outbreak of tuberculosis caused by multiple-drug-resistant tubercle bacilli among patients with HIV infection. *Ann Intern Med*. 1992;117:177-83.
4. Pearson ML, Jereb JA, Frieden TR, Crawford JT, Davis BJ, Dooley SW, et al. Nosocomial transmission of multidrug-resistant *Mycobacterium tuberculosis*. A risk to patients and health care workers. *Ann Intern Med*. 1992;117:191-6.
5. Beck-Sague C, Dooley SW, Hutton MD, Otten J, Breeden A, Crawford JT, et al. Hospital outbreak of multidrug-resistant *Mycobacterium tuberculosis* infections. Factors in transmission to staff and HIV-infected patients. *JAMA*. 1992;268:1280-6.
6. Jereb JA, Burwen DR, Dooley SW, Haas WH, Crawford JT, Geiter LJ, et al. Nosocomial outbreak of tuberculosis in a renal transplant unit.

- application of a new technique for restriction fragment length polymorphism analysis of *Mycobacterium tuberculosis* isolates. *J Infect Dis.* 1993;168:1219-24.
7. Coronado VG, Beck-Sague C, Hutton MD, Davis BJ, Nicholas P, Vil-lareal C, et al. Transmission of multidrug-resistant *Mycobacterium tuberculosis* among persons with human immunodeficiency virus infection in an urban hospital: epidemiologic and restriction fragment length polymorphism analysis. *J Infect Dis.* 1993;168:1052-5.
 8. Ikeda RM, Birkhead GS, DiFerdinando GT Jr, Bornstein DL, Dooley SW, Kubica GP, et al. Nosocomial tuberculosis: an outbreak of a strain resistant to seven drugs. *Infect Control Hosp Epidemiol.* 1995;16:152-9.
 9. Dooley SW Jr, Castro KG, Hutton MD, Mullan RJ, Polder JA, Snider DE Jr. Guidelines for preventing the transmission of tuberculosis in health-care settings, with special focus on HIV-related issues. *MMWR Morb Mortal Wkly Rep.* 1990;39(RR-17):1-29.
 10. Guidelines for preventing the transmission of *Mycobacterium tuberculosis* in health-care facilities, 1994. Centers for Disease Control and Prevention. *MMWR Morb Mortal Wkly Rep.* 1994;43(RR-13):1-132.
 11. Stroud LA, Tokars JI, Grieco MH, Crawford JT, Culver DH, Edlin BR, et al. Evaluation of infection control measures in preventing the nosocomial transmission of multidrug-resistant *Mycobacterium tuberculosis* in a New York City hospital. *Infect Control Hosp Epidemiol.* 1995;16:141-7.
 12. Blumberg HM, Watkins DL, Berschling JD, Antle A, Moore P, White N, et al. Preventing the nosocomial transmission of tuberculosis. *Ann Intern Med.* 1995;122:658-63.
 13. Wenger PH, Otten J, Breeden A, Orfas D, Beck-Sague CM, Jarvis WR. Control of nosocomial transmission of multidrug-resistant *Mycobacterium tuberculosis* among health care workers and HIV-infected patients. *Lancet.* 1995;345:235-40.
 14. van Embden JD, Cave MD, Crawford JT, Dale JW, Eisenach KD, Gicquel B, et al. Strain identification of *Mycobacterium tuberculosis* by DNA fingerprinting: recommendations for a standardized methodology. *J Clin Microbiol.* 1993;31:406-9.
 15. Chaves F, Yang Z, el Hajj H, Alonso M, Burman WJ, Eisenach KD, et al. Usefulness of the secondary probe pTBN12 in DNA fingerprinting of *Mycobacterium tuberculosis*. *J Clin Microbiol.* 1996;34:1118-23.
 16. Caiaffa WT, Graham NM, Galai N, Rizzo RT, Nelson KE, Vlahov D. Instability of delayed-type hypersensitivity skin test anergy in human immunodeficiency virus infection. *Arch Intern Med.* 1995;155:211-7.
 17. Dean AG, Dean JA, Coulombier D, Brendel KA, Smith DC, Burton AH, et al. Epi Info, Version 6: A Word Processing, Database, and Statistics Program for Epidemiology on Microcomputers. Atlanta, GA: Centers for Disease Control and Prevention; 1994.
 18. Fridkin SK, Manangan L, Bolyard E, Jarvis WR. SHEA-CDC TB survey, Part I: Status of TB infection control programs at member hospitals, 1989-1992. *Society for Healthcare Epidemiology of America. Infect Control Hosp Epidemiol.* 1995;16:129-34.

Those people who have no knowledge of ethics, who are fearful of people because of fearfulness of soul, who when struck by misfortune or disaster wail and weep, and who when they receive something good, though joy is great, given the defective education of their souls, imagine that they have received an uncommonly great good and in their pride become more arrogant. However, for those who decide in favor of ethics, their souls gain in strength. They are truly heroes, so that their souls are always slightly influenced and altered by good and evil. The more spiritual training a man has, no matter his religion or change of circumstances, then happiness or unhappiness when receiving a great good or evil is less unsettling than those who do not believe. When struck by a great happiness or unhappiness, those who have the ethical and philosophical belief are less elevated by or unsettled and therefore bear happiness or sorrow more bravely.

Moses Maimonides
The Guide to Good Health for the Al Afdal
 13th century

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Nosocomial aspergillosis and building construction

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Healthcare-associated infections (HAI) with *Aspergillus* pose a serious threat to those most severely immune suppressed patients. Outbreaks of nosocomial aspergillosis have occurred mainly among neutropenic patients, but with several important exceptions. HAI due to aspergillosis has occurred in association with environmental disturbances including but not limited to: hospital construction, maintenance, demolition and renovation; contaminated fireproofing materials; air filters in hospital ventilation systems, and via contaminated carpeting. It behooves those in the practice of patient care to prevent these situations before they occur, as opposed to dealing with them once they happen. The framework of the six links in the infectious disease process will be used to examine healthcare-associated invasive aspergillosis: causative agent, portal of entry, susceptible host, portal of exit, reservoir and mode of transmission. Two particular interventions: the Protective Environment (PE), and the Infection Control Risk Assessment (ICRA), will be outlined. Building construction projects and the number of neutropenic patients are likely to continue to increase. Therefore, future directions need to focus on reducing the susceptibility of the susceptible host and reducing the exposure to *Aspergillus* from environmental sources. In addition, recently released guidelines with control measures aimed at reducing environmental exposure to *Aspergillus* need to be further studied.

Keywords nosocomial aspergillosis, healthcare-associated aspergillosis, construction, aspergillosis outbreaks, nosocomial infections

Introduction

Healthcare-associated infections (HAI) with *Aspergillus* pose a serious threat to those most severely immune suppressed patients. Outbreaks of nosocomial aspergillosis have occurred mainly among neutropenic patients, but with several important exceptions. HAI due to *Aspergillus* have occurred in association with environmental disturbances including but not limited to: hospital construction, maintenance, demolition and renovation; contaminated fireproofing materials; air filters in hospital ventilation systems, and via contaminated carpeting. The framework of the six links in the infectious disease process will be used to examine

healthcare-associated invasive aspergillosis. Two infection control measures designed to protect the severely immune suppressed form HAI due to aspergillosis, the Protective Environment and the Infection Control Risk Assessment will be described in detail. Finally, implications for the future will be presented.

Background

It is estimated that healthcare-associated infections (HAI) account for approximately 1.7 million infections and 99,000 associated deaths each year in the United States. Of these HAI: the breakdown is as follows: 32% urinary tract infections, 22% surgical site infections, 15% pneumonia, and 14% bloodstream infections [1]. It is important to note that even though pneumonia is not the most frequently occurring form of HAI, this type of HAI carries with it the highest mortality rate [2]. Fungal infections comprise 9% of all HAIs. Among fungal infections, *Candida* accounts for 85.6% and

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Aspergillus 1.3% (<2%) respectively. It has also been estimated that between 1980 and 1990, 2.0–3.8%/1,000 patient discharges had HA fungal infections [2,3]. Healthcare-associated *Aspergillus* infections are most frequently due to *A. fumigatus*, *A. flavus*, and then followed by other species. Pneumonia is the most common clinical presentation for aspergillosis and therefore patients who acquire aspergillosis have a very high mortality rate. The mortality rates reported in the literature have been as high as 95% in certain cases [3,4].

It is difficult to provide a specific incidence for aspergillosis cases, as this is not one of the nationally notifiable diseases or conditions. Thus, currently no national surveillance data exists. As an example, a population-based study conducted in San Francisco, California estimated the incidence of aspergillosis to be 1–2 cases/per 100,000 persons/per year. Currently, the Centers for Disease Control is conducting active surveillance among hematopoietic stem cell transplants & solid organ transplant recipients in selected US hospitals [4].

Components of the infectious disease process in relation to healthcare-associated aspergillosis

It is important to note that healthcare-associated aspergillosis is a global problem. Numerous outbreaks have been reported in the literature from many countries [3,5]. In this section, the components of the infectious disease process and their relationship to acquisition of healthcare-associated aspergillosis will be outlined. Case examples to illustrate these components will be included.

There are six links in the chain of the infectious disease process. These are: causative agent, mode of transmission, susceptible host, portal of entry, portal of exit, and reservoir [6]. The ‘causative agent’ is defined as a biologic, physical or chemical entity capable of causing disease. In cases of healthcare-associated aspergillosis, the causative agent includes all species of *Aspergillus* that have caused infection in patients. Rather than limit the number of species, it is important to emphasize that *Aspergillus* is a fungus, ubiquitous in nature, which has been recovered from numerous environmental sources and may continue to be present as long as there are activities which disrupt it from its reservoir. The species of *Aspergillus* most frequently acting as the causative agent in 53 outbreaks of healthcare-associated invasive aspergillosis affecting 458 patients was *fumigatus* (154 cases), *flavus*

(101 patients), and no species identification was conducted in 108 cases [5].

The ‘mode of transmission’ is the mechanism of transfer of an infectious agent from a reservoir to a susceptible host. In the HAI context, despite one report to the contrary, aspergillosis is not transmissible from person to person. In one report, debridement and dressing of a wound infected with aspergillus was the documented source of airborne transmission of this pathogen between patients in a transplant intensive care unit [7]. There have been no other reports to date where person-to-person transmission resulted in cases of invasive aspergillosis. Thus, in this context, the mode of patient-to-patient transmission is not a major component in the infectious disease process on which to place focused intervention efforts to prevent healthcare-associated aspergillosis.

The ‘portal of entry’ is defined as the path by which an infectious agent enters the susceptible host. Portals of entry associated with human hosts are numerous, and similar to the portals of exit. In healthcare facilities, patients have many portals of entry and numerous opportunities for the entry of infectious agents, when the first line of defense, the skin, is entered or interrupted. When specifically examining HAI with *Aspergillus*, the portal of entry in the majority of reported cases has been through the pulmonary tract, by inhalation of conidia. [3,5]. However, there are other reports in the literature describing a different portal of entry than the pulmonary tract. One notable report was a case series from Saudi Arabia. Five cases of *Aspergillus* ophthalmitis occurred within a 3-week period coinciding with hospital construction. The outcome for all five cases was enucleation or evisceration. The authors noted that the primary period for optimal growth and multiplication of *A. fumigatus* (the causative organism in these cases) is January through March, and this cluster occurred during January and February [8].

In another report, the portal of entry was direct inoculation of *Aspergillus* spores into surgical and burn wounds of five patients. In these cases, the outside of the dressing supply packages became contaminated during construction in the central inventory control area, resulting in direct inoculation of *Aspergillus* spores into large exposed skin surfaces. [9]. In a report from Switzerland, two cases of fatal pulmonary aspergillosis occurred in patients who were intubated and mechanically ventilated after a routine air filter change had occurred in the same intensive care unit room. In these cases, it is postulated that the portal of entry was by a high inoculum of spores during mechanical ventilation [10].

This is an important aspect regarding the portal of entry for HAI *Aspergillus*. Even though the pulmonary tract has been the most common portal of entry, these other examples underscore the importance of reducing patient exposures to *Aspergillus* conidia released from environmental reservoirs.

The definition of a 'portal of exit' is the path by which an infectious agent leaves the reservoir. Portals of exit associated with human and animal reservoirs are the following: the respiratory tract, genitourinary tract, gastrointestinal tract, the skin/mucous membranes, transplacentally from mother to infant, and via blood. In a healthcare-associated situation, the portal of exit is closely related to the mode of transmission. As the majority of HAI with *Aspergillus* are not transmitted from person to person, the emphasis on focusing control measures on preventing the exit of that organism from the infected patient does not appear to a major component. The one noted exception, person-to-person transmission by the airborne route, was theorized to occur from aerosolization of a patient's wound infected with *Aspergillus species* when the wound was debrided and dressed. Aerosolization of spores from the wound was the portal of exit in this instance [7].

The 'susceptible host' is a person or animal lacking effective resistance to a particular agent. Susceptible hosts for healthcare-associated *Aspergillus* infections have included, in decreasing order of frequency, patients with hematological malignancies (in particular, allogeneic hematopoietic stem cell transplant patients (HSCT), solid organ transplants, other immune suppressed patients, and non-immune suppressed patients [5]. The majority of reports have been from HSCT patients, with high fatality rates [5]. One report described two cases of fatal invasive aspergillosis in two patients with chronic obstructive pulmonary disease but without immune suppression. Risk factors for the cases included room placement and intubation. Both patients had been in the same room and died 16 and 22 days after intubation respectively. Both had negative sputum cultures before they were intubated [10]. In the previously mentioned outbreak causing five cases of *Aspergillus* ophthalmitis, the affected cases were patients undergoing cataract surgery [8].

The 'reservoir' is a place in which an infectious agent can survive but may or may not multiply. The three most common reservoirs associated with hospital-acquired infectious agents include patients, healthcare personnel and the healthcare equipment/environment. When focusing on HAI due to *Aspergillus*, there have been numerous reports tracing the source of cases or outbreaks to construction conducted in healthcare facilities. The two main environmental sources have

included unfiltered outside air entering hospital through gaps in filters, windows, backflow of contaminated air; and moist environments (e.g., plumbing, leaks, rainwater, air conditioning condensate, etc.). However, it is important to note that there have been no reported outbreaks of *Aspergillus* traced to water sources [5].

Examples of additional areas which have served as reservoirs for HAI aspergillosis include but are not limited to the following: air filters, fireproofing materials, air conditioners, duct systems, and dust above false ceilings [10–14]. These examples illustrate the need for efforts to be undertaken to reduce the opportunities for *Aspergillus* spores to leave their reservoirs during construction and other activities which release and disperse the spores.

When outbreak investigations have been conducted, positive cultures have been found from ceiling tiles, carpet, fireproofing materials, and particleboard frames of air filters. This raises issues regarding environmental culturing for *Aspergillus*. In general, routine culturing of the environment is not recommended except in a few specific circumstances. These include monitoring of dialysis water and dialysate, infant formulas, and when implicated in an epidemiologic investigation. This culturing, when conducted, should be done in conjunction with Infection Control & the Hospital Epidemiologist [15].

Another issue with environmental cultures is determining how much *Aspergillus* is required to cause an infection. In 24/53 outbreak articles, the concentration of airborne fungi in patient care areas ranged from 0–100 spores/m³. However, even spore counts <1 cfu/m³ were sufficient to cause infection in high-risk patients [5]. This is an area requiring more investigation.

Reviewing the six links in the chain of the infectious disease process in relation to HAI aspergillosis leads to the following issues. First, as an infectious agent, *Aspergillus* species are ubiquitous in nature. The portal of entry for most cases to date has been the respiratory tract, with some notable exceptions. The portal of exit and mode of transmission have for the most part, not been as important factors in nosocomial transmission. The HSCT patient and solid organ transplant patients have been the susceptible hosts in the majority of reports. The reservoir of *Aspergillus* spores is the most problematic link in this chain, and control efforts to prevent release of the spores during activities such as construction, demolition and renovation must be emphasized. When this is unavoidable, then the most susceptible hosts need to be protected in the healthcare environment.

Control measures

It is clear up to this point, that environmental reservoirs of *Aspergillus* disturbed during periods of construction, demolition and renovation have been suspected as the source in numerous case and outbreak reports in healthcare facilities. Control measures that have been used to reduce risk of healthcare associated aspergillosis have included high efficiency particulate airflow (HEPA) filter air purifiers, application of copper-8-quinolinolate (fungicide for non-porous construction materials), sealing windows, replacement of dust-accumulating horizontal blinds with vinyl, roller-type blinds, and systematic and regular surface cleaning (eliminating upholstered furniture and carpets) [15,16]. One study from Canada had, as its goal, to determine the incidence of aspergillosis in patients with leukemia or bone marrow transplants during a construction-associated outbreak and the effect of environmental control program on the incidence of aspergillosis. Thirty-six cases of healthcare-associated invasive aspergillosis occurred from January 1988 through September 1993. The incidence density preconstruction was 3.16/1000 days at risk. During construction activity before control measures were initiated, the incidence density increased to 9.88/1000 days at risk. When control measures were started and continued during the construction period, the incidence density decreased to a pre-construction level, to 2.91/1000 days at risk [17]. In a retrospective cohort study from a cancer center in the USA, 10(18%) of 55 hematology unit patients admitted from July to December 1992 were diagnosed as having invasive aspergillosis with *A. flavus* as compared with 0(0%) of 36 from January to June 1992 in the same unit. High air counts of *Aspergillus* conidia in a neighboring unit were considered to be the source of the cases. Once high efficiency particulate air filtration was added to the ventilation system of the hematology unit, there were only 2 more nosocomial aspergillosis cases in the 2 years after this outbreak. [18].

Protective environment

In 2003 and then again in 2007, the Centers for Disease Control and Prevention have recommended an infection control strategy to reduce the risk of healthcare-associated aspergillosis. This strategy is termed the 'Protective Environment' (PE) [15,19]. This recommendation applies only to acute care hospitals that provide care to hematopoietic stem cell transplant (HSCT) patients. Included in the PE recommendation are single-patient rooms, specific ventilation requirements,

and increased cleaning frequency to decrease dust accumulation. The 2007 guideline recommends respiratory protection (such as an N-95 particulate respirator) for HSCT patients, who are medically fit, when leaving the Protective Environment during periods of construction [19].

It is interesting to note the evolution of the Protective Environment concept. In the 1970s, the CDC first introduced a category of isolation called 'Reverse Isolation'. This required use of an aseptic environment, protective apparel for all entering the room, and special ventilation. In their next two guideline revisions 1983 and 1996, the category was removed altogether with the caveat that studies had not demonstrated the effectiveness of this category in reducing nosocomial infections. Reports of numerous outbreaks of nosocomial aspergillosis infections and their links to hospital construction and renovation were responsible, in part, for the latest term 'Protective Environment' which applies to a specific type of immune suppressed patient group, those with hematopoietic stem cell transplants [15,19]. The CDC states that there are no published reports to support the use of a Protective Environment for either solid organ transplant patients or other immune suppressed patients [19]. The numerous recommendations have varying categories, from IA to II, depending upon what types of studies can support them and /or whether there is a strong theoretical rationale or panel of experts to support them. This is an area with need for further investigation to determine the effectiveness of specific recommendations in reducing healthcare-associated aspergillosis.

Infection control risk assessment

An additional infection control strategy is the Infection Control Risk Assessment (ICRA). The ICRA is a multidisciplinary process focusing on reducing risk from infection throughout facility planning, design, and construction (including renovation) activities. A multidisciplinary team considers the environment, infectious agents, human factors and the impact of the proposed project in this process. The ICRA is a step-by-step process that begins with identifying the type of construction project activity, assessing the at-risk patient population and concludes with determining infection control recommendations for each class of activity rated A-D. The ICRA is part of the American Institute of Architects' *Guidelines for Design and Construction of Health Care Facilities* [20].

Even though designed as guidelines, the Joint Commission for the Accreditation of Healthcare Organizations (JCAHO), in their Environment of Care

Table 1 Levels of infection risk, from low to high, according to hospital department/unit [22].

Low risk	Medium Risk	High Risk	Highest Risk
Office areas	Cardiology Echocardiography Endoscopy Nuclear Medicine Physical Therapy Radiology/Magnetic Resonance Imaging Respiratory Therapy	Critical Care Units Emergency Department Labor & Delivery Laboratories Newborn Nursery Outpatient Surgery Pediatrics Pharmacy Post Anesthesia Care Unit Surgery Units	Any area with immune-suppressed Burn Unit Cardiac Cath Lab Central Sterile Supply Intensive Care Unit Medical Unit Negative Pressure Isolation Room Oncology Operating Rooms (including C-Section)

section, requires that the ICRA be followed by all healthcare facilities. In addition to these guidelines, JCAHO requires daily logs to be kept during the construction projects (including weekends and holidays) and that facilities comply with the AIA guidelines. Therefore, if a healthcare facility wishes to receive JCAHO accreditation, these guidelines must be followed [21].

There are four steps in the ICRA process. Step One is to identify the type of construction project activity. There are four categories of construction project activity ranging from A–D. Type A activities are those that are non-invasive, including, not limited to: (i) removal of ceiling tiles where no dust is expected, (ii) painting without sanding, and (iii) wall covering, electrical trim work, minor plumbing, and activities which do not generate dust or require cutting of walls or access to ceilings other than for visual inspection. The important condition for an activity to fit into Category A is that it does not produce any dust. Type B activities include small scale, short duration activities that create minimal dust. Examples include: (i) installation of telephone and computer cabling, (ii) access to chase spaces, and (iii) cutting of walls or ceilings where dust migration can be controlled. The key to being categorized as a Type B activity is a project of short duration where minimal dust is produced. Type C Activities include work generating moderate to increased level of dust or requires demolition/removal of any fixed building components. Examples include but are not limited to (i) sanding of walls for painting/

wall covering, (ii) removing floor coverings, ceiling tiles, and casework, and (iii) new wall construction. Type C also includes any activity which cannot be completed in a single work shift. Type C activities are dust generating and/or of longer duration. Type D Activities apply to major demolition and construction projects, including renovation. Examples of Type D activities include those requiring heavy demolition or removal of a complete cabling system or new construction. The key to type D is that this includes major demolition or construction [22].

Step Two in the ICRA process is to identify the patient risk group that will be affected (see Table 1). If more than one risk group is affected, the higher group should be selected. It is important to mention that for all construction classes, the patient must be removed from the room while work is performed [22].

Step Three is to match the patient risk group (Low, Medium, High, and Highest) with the construction project type (A, B, C, D) to find the class of precautions (I–IV) that need to be followed (see Table 2). To determine the class of precautions required during a particular project, select the risk group, and then follow it to the corresponding project type. The classes of precautions are the levels of infection control activities required to be followed during the particular project.

To illustrate how this process works, suppose there needs to be a new computer system installed in the Nuclear Medicine Department. This job will require three days to complete. Thus, this is a Type C activity.

Table 2 Matrix of project category type, patient risk group and class of required infection control precautions [22].

Patient Risk Group	Project Type A	Project Type B	Project Type C	Project Type D
LOW Risk	Class I	Class II	Class II	Class III/IV
MEDIUM Risk	Class I	Class II	Class III	Class IV
HIGH Risk	Class I	Class II	Class III/IV	Class IV
HIGHEST Risk	Class II	Class III/IV	Class III/IV	Class IV

The Nuclear Medicine Department is a medium risk area. Given this information, one can determine that Class III precautions need to be followed for this project.

Conclusion

Building construction projects and the number of neutropenic patients are likely to continue to increase in number, thus augmenting the risk and occurrence of healthcare-associated aspergillosis. It is also possible that advances in technology may require neutropenic patients to remain in protective environment for longer than the 100 days currently necessary. Such patients must be protected from infections. Based upon an analysis of the infectious disease process in relation to healthcare-associated *Aspergillus* infections, future directions need to focus on reducing the susceptibility of the host and reducing the exposure to *Aspergillus* from environmental reservoirs. Future research questions may need to include how to detect the smallest numbers of colonies in the environment, how to make additional materials fungicidal, how to make patients non-neutropenic and the potential for vaccines against *Aspergillus*. Investigators in this field are encouraged to review research that has been conducted with a critical eye and contribute to future study designs. It behooves those in the practice of patient care to prevent aspergillus infections before they occur, as opposed to dealing with them once they happen. Recently released guidelines, such as the Protective Environment and the Infection Control Risk Assessment, take this proactive approach, with control measures related to reducing environmental exposure to *Aspergillus* spores by susceptible patients. However, these measures need to be further studied for their effectiveness in reducing healthcare-associated aspergillosis.

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References

- 1 Klevens RM, Edwards JR, Richards CL, *et al.* Estimating healthcare-associated infections and deaths in U.S. hospitals, 2002. *Public Health Rep* 2007; **122**: 160–166.
- 2 National Nosocomial Infection Surveillance (NNIS) Report, data summary from 1992 through June 2004, issued October 2004. *Am J Infect Control* 2004; **32**: 470–485.
- 3 Trick WE, Jarvis WR. Epidemiology of nosocomial fungal infection in the 1990s. *Rev Iberoam Micol* 1998; **15**: 2–6.
- 4 Aspergillosis, Mycotic Diseases Branch [webpage on the internet]. Atlanta: Centers for Disease Control and Prevention; [updated 6 December 2005; cited 15 January 2008]. Available from: http://www.cdc.gov/ncidod/dbmd/diseaseinfo/aspergillosis_t.htm
- 5 Vonberg RP, Gastmeier P. Nosocomial aspergillosis in outbreak settings. *J Hosp Infect* 2006; **63**: 246–254.
- 6 Jackson M. General principles of epidemiology. In: Olmstead RN (ed.). *APIC Infection Control and Applied Epidemiology: Principles and Practice*. St. Louis: Mosby, 1996: 1–19.
- 7 Pegues DA, Lasker BA, McNeil MM, *et al.* Cluster of cases of invasive aspergillosis in a transplant intensive care unit: evidence of person-to-person airborne transmission. *Clin Infect Dis* 2002; **34**: 412–416.
- 8 Tabbara KF, Jabarti AA. Hospital-construction-associated outbreak of ocular aspergillosis after cataract surgery. *Ophthalmology* 1998; **105**: 522–526.
- 9 Bryce EA, Walker M, Scharf S, *et al.* An outbreak of cutaneous aspergillosis in a tertiary-care hospital. *Infect Control Hosp Epidemiol* 1996; **17**: 170–172.
- 10 Pittet D, Huguenin T, Dharan S, *et al.* Unusual case of lethal pulmonary aspergillosis in patients with chronic obstructive pulmonary disease. *Am J Resp Crit Care Med* 1996; **154**: 541–544.
- 11 Aisner J, Schimpff SC, Bennett JE, Young VM, Wiernik PH. *Aspergillus* infections in cancer patients: association with fire-proofing materials in a new hospital. *JAMA* 1976; **235**: 411–412.
- 12 Lentino JR, Rosenkranz MA, Michaels JA, *et al.* Nosocomial aspergillosis: A retrospective review of airborne disease secondary to road construction and contaminated air conditioners. *Am J Epidemiol* 1982; **116**: 430–437.
- 13 Sarubbi FA, Kopf HB, Wilson MB, McGinnis MR, Rutala WA. Increased recovery of *Aspergillus flavus* from respiratory specimens during hospital construction. *Am Rev Respir Dis* 1982; **125**: 33–38.
- 14 Krasinski K, Holzman RS, Hanna B, *et al.* Nosocomial fungal infections during hospital renovation. *Infect Control* 1985; **6**: 278–282.
- 15 Centers for Disease Control and Prevention (CDC). Guidelines for environmental infection control in healthcare facilities: recommendations of CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC). *MMWR* 2003; **52** (No. RR-10): 1–44.
- 16 Tablan OC, Anderson LJ, Arden NH. Guidelines for preventing healthcare-associated pneumonia 2003: recommendations of the Centers for Disease Control and the Healthcare Infection Control Practices Advisory Committee (HICPAC). *MMWR* 2004; **53**(RR-3): 1–36.
- 17 Loo VG, Bertrand C, Dixon C, *et al.* Control of construction-associated aspergillosis in an antiquated hematology unit. *Infect Control Hosp Epidemiol* 1996; **17**: 360–364.
- 18 Hahn T, Cummings KM, Michalek AM, *et al.* Efficacy of high-efficiency particulate air filtration in preventing aspergillosis in immune compromised patients with hematological malignancies. *Infect Control Hosp Epidemiol* 2000; **21**: 135–136.
- 19 Siegel JD, Rhinehart E, Jackson M, Chiarello L and the Healthcare Infection Practices Advisory Committee. 2007 Guidelines for isolation precautions: preventing transmission of infectious agents in healthcare settings. [June 2007; cited 15 January 2008].

- 2008]. Available from: <http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/Isolation2007.pdf>
- 20 American Institute of Architects (AIA). *Guidelines for Design and Construction of Health Care Facilities*. The Facilities Guideline Institute, Washington DC, USA, 2006.
 - 21 Joint Commission for the Accreditation of Healthcare Organizations. *Comprehensive Accreditation Manual for Hospitals: The Official Handbook*. Joint Commission Resources, Illinois, USA, 30 November 2007.
 - 22 Infection Control Risk Assessment Matrix of Precautions for Construction & Renovation. APIC [webpage on the internet]. Association for Professionals in Infection Control and Epidemiology; [updated 2005; cited 15 January 2008]. Available from: http://www.apic.org/AM/Template.cfm?Section=ICRA_Matrix_Construction_and_Renovation&Template=/CM/ContentDisplay.cfm&ContentID=3788

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Cystic Fibrosis our focus

Mycobacterium abscessus

Recommendations for infection prevention and control

November 2017

Report of the Cystic Fibrosis Trust *Mycobacterium abscessus*
Infection Control Working Group

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Grading scheme for recommendations used in *M. abscessus*

The criteria for the grading of recommendations in this document are based upon a paper by Petrie et al (1995) published on behalf of the Scottish Intercollegiate Guidelines Network.

Much of the data in the document is derived from observational studies where randomisation is not appropriate or possible, however a lot is also from peer reviewed scientific studies. The above grading is therefore not always appropriate.

Levels of evidence

Level	Type of evidence (based on AHCPR, 1992)
Ia	Evidence obtained from meta-analysis of randomised controlled trials.
Ib	Evidence obtained from at least one randomised controlled trial.
IIa	Evidence obtained from at least one well designed controlled study without randomisation.
IIb	Evidence from at least one other type of quasi-experimental study.
III	Evidence obtained from well-designed, non-experimental, descriptive studies, such as comparative studies, correlation studies or case control studies.
IV	Evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities.

Grading of recommendations

Grade	Type of recommendation (based on AHCPR, 1992)
A (levels Ia, Ib)	Requires at least one randomised controlled trial as part of the body of literature, of overall good quality and consistency, addressing the specific recommendation.
B (levels IIa, IIb, III)	Requires availability of well conducted clinical studies but no randomised clinical trials on the topic of the recommendation.
C (level IV)	Requires evidence from expert committee reports or opinions and/or clinical experience of respected authorities. Indicates absence of directly applicable studies of good quality.

References

- Petrie GJ, Barnwell E, Grimshaw J, on behalf of the Scottish Intercollegiate Guidelines Network. Clinical guidelines: criteria for appraisal for national use. Edinburgh: Royal College of Physicians, 1995.
- Agency for Health Care Policy and Research (AHCPR). Acute pain management, operative or medical procedures and trauma 92-0032. Clinical practice guidelines. Rockville, Maryland, USA: Agency for Healthcare Policy and Research Publications, 1992.

Summary of main recommendations

- All cystic fibrosis (CF) services must have a local infection control guideline that addresses *M. abscessus*.
- All CF services must routinely screen for non-tuberculous mycobacteria (NTM) and forward *M. abscessus* isolates to an appropriate reference laboratory for sub-speciation and strain typing.
- All patients with *M. abscessus* colonisation/infection must be segregated.

Key references

- US Cystic Fibrosis Foundation and European Cystic Fibrosis Society consensus recommendations for the management of non-tuberculous mycobacteria in individuals with cystic fibrosis. Thorax 2016; 71: i1-i22.
- British Thoracic Society Guidelines for the Diagnosis and Management of Non-Tuberculous Mycobacterial Pulmonary Disease (NTM-PD). Thorax 2017; 72: ii1-ii64.

1. Introduction

This document provides guidance on infection control measures for *Mycobacterium abscessus* in cystic fibrosis. A separate working group (jointly representing the European Cystic Fibrosis Society and North American Cystic Fibrosis Foundation) has published guidelines on screening and treatment for non-tuberculous mycobacteria (NTM).¹ Guidance from the British Thoracic Society on the diagnosis and management of NTM is also available.²

2. Background

Recent research has found evidence for cross-infection by *M. abscessus*.³⁻⁵ Cross-infection outbreaks have been reported at a US CF centre involving five patients³ and at a UK CF centre involving 11 people with CF, despite having infection prevention policies and guidelines based on best practice at the time.⁴ Another UK study found no clear evidence of direct cross-infection.⁶ A study published in 2016 provided evidence of shared strains of *M. abscessus* species among patients with CF across a number of CF centres worldwide.⁵ At present, the mode of transmission is unclear.

At the US CF centre that reported the cross-infection outbreak, no further new cases were detected after implementation of infection control measures comprising staff and patient education, environment sterilisation and patient isolation.⁷

A suspected *M. abscessus* outbreak was reported involving 9 of 19 patients at a joint adult/paediatric clinic in Hawaii. The source of the outbreak was not identified but an investigation revealed potential issues with adherence to local infection control guidance for cleaning and maintenance of shared equipment, including bronchoscopes and spirometers.⁸

Data from the UK CF Registry show that the prevalence of *M. abscessus* colonisation/infection has remained relatively static between 2014 and 2016 (table 1).⁹

Table 1

	2014 (n=9532)	2015 (n=9587)	2016 (n=9695)
<i>M. abscessus</i> prevalence	300 (3.1%)	321 (3.3%)	337 (3.4%)

Specialist CF care has been shown to be beneficial, with improved clinical outcomes for people with cystic fibrosis.^{10, 11} Avoiding clinic attendance due to concerns about *M. abscessus* infection is likely to be harmful as it may seriously interfere with medical care, which will far outweigh any potential risk of acquiring *M. abscessus* infection.

3. Definition of patients with *M. abscessus* colonisation/infection for the purpose of infection control measures

A patient is defined as having *M. abscessus* colonisation/infection if they fall in to one or more of the following groups.

1. Patients who have had *M. abscessus* isolated from sputum or bronchoalveolar lavage (BAL) cultures within the last 12 months (whether or not they are symptomatic for *M. abscessus* infection).
2. Patients who are currently prescribed treatment for *M. abscessus*.
3. Patients who have completed treatment for *M. abscessus* within the last 12 months.

For the above patients to be subsequently considered free of *M. abscessus*, quarterly sputum samples must have tested negative for mycobacteria when a patient is not receiving treatment, with an interval of one year between the first negative sample and last negative sample. For instances where sputum cannot be obtained, a negative BAL one year off treatment would suffice.

Current evidence suggests that in applying infection control recommendations there should be no distinction between smear positive and smear negative cases of *M. abscessus* colonisation/infection.⁴

3.1 Recommendations

- The patient should be kept informed of their infection status [C].
- If subsequent sputum samples become negative for *M. abscessus*, the patient should still be regarded as a potential carrier from the date of the first negative sample for a total of at least twelve months. A minimum of four negative sputum samples are required during this twelve-month period, with the final negative sample at least twelve months after the first negative sample. For instances where sputum cannot be obtained, a negative BAL one year off treatment would suffice [C].
- For infection control, there should be no distinction between smear positive and smear negative cases of *M. abscessus* colonisation/infection [C].

4. Screening of patients with CF for *M. abscessus* infection

Screening for NTM is an important part of the care of patients with cystic fibrosis. The US Cystic Fibrosis Foundation/European Cystic Fibrosis Society consensus guidance¹ on NTM screening for people with cystic fibrosis is published and accessible via this link:

http://thorax.bmj.com/content/71/Suppl_1.toc.

4.1 Recommendations

- Routine screening for NTM is recommended at least once a year for all individuals able to produce sputum, with microbiological processing of samples [C].
- Cough swabs should not be used [C].
- Consider induced sputum or BAL for patients unable to produce sputum at will (where there is clinical suspicion of infection) [C].
- For CF centres where cross-infection with *M. abscessus* is suspected, more frequent sampling for NTM should occur [C].
- All *M. abscessus*-positive patients must have an isolate referred to the appropriate reference laboratory for sub-speciation and strain typing [C].

5. Preventing spread

The mode of transmission of *M. abscessus* in cross-infection outbreaks is unclear. General infection control measures should be adhered to.¹¹

5.1 Recommendations

- Each CF service must have its own local infection control guideline that covers *M. abscessus* and its use by regular audit is recommended [C].
- The specialist CF centre/CF clinic and local infection control team should know the incidence and prevalence of *M. abscessus* in their CF population [C].
- Current inpatient and outpatient facilities should be evaluated for their present air exchange and air flow and measures taken to optimise this wherever possible [C].

- Patients with CF with *M. abscessus* colonisation/infection must be segregated from each other and from all other people with cystic fibrosis. The methods used to segregate patients should be determined by local guidelines and must take into account communal areas such as pharmacy and radiology [C].
- CF centres should educate staff, patients and visitors in the need to adhere to cross infection prevention measures within all areas of the CF centre and the wider, communal areas of the hospital [C].
- A high standard of hygiene should be practised by staff, in particular hand washing; alcohol gels or other suitable preparations must be available in every room [C].
- If CF clinics suspect they have cross-infection with *M. abscessus*, advice from the local infection control team should be sought [C].
- Patients must be seen in well-ventilated rooms [C].
- Rooms must be left with the door closed, with at least an hour (amended depending on knowledge of air flow/exchange) between patients to allow for dispersion of possible airborne contamination and then cleaned according to local infection control guidelines [C].
- Gloves and aprons/gowns must be worn and hand washing with soap and water must be performed before and after contact with each patient with *M. abscessus* colonisation/infection and/or their immediate environment [C].
- Staff may wish to wear masks when in contact with patients with *M. abscessus* colonisation/infection. There is currently insufficient evidence to recommend the routine use of masks by healthy staff. Staff should follow local policies [C].
- Patients may wish to wear masks. There is currently insufficient evidence to recommend the routine use of masks by patients, but local policies should be followed [C].
- Patients must wash their hands with soap and water before use of a spirometer or other handheld apparatus [C].
- Spirometry should be performed in the patient's own room. Other respiratory function tests should be performed in a well-ventilated room away from other patients [C].
- Collection of respiratory samples must take place in the patient's own room [C].
- Sputum pots should be covered and soiled tissues must be disposed of in the clinical waste bin immediately after use. Sputum should not be expectorated down toilets, sinks, washbasins or in showers [C].
- Airway clearance techniques and any other physiotherapy procedures must be carried out in the patient's own room [C].
- Equipment must be single-patient use where possible [C].
- Patients should be encouraged to use their own possessions and equipment in hospital [C].
- All other equipment and surfaces must be cleaned and dried between patients, according to local infection control guidelines [C].
- After a room is vacated by a patient with *M. abscessus* colonisation/infection it should undergo terminal cleaning as per local hospital guidance [C]. An example from the CF centre in Papworth can be found in **Appendix 1**.
- Inpatients should have well-ventilated single rooms with their own bathroom. Negative pressure rooms should be used where available [C].
- Exercise should be performed in a patient's own room with the door closed and any equipment appropriately decontaminated after use. If exercise is performed in a communal area this must be on an individual basis, at the end of the day and the room terminally cleaned after use [C].
- Disinfection of bronchoscopes, irrespective of the purpose they are used for, should comply with the national policy 'Management and decontamination of flexible endoscopes (HTM 01-06)' [C]. The policy is accessible via this link: <https://www.gov.uk/government/publications/management-and-decontamination-of-flexible-endoscopes>.

6. Future recommendations for cystic fibrosis clinic facilities

6.1 Recommendations

- Any new facilities for patients with CF must take into account the potential for cross-infection with *M. abscessus*. This must include the provision of enhanced ventilation for both inpatient and outpatient care and adequate ventilation in other areas [C].
- Any new facilities should consider the space required for integration of exercise equipment into inpatient rooms [C].

7. References

1. US Cystic Fibrosis Foundation and European Cystic Fibrosis Society. Consensus recommendations for the management of non-tuberculous mycobacteria in individuals with cystic fibrosis. *Thorax* 2016; 71: i1-i22.
2. British Thoracic Society. Guidelines for the Diagnosis and Management of Non tuberculous Mycobacterial Pulmonary Disease (NTM PD). *Thorax* 2017; 72 suppl. 2: ii1-ii64
3. Aitken ML, Limaye A, Pottinger P, Whimbey E, Goss CH, Tonelli MR, Cangelosi GA, Dirac MA, Olivier KN, Brown-Elliott BA, McNulty S, Wallace RJ Jr. Respiratory outbreak of *Mycobacterium abscessus* subspecies *massiliense* in a lung transplant and cystic fibrosis center. *Am J Respir Crit Care Med* 2012; 185: 231-232.
4. Bryant JM, Grogono DM, Greaves D, Foweraker J, Roddick I, Inns T, Reacher M, Haworth CS, Curran MD, Harris SR, Peacock SJ, Parkhill J, Floto RA. Whole-genome sequencing to identify transmission of *Mycobacterium abscessus* between patients with cystic fibrosis: a retrospective cohort study. *Lancet* 2013; 381: 551-1560.
5. Bryant JM, Grogono DM, Rodriguez-Rincon D, Everall I, Brown KP, Moreno P, et al. Emergence and spread of a human-transmissible multidrug-resistant nontuberculous mycobacterium. *Science* 2016; 354: 751-757.
6. Harris KA, Underwood A, Kenna DTD, Brooks A, Kavaliunaite E, Kapatai G, Tewolde R, Aurora P, Dixon G. Whole-Genome Sequencing and Epidemiological Analysis do not Provide Evidence for Cross-transmission of *Mycobacterium abscessus* in a Cohort of Pediatric Cystic Fibrosis Patients. *Clin Infect Dis* 2015; 60: 1007-1016.
7. Kapnadak SG, Hisert KB, Pottinger PS, Limaye AP, Aitken ML. Infection control strategies that successfully controlled an outbreak of *Mycobacterium abscessus* at a cystic fibrosis center. *Am J Infect Control* 2016; 44: 154-159.
8. Johnston DI, Chisty Z, Gross JE, Park SY. Investigation of *Mycobacterium abscessus* outbreak among cystic fibrosis patients, Hawaii 2012. *J Hosp Infect* 2016; 94: 198-200.
9. The UK Cystic Fibrosis Registry Annual Data Report 2015.
10. Mahadeva R, Webb K, Westerbeek RC, Carroll NR, Dodd ME, Bilton D, et al. Clinical outcome in relation to care in centres specialising in cystic fibrosis: cross sectional study. *BMJ* 1998; 316: 1771-1775.
11. Cystic Fibrosis Trust. Standards for the Clinical Care of Children and Adults with cystic fibrosis in the UK. Second edition, 2011.
12. Cystic Fibrosis Trust. Laboratory Standards for Processing Microbiological Samples from Patients with Cystic Fibrosis. Report of the UK Cystic Fibrosis Trust Microbiology Laboratory Standards Working Group, 2010.

Appendix 1: Example of terminal cleaning protocol from Papworth Hospital

Stage 1	<i>M. abscessus</i> + ve in-patient (LOS 1 night +) plus post bronchoscopy day cases and any patients isolated with pink precautions*	Ambulatory <i>M. abscessus</i> care episode (no overnight stay) CTBI*
	Nursing staff Dispose to clinical waste any disposable items/ items that cannot be cleaned.	Ventilate the room as soon as the patient vacates the room (open door and window)
	Dispose of any bed linen into red water soluble bag and then into a white plastic laundry bag.	Nursing staff Dispose to clinical waste any disposable items/ items that cannot be cleaned.
	Domestic staff/PEA Dispose to orange bag (offensive waste stream) any disposable curtains from room.	Domestic staff/PEA Dispose to orange bag (offensive waste stream) clinical waste/curtains from room.
	Leave room for an hour before taking any further action.	Ventilate the room for one hour prior to cleaning.
Stage 2	Nursing staff Wearing Personal Protective Equipment (long-sleeved gown, gloves, surgical mask, eye protection) and taking care not to splash, use bottle brush or sponge stick to clean sink and shower outlets ensuring all visible gunk rinsed away. Flush shower and sink outlets with tap water for five minutes.	Nursing staff Use a chlorine based product (Tristel™ product, with the appropriate contact time as provided by the manufacturer) to clean all surfaces and medical equipment.
Stage 3	Nursing staff Use a chlorine based product (Tristel™ product, with the appropriate contact time as provided by the manufacturer) to clean all surfaces and medical equipment.	Domestic staff/PEA Complete final exit clean.
Stage 4	Domestic staff Complete final exit clean	
Stage 5	Nursing staff Contact ISS through operational support to arrange HPV clean.	Re-introduce room for clinical use.
Stage 6	Nursing staff If the room is being swabbed please contact trained nursing staff for environmental sampling.	
Stage 7	Re-introduce room for clinical use	

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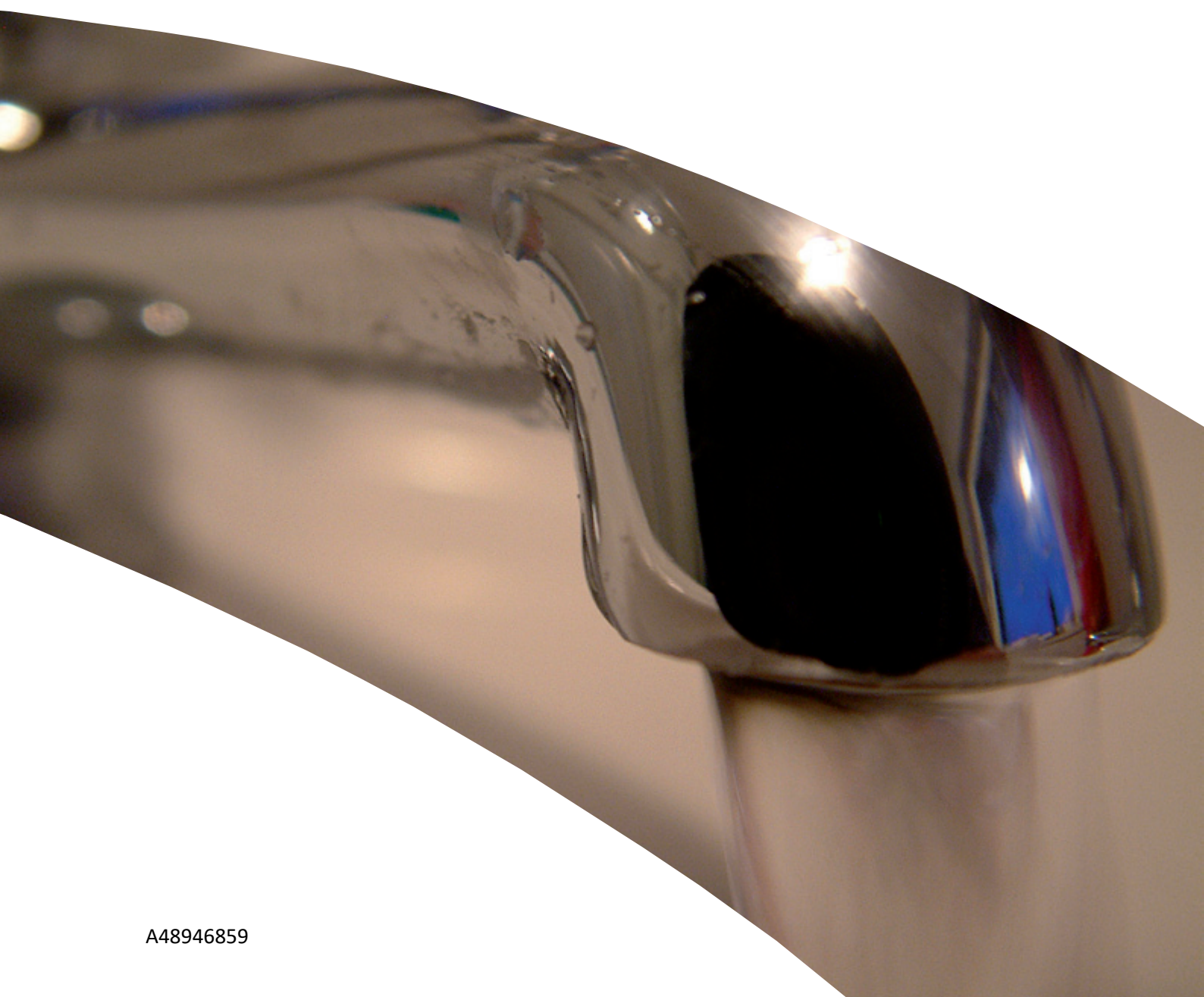
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Environment and sustainability
Health Technical Memorandum
07-04: Water management and
water efficiency – best practice
advice for the healthcare sector



Environment and sustainability

Health Technical Memorandum 07-04:

Water management and water efficiency – best practice advice for the healthcare sector

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Preface

About Health Technical Memoranda

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

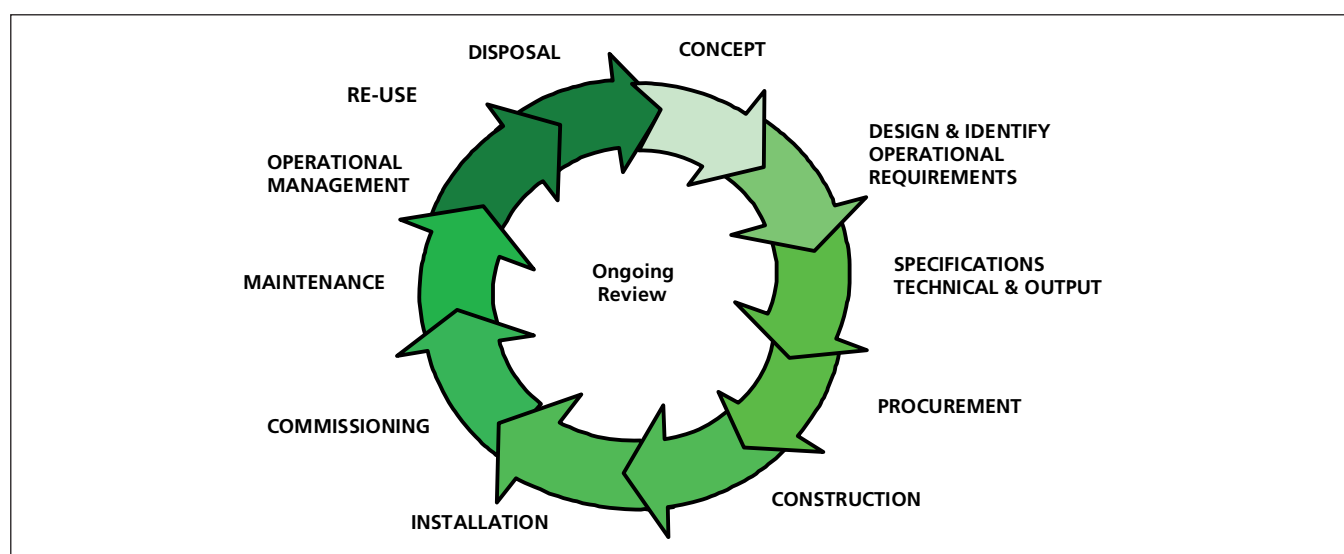
The focus of Health Technical Memorandum guidance remains on healthcare-specific elements of standards, policies and up-to-date established best practice. They are applicable to new and existing sites, and are for use at various stages during the whole building lifecycle.

main source of specific healthcare-related guidance for estates and facilities professionals.

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

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

Figure 1 Healthcare building life-cycle



Healthcare providers have a duty of care to ensure that appropriate governance arrangements are in place and are managed effectively. The Health Technical Memorandum series provides best practice engineering standards and policy to enable management of this duty of care.

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

Healthcare-specific technical engineering guidance is a vital tool in the safe and efficient operation of healthcare facilities. Health Technical Memorandum guidance is the

Structure of the Health Technical Memorandum suite

The series contains a suite of nine core subjects:

Health Technical Memorandum 00

Policies and principles (applicable to all Health Technical Memoranda in this series)

Health Technical Memorandum 01

Decontamination

Health Technical Memorandum 02

Medical gases

Health Technical Memorandum 03
Heating and ventilation systems

Health Technical Memorandum 04
Water systems

Health Technical Memorandum 05
Fire safety

Health Technical Memorandum 06
Electrical services

Health Technical Memorandum 07
Environment and sustainability

Health Technical Memorandum 08
Specialist services

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

Example: Health Technical Memorandum 06-02 represents:

Electrical Services – Electrical safety guidance for low voltage systems

In a similar way Health Technical Memorandum 07-02 represents:

Environment and Sustainability – EnCO₂de.

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

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

DH Estates and Facilities Division wishes to acknowledge the contribution made by professional bodies, engineering consultants, healthcare specialists and NHS staff who have contributed to the production of this guidance.

Figure 2 Engineering guidance



Executive summary

During 2002/2003, the NHS in England consumed 40.3 million cubic metres of water and produced 34.4 million cubic metres of sewage. This comes at a cost – not just financial, but at a cost to the environment.

Financial savings of up to 20% may be achieved through water-efficiency measures, with little or no cost in investment. This translates to a possible saving of £9.5 million per year.

Much of these savings can be immediately realised through minor repairs to existing infrastructure and through staff behaviour, while others may require an initial capital investment that can be recovered within a specified payback period.

This Health Technical Memorandum encourages investigating these possible savings. Its principal remit is

to encourage the efficient management of water and to promote the economic and environmental benefits of doing so. Additionally, it examines water-management decisions in the context of:

- patient health and well-being;
- social and behavioural aspects; and
- available and appropriate technology.

Methods for auditing facilities are outlined, with common areas of high water use discussed and technical solutions proposed. Guidance on establishing necessary social and behavioural aspects such as staff awareness, appropriate use of technology and a clear definition of responsibilities are also outlined.

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1 Introduction

1.1 This guidance document lays out the steps to developing a water strategy for healthcare facilities. Its principal remit is to encourage the efficient management of water and to promote the economic and environmental benefits of doing so. Additionally, it examines water-management decisions in the context of:

- patient health and well-being;
- social and behavioural aspects; and
- available and appropriate technology.

It is relevant to all healthcare facilities, not just hospitals.

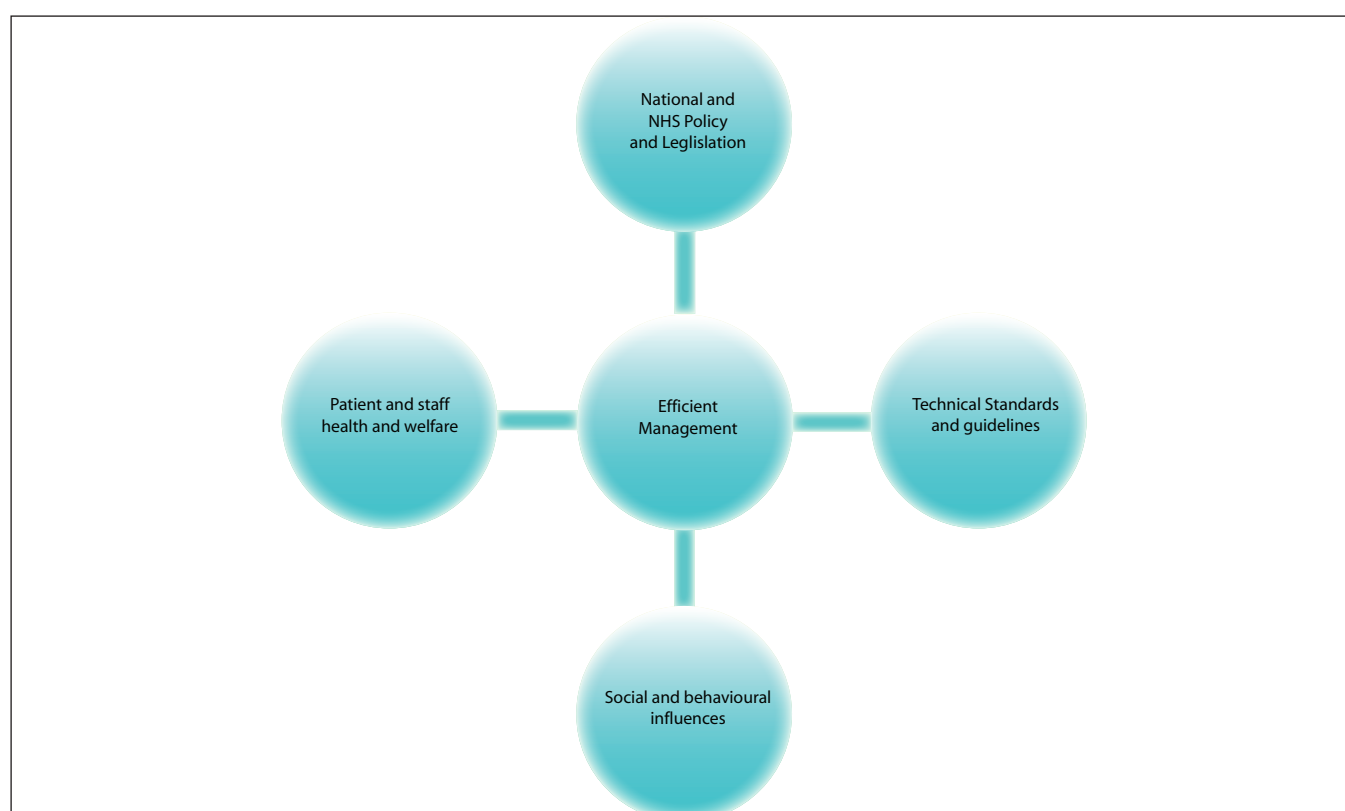
1.2 The document refers to national or NHS policy and guidelines where appropriate, outlining a comprehensive approach to water management (see Figure 1).

1.3 Methods for auditing facilities are outlined, with common areas of high water use discussed and technical solutions proposed. Guidance on establishing necessary social and behavioural aspects such as staff awareness, appropriate use of technology and a clear definition of responsibilities are also outlined.

Action checklist

1.4 The following table is a summary of actions and their associated savings in terms of water and costs. It is not an exclusive list, but rather represents a first glimpse of how water savings can be accomplished. These items are discussed in more detail in [Chapter 6](#).

Figure 1 Efficient water management in context



Item	Typical percentage of total healthcare consumption	Typical consumption rate	Potential actions
WCs	24	6–9 L flush	• Install a cistern displacement device – saving approximately 1 L per flush • Retrofit to a dual flush or lower flush system – giving the option for a half flush. (Note: Where dual-flush toilets are specified, they should have guidance or symbols instructing the user on the appropriate operation of the flushing device) • Replace old WCs with those that give a flush volume of up to 6 L (maximum)
Urinals	5	500–900 L per day	• Controlled flushing through foot triggers or motion sensors can reduce consumption by 120–200 L per day • Waterless urinals
Taps	13	400 L per day	• Flow restrictors, non-concussive self-closing taps and sensor^a taps can reduce consumption by up to 50% (Note: the choice of tap should be appropriate for the intended use)
Leak detection	15–30	Small leak: 6 L per hour Large leak: 400–800 L per hour	Inspect all fixtures and fittings, graph monthly bills, or conduct internal monitoring through submetering to identify possible leaks
Boiler	Variable	Intense energy consumption means costs are much higher than water alone	• Adjust boiler blowdown amount and frequency to reduce waste and to control total dissolved solids (TDS) • Collect and reuse steam condensate • Control steam losses

See Health Technical Memorandum 00 for guidance on recommended sanitary assemblies in healthcare facilities.

Also refer to the compliance criteria in BREEAM Healthcare.

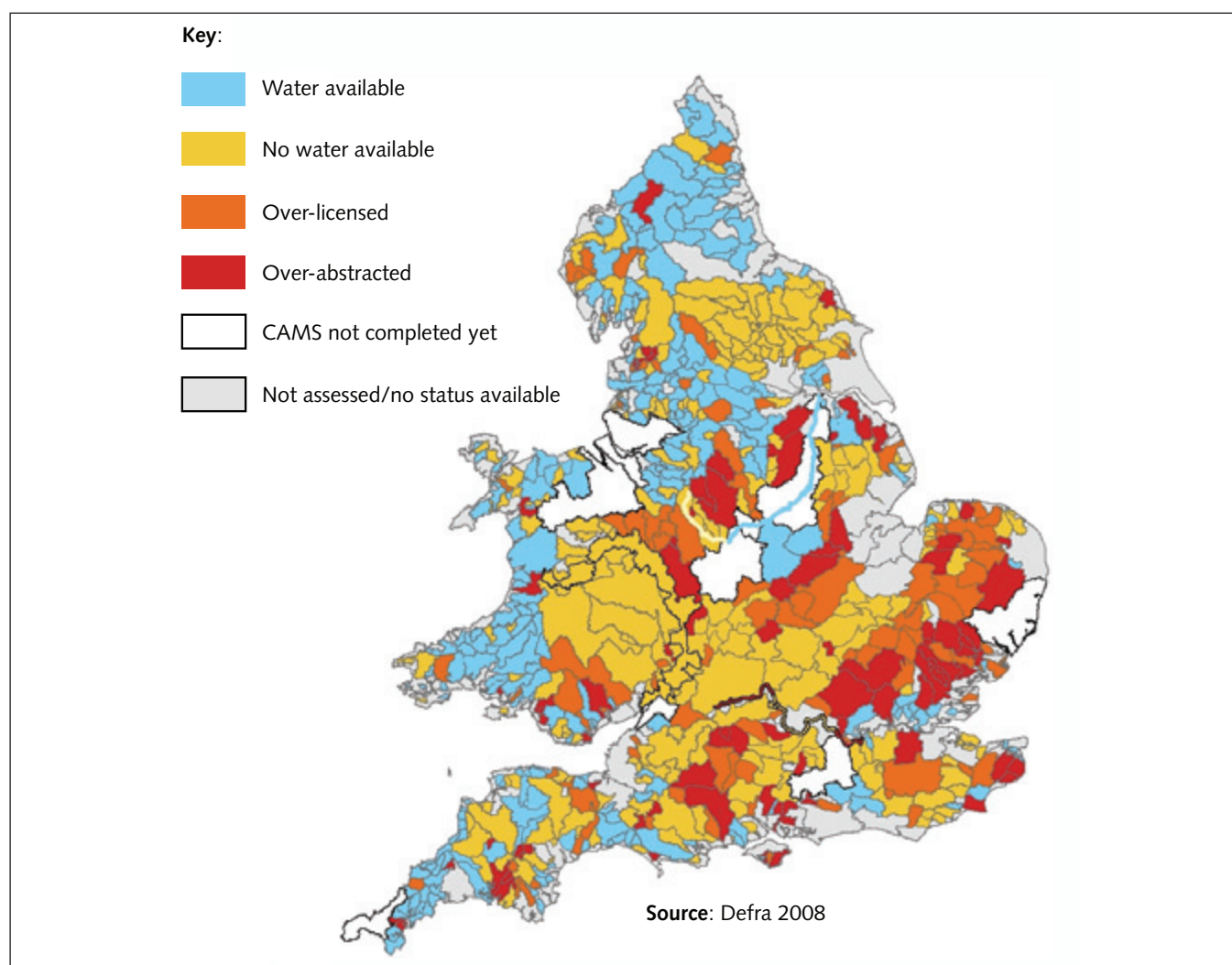
^a Automatic or sensor taps will only be effective when properly maintained and kept in good working order.

2 Managing water wisely in healthcare facilities

Water resources in the UK

- 2.1 The UK's water resources are coming under increasing pressure. There is a risk that demand might exceed the total amount of water that can be abstracted from rivers and underground supplies, a situation that could lead to environmental damage and degradation. The Environment Agency has estimated that many aquifers are already over-abstracted. (Figure 2 summarises the water resource availability for each catchment in England and Wales.)
- 2.2 In highly urbanised regions such as southern England, the natural environment is now seriously under threat from water abstraction. For some areas of the South East, the availability of water per head has grown sufficiently serious to be comparable with that of some Middle-Eastern countries. There is a need, therefore, to relieve pressure by implementing better and more informed water-management strategies.
- 2.3 In addition to growing pressures on water resources from housing and commercial development,

Figure 2 Water resource availability for England and Wales



climate change will significantly alter the way the UK uses its water resources, as well as the nature of water resources themselves. Summers are projected to become hotter and drier, and winters wetter. Accompanying this change in seasons will be an increased incidence and intensity of droughts and floods. Water will therefore be a crucial aspect of climate-change adaptation.

- 2.4 Furthermore, water use has a direct association with climate-change mitigation. Significant amounts of energy are used in the supply and treatment of water. Water UK (2007) estimates place the carbon costs of water supply at around 0.271 grams of CO₂ per litre, a figure likely to be much higher if the water is heated. Therefore, a more efficient use of water in healthcare facilities could result in a significant reduction of their carbon footprint.
- 2.5 In the context of increased development, climate change and limited water resources, the Department for Environment, Food and Rural Affairs (Defra) has observed that maintaining a reliable supply of water is no longer uniquely the remit of water suppliers. Measures need to be taken on the part of those using water to improve efficiency (Defra, 2007).

Social responsibility and sustainable development

- 2.6 The NHS has the largest and most complex estate portfolio in Europe. These estates will have an impact on their surroundings, be it in terms of culture, economy or the environment.
- 2.7 Managing water efficiently across the healthcare estate will require a wide range of approaches and will ultimately have a large impact on the healthcare sector's environmental footprint.
- 2.8 A clear and ambitious water strategy (see [Chapter 5](#)) will not only help to mitigate the environmental impacts of healthcare facilities, but will also serve to promote the sustainability of those facilities to those who use them and to the wider public.

Refer also to:

- BREEAM Healthcare;
- The Good Corporate Citizenship model.

3 Legislative and policy-related responsibilities

3.1 In addition to Defra's broad twin-track policy on water resources (Defra, 2008), a mounting volume of national and international policy and legislation specifically calls for actions to be taken to improve water efficiency and management.

European policy and legislation

3.2 The European Commission's communication on drought and water scarcity (COM (2007) 414 final) estimates that 20% of all water consumed in the EU is wasted and states that:

"Water saving must become the priority and all possibilities to improve water efficiency must therefore be explored."

3.3 The Water Framework Directive (2000/60/EC) sets out requirements and measures to improve water efficiency.

3.4 The Integrated Pollution Prevention and Control (PPC) Directive (96/61/EC) has now been transposed into law by the Pollution Prevention and Control Act 1999 and the Pollution Prevention and Control (England and Wales) Regulations 2000 (as amended).

National policy and legislation

Water Act 2003

3.5 The Water Act 2003 established that it is the responsibility of all public bodies to conserve water.

3.6 The Act also:

- introduced time limits for all new abstraction licences;
- introduced the facility to revoke abstraction licences that cause serious environmental damage;

- introduced greater flexibility to raise or lower licensing thresholds;
- deregulated small and environmentally insignificant abstractions;
- extended licensing to abstractors of significant quantities presently outside the licensing system.

3.7 The Environment Agency is developing catchment abstraction management strategies (CAMS) that aim to provide a structured approach to local water resources management, recognising the reasonable needs of abstractors and the needs of the environment. This fits in with the needs of the Water Framework Directive (2000/60/EC) mentioned in paragraph 3.3. The Environment Agency assesses any new application for a licence against the CAMS.

In Scotland, the Scottish Building Standards Agency has issued guidance on water use and efficiency.

In Northern Ireland, under the Water Act (Northern Ireland) 1972, the Environment and Heritage Service (EHS) is required to promote the conservation of the water resources of Northern Ireland and to promote the cleanliness of water in waterways and underground strata.

Water Supply (Water Fittings) Regulations 1999

3.8 All water fittings are covered by the Water Supply (Water Fittings) Regulations 1999 for England and Wales. This legislation includes information on the water use of individual appliances.

3.9 Implementation of the Regulations is overseen by the Water Regulations Advisory Scheme (WRAS).

Note

In England and Wales, the Water Supply (Water Fittings) Regulations and the Building Regulations are to be updated to include greater emphasis on water efficiency.

In Scotland, water fittings are covered by the Water Byelaws (2004).

In Northern Ireland, water fittings are governed by the Water Regulations (Northern Ireland) 1991. The Water and Sewerage Services (Miscellaneous Provisions) (Northern Ireland) Order 2006 introduces provisions relating to information sharing in connection with water and sewerage charges and introduces controls on the abstraction and impounding of water.

- 3.11 Defra's (2008) current water strategy cites water efficiency as playing a prominent role in achieving a sustainable supply–demand balance, and encourages industrial and commercial sectors to lead by example through initiatives such as voluntary agreements.

Code for Sustainable Homes

- 3.12 All new public-building developments are subject to obligatory water efficiency benchmarks as defined in the 2006 Code for Sustainable Homes. It is likely that a non-domestic version of the Code will be produced in the next two years.

A list of regulators and other independent bodies involved in water management is given in [Chapter 9](#).

Water strategy

- 3.10 The Government has set a target of a 25% reduction in water use in its office and non-office estates by 2020, relative to 2004/2005 levels (Defra, 1999).

4 Economic benefits

- 4.1 It is likely that the trend of emerging policy and legislation with regard to water efficiency and management will continue, as will increases in water prices. In highly stressed areas, restrictions on water use may be enforced more frequently during drought periods. Acting sooner rather than later will establish standards of water management and reporting, which pre-empt these changes and limit the associated risks to healthcare services.
- 4.2 During 2002/2003, the NHS in England consumed 40.3 million cubic metres of water and produced 34.4 million cubic metres of sewage. Healthcare estates are likely to be classified as non-domestic and charged through a combined flat rate and a volumetric rate, the flat-rate portion being determined by the size of the supply pipe and/or meter entering the property. This Health Technical Memorandum encourages investigating the possible savings that can be achieved not only through a reduction in the volume of water consumed, but possibly through a downsizing of supply pipes and/or meters in order to match the reduced consumption.

Note

The Water Services Regulation Authority (Ofwat) has published proposals to change the water supply licensing (WSL) regime to extend competition in the water and sewerage industry. The aim is to deliver economic as well as environmental benefits. Visit Ofwat's website for more information.

Potential savings

- 4.3 Water UK (2003) estimated that, in total, financial savings of up to 20% may be achieved through water-efficiency measures in healthcare estates, with little or no cost in investment. This translates to a possible saving of £9.5 million per year (at 2001 prices).
- 4.4 Much of these savings can be immediately realised through minor repairs to existing infrastructure and through staff behaviour, while others may require an initial capital investment that can be recovered within a specified payback period.
- 4.5 Some types of water-efficiency activity will also incur savings in energy costs, as less water is required to be heated.

Reducing water waste and its associated savings

- 4.6 The following examples show the types of measure – and their associated savings – that can be taken to reduce water consumption. They are examples of practical actions that have been used in the healthcare sector.
- 4.7 Examples 1 and 2 show how large savings can be made with very little capital expenditure and no actual or perceived impact on hygiene. Examples 3 and 4 show that large savings can be made with payback periods of a couple of years, if more money is invested. In addition, example 4 shows that action can be taken in clinical areas without compromising hygiene.

Note

Other actions to save water may be more appropriate for different estates, and a choice of the best action to take can only be made after a preliminary audit.

Example 1: identifying leaks

It was estimated that 15–30% of hospital consumption could be attributed to leakage. A small leak was potentially found to lose around 6 L per hour, leading to the loss of 53 m³ per year. More significant leaks were found to potentially lose up to 3500–7000 m³ per year, costing approximately £6400 a year. After identifying and repairing two major leaks, one NHS hospital reported savings of £100,000 a year (source: Water UK, 2003).

Example 2: urinal flushing

Public urinals in one hospital were set to flush automatically every 20 minutes and retrofitted with water-saving devices, which limit unnecessary flushes. Each fitting cost £120 per unit, saving £234 of water each year, resulting in a six-month payback period (source: Water UK, 2003).

Example 3: steam traps

South Manchester Hospital Trust installed a low-maintenance steam-trap system to conserve water. The cost of the project was £24,000, saving £1750 a year on water costs and £8600 on energy costs. The payback period was around 28 months (source: Carbon Trust, 2000).

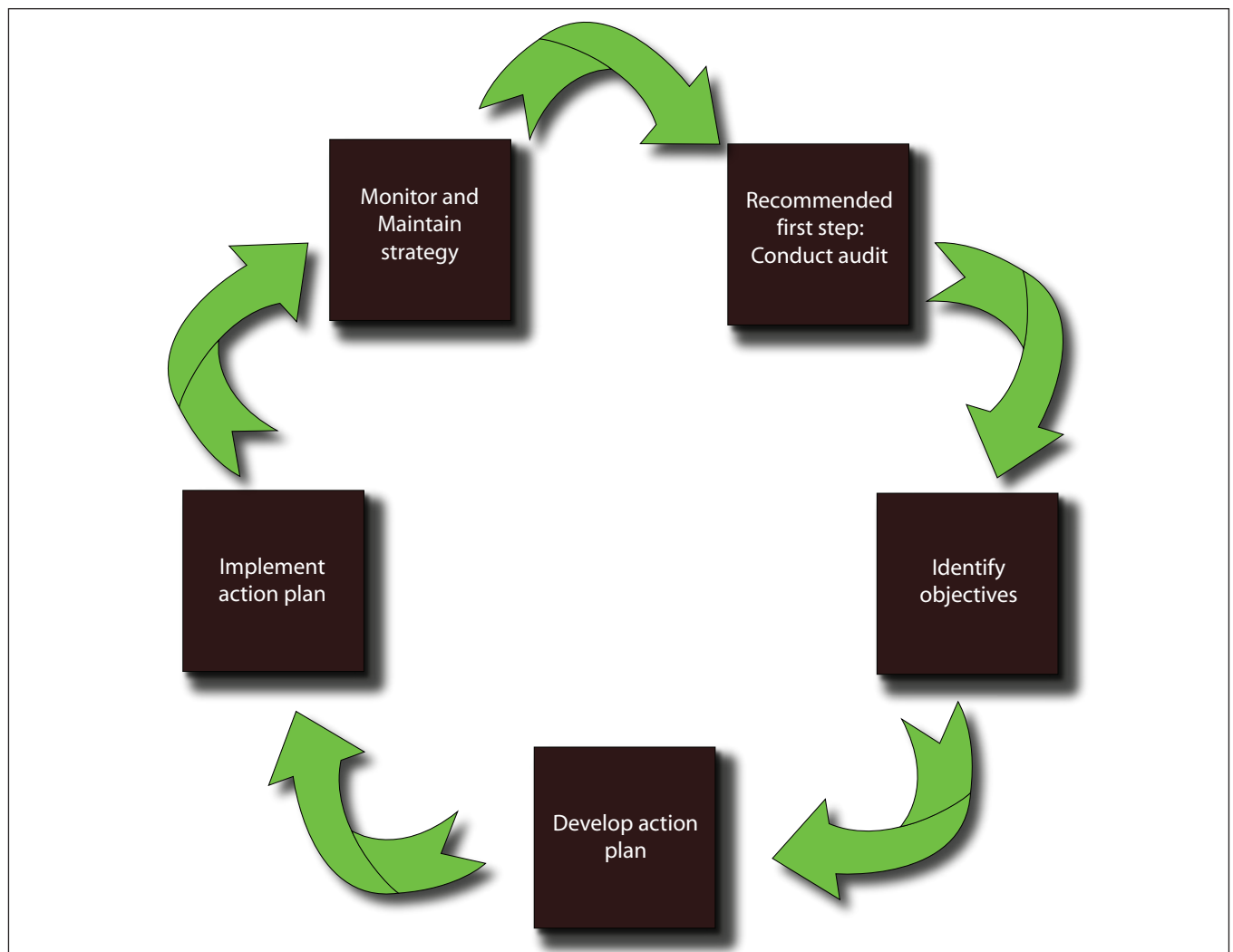
Example 4: wastewater recycling

East Kent and Canterbury Trust made huge savings in its renal unit. A significant amount of wastewater was produced by the hospital's reverse osmosis plant. The project installed holding tanks and pipework that allowed the wastewater to be reused for urinal and WC flushing in the main operating theatres and the emergency care department, topped up with mains water when needed. The project reduced mains water consumption by 33%, saving £7000 a year. This allowed for project costs to be recovered in less than three years (source: Environment Agency, 2005).

5 Developing a water strategy

- 5.1 The best way to approach water management within any site or building is to develop a strategic plan. One of the main aspects of a water strategy is water efficiency, but it should be much wider than that, encompassing all water issues. The strategy should cover everything from flooding to hygiene – even if specific sections just state that the issue is covered elsewhere. The aim is to act as a central reference for all water issues.
- 5.2 A water strategy will not be static; rather it will be a continuous process of monitoring, adaptation and implementation, which feeds into a live document (see Figure 3). The process can be entered at any stage, depending on where the site/building is with regard to water management. However, it is recommended that the first step is an audit.

Figure 3 The water strategy process



Establishing and maintaining a framework of management

- 5.3 In developing a water strategy, stakeholders from various organisational levels should be involved (see Figure 4).

Senior management

- 5.4 In preparation for developing a water strategy, the issue of water management should be raised at a senior management level and support secured. Senior management should also discuss the possibility of integrating water-efficiency goals into key performance indicators.

Water champions

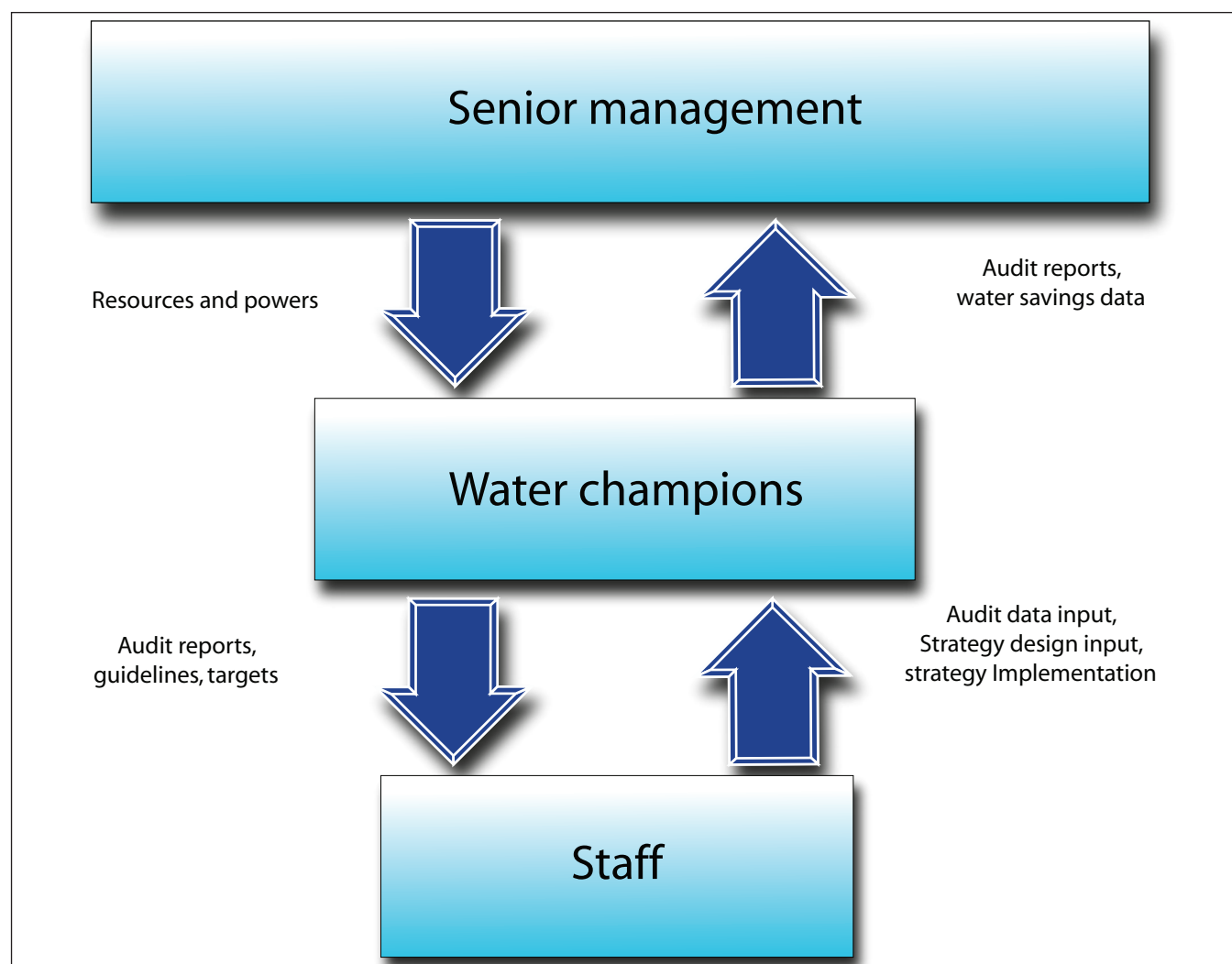
- 5.5 Senior management should designate a water champion and provide the necessary resources and powers to conduct a water audit and coordinate the

water strategy. Champions will act as coordinators for implementation, sources of information and a channel for reporting to senior management.

Staff involvement

- 5.6 Water is often misconceived as effectively limitless and costless. Efficient management is hampered by a lack of staff awareness, leading to potential savings in water bills and increased environmental integrity being overlooked in the past.
- 5.7 The development of a water strategy should be seen as an opportunity to raise staff awareness as well as to gather input.
- 5.8 Water use is an emotive issue, and staff should be informed of the project to develop a water strategy and be given regular information during the process.

Figure 4 Framework of responsibilities for water management



- 5.9 The development of the strategy should also, where possible, be an interactive process with adequate provision for staff to comment or contribute to the strategy. All staff will have a view on water, but the strategy should particularly involve those who use water in their duties or would be affected by the strategy.
- 5.10 Daily routines should be investigated to identify patterns of water use.
- 5.11 Finally, it may be of particular significance to discuss changes in water management with medical, nursing and infection-control staff in order to ensure that all parties are satisfied that there is no compromise to clinical care, hygiene or infection control.

Building management systems

- 5.12 A building management system (BMS) is a computer-based centralised procedure that helps to manage, control and monitor certain engineering services within a building or a group of buildings. If used appropriately, such a system ensures efficiency and cost-effectiveness in terms of labour and energy costs, and provides a safe and more comfortable environment for the building's occupants.
- 5.13 A BMS is operated from a central station, usually a personal computer, from which the user is able to analyse updated monitor values received from outstation sensors, actuators and stand-alone controllers.
- 5.14 With the installation of water submeters, temperature sensors and reporting procedures at key points in a building, a BMS may support water management through the following:
- monitoring of water consumption and the identification of leaks or excessive consumption (see [paragraphs 5.27–5.39](#));
 - monitoring of water temperature for health and safety reasons (see [paragraphs 5.25–5.26](#) and [paragraphs 7.22–7.30](#));
 - management of boilerhouses and cooling-tower cycles and maintenance (see [paragraphs 6.1–6.14](#));
 - scheduling of maintenance events.
- 5.15 Water champions should be assigned responsibility to cooperate with BMS managers in integrating water management into the BMS.

- 5.16 Further information on BMS installation and operation can be found in Health Technical Memorandum 2005 – ‘Building management systems’.

Metering and submetering

Metering

- 5.17 Information from water meters can be used by both water and sewerage service providers to carry out assessments for charging purposes and to aid water management within a facility.
- 5.18 Beyond the main service meter, additional submeters may be installed at floor, section or appliance level to provide data on internal rates of consumption. In all cases, it is important that the meter be appropriately sized according to average flow rate measured.
- 5.19 Main service meters that measure water entering from the supply network should be appropriately sized, as there is often a component of service charges which is based on meter size. Sizes may need to be reviewed after efficiency measures have been made inside the building, as flow rates may decrease.
- 5.20 Water meters should be properly installed, maintained and used according to the manufacturer's instructions. The meter supplier should calibrate the meter and check its accuracy.

Submetering

- 5.21 Submeters allow for management to measure consumption according to sections of the system. These can be especially useful for conducting water audits, by which areas of high use can be more precisely detected.
- 5.22 For monitoring purposes, submetering will also show area-specific rises in water consumption, indicating possible leakage.
- 5.23 The possibility of integrating submeters into building management systems should be considered.
- 5.24 For a case study of the use of meters in water management, see [Chapter 13](#).

Water quality, infection control, staff and patient welfare

- 5.25 While this document's principal focus is on water efficiency in healthcare facilities, many decisions

regarding water management will be affected by priority areas of water quality, infection control, and patient and staff welfare.

- 5.26 Where standards in water efficiency overlap with those in infection control and patient and staff welfare, existing guidance is referred to and should be consulted before management decisions are made (see Table 1). Further discussion of water quality issues can be found in [paragraphs 7.22–7.30](#).

Conducting an audit

- 5.27 A water audit is similar to a financial audit and can be as simple or as detailed as appropriate to meet circumstances and needs. In short, the audit looks at the amount of water entering the site, the amount leaving the site and the amount consumed. This basic calculation should provide an overview of costs, potential savings and areas of wastage. It will also highlight discrepancies, which will indicate leakage or other losses. The initial audit should

Table 1 Key health concerns and relevant documents

Key quality and health concerns	Relevant document
The control of water-borne infections, in particular legionellosis	- Health Technical Memorandum 04-01 – ‘The control of Legionella, hygiene, “safe” hot water, cold water and drinking water systems’ - Health Facilities Note 30 – ‘Infection control in the built environment’
The control of infection transmission pathways through appropriate choice of technology and through staff training on cleaning and personal washing	- Health Facilities Note 30 - Health Building Note 00-10 Part C - NHS Healthcare Cleaning Manual
The needs of vulnerable patients, such as vulnerability to scalding, ergonomic design and accessibility	- Health Technical Memorandum 04-01 - Health Building Note 00-02 – ‘Sanitary spaces’ - Health Technical Memorandum 00
Providing adequate points of access for drinking water and promoting the health benefits of hydration within the NHS estate and in the wider community.	Water UK has established the Water for Health Alliance, an industry initiative to promote the health benefits of hydration. The initiative includes guidelines for hospitals, available at www.wateratwork.org.uk/?page_id=13

Note

Planning teams should note the contents of ‘[The Health Act 2006: Code of practice for the prevention and control of healthcare associated infections](#)’ (Department of Health, January 2008). This code of practice sets out criteria by which managers of healthcare organisations are to ensure that patients are cared for in a clean environment and where the risk of healthcare-associated infections is kept as low as possible. The document contains a comprehensive list of the Department’s guidance on the prevention of healthcare-associated infection.

Case study: combining water efficiency and infection control and patient welfare

Dorset County Hospital, Dorchester, has embarked on a programme to change all of its WC flush valves and taps to non-touch types. This is partly due to the water efficiency achieved, but mainly because there is mounting evidence that non-touch products offer significant benefits to improving hand hygiene.

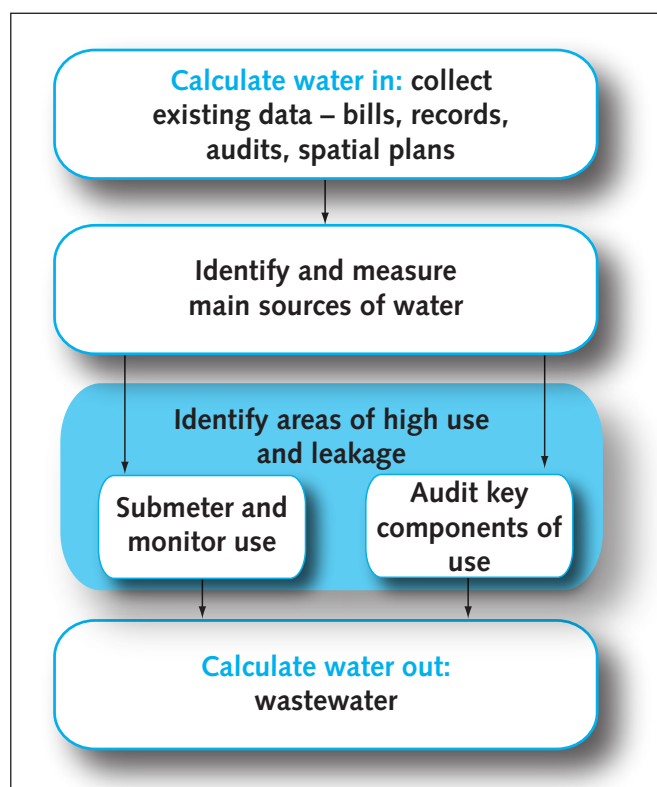
The same hospital had an outbreak of *Clostridium difficile*. There were no cases of the disease in areas

where non-touch taps were used. While it may be coincidental to some extent, it demonstrated the potential of hand hygiene and the benefits of non-touch taps.

Non-touch products not only offer water-saving and infection control benefits, but also convenience and ease of use for children and people with disabilities.

also aim to establish a framework for ongoing monitoring of water consumption inside the building or site (see Figure 5).

Figure 5 The water auditing process



- 5.28 In seeking support for conducting an audit, healthcare organisations should designate a key accounts manager to liaise with the local water company. Some water companies are able to offer water audits to high-consumption customers (see also [Chapter 11](#)).

Calculating water coming in

- 5.29 Existing data (such as bills, records and spatial plans of the site) should be collated, and also any other previous audits or reports on water. These should then be used to identify the main sources of water in the building or site, which may consist of private water supplies (for example boreholes), mains supply, bottled water, rainwater harvesting or water recycled within the building.
- 5.30 Plotting monthly water bills against time on a graph can help to analyse trends in water use and identify a departure from normal consumption levels. A gradual increase in monthly consumption may indicate a leak.

- 5.31 The possibility of downgrading to a smaller supply-pipe meter should be investigated, based on the data gathered, as this will reduce standing charges for water and sewerage services.

Note

In the analysis of water bills, account needs to be taken of any price increases, any appliances installed or removed, and significant changes in usage such as any ward closures etc.

Identifying areas of high use and leaks

- 5.32 Once the net use of water for a building has been estimated, areas of high use should be identified, as these provide the largest potential for savings. In some cases, a simple paper audit listing water-consuming fixtures and fittings within the facility, as well as their condition, will be a sufficient preliminary audit. Reference to [Chapter 6](#) should be made when considering which components to include in the audit.
- 5.33 In larger facilities, submeters provide a means of mapping water flows and analysing consumption according to different sections of the building. For more detailed audits, it may be worth installing submeters for audit and monitoring purposes. Gathering data on water use in different sections of the building may also identify leaks that are not immediately visible in monthly building-wide water consumption.
- 5.34 Identifying and repairing leaks is relevant to both efficiency and health in facilities. Metered charges will be reduced, as will the risk of contamination of the water supply. Engineering work that exposes pipework and/or produces a large amount of dust should be screened for infection risk (see [Health Facilities Note 30](#)).
- 5.35 Measuring flows during periods of low use (typically at night-time) can reveal unusually high base flows, which can indicate a leak in the area supplied. This may not be the case for buildings such as hospitals, in which daily patterns of water use are erratic and do not drop sufficiently at night-time. In such cases, metering may only be able to identify major long-term leaks (see [Figure 7](#)).
- 5.36 [Figure 6](#) is a hypothetical example, showing baseline consumption standing at 30 L per hour during night hours, possibly indicating a leak. [Figure 7](#) is an actual example of a hospital's

monthly consumption, illustrating a major leak that occurred in March 2000.

- 5.37 The healthcare facility's local water company should be able to assist in identifying leaks and anomalously high use. Almost all companies will offer free advice and some will offer free hands-on support.
- 5.38 They will also be able to advise on which types of meter to install and whether advanced metering technology would be useful.

In Scotland and Northern Ireland, Scottish Water and Northern Ireland Water, respectively, are the single providers of water. (With regard to commercial customers in Scotland, 1 April 2008 saw the introduction of competition in water services. Therefore, service providers are likely to vary.)

Welsh customers are mostly served by Dŵr Cymru (Welsh Water), with small portions served by Dee Valley Water and Severn Trent Water.

Calculating water coming out

- 5.39 As water services are charged according to separate water and sewerage charges, the amount of

wastewater discharged into sewerage pipes should be calculated. Often this is more difficult than calculating the water coming in, as it tends not to be metered. It is advisable to check the following:

- the location of sewer outflows;
- where rainwater drainage goes;
- whether there are any septic tanks or soakaways;
- whether any water is taken off site;
- steam losses.

Identifying objectives and developing an action plan

- 5.40 Having conducted a water audit, it should be possible to identify key objectives. These may be focused on identified leaks or may involve changing the management of water in those sections of the building with high water use.
- 5.41 In developing an action plan, both behavioural and technological options for management should be considered. As mentioned above, staff involvement in the design as well as the implementation of an action plan is essential. The initial results of the

Figure 6 Hypothetical daily consumption

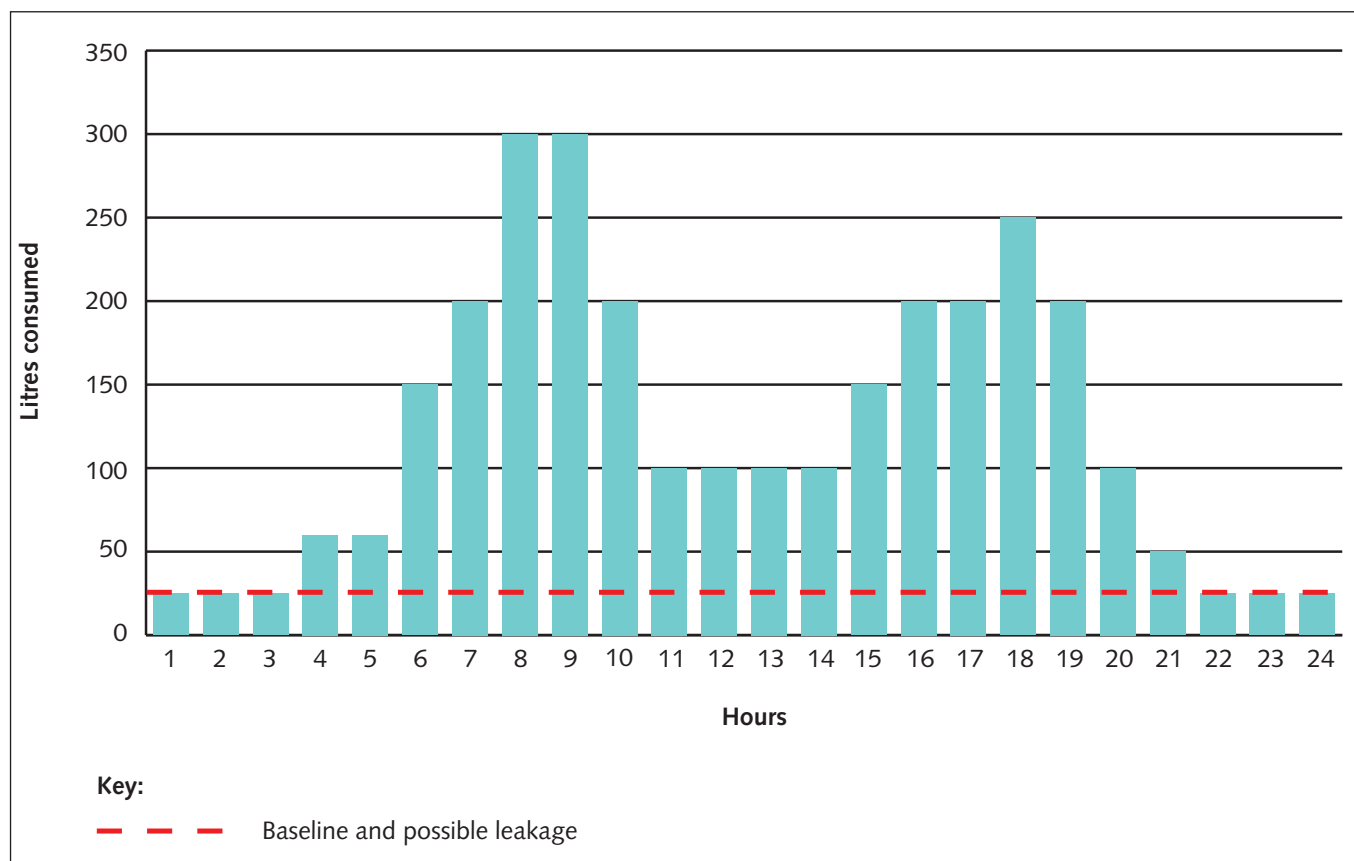
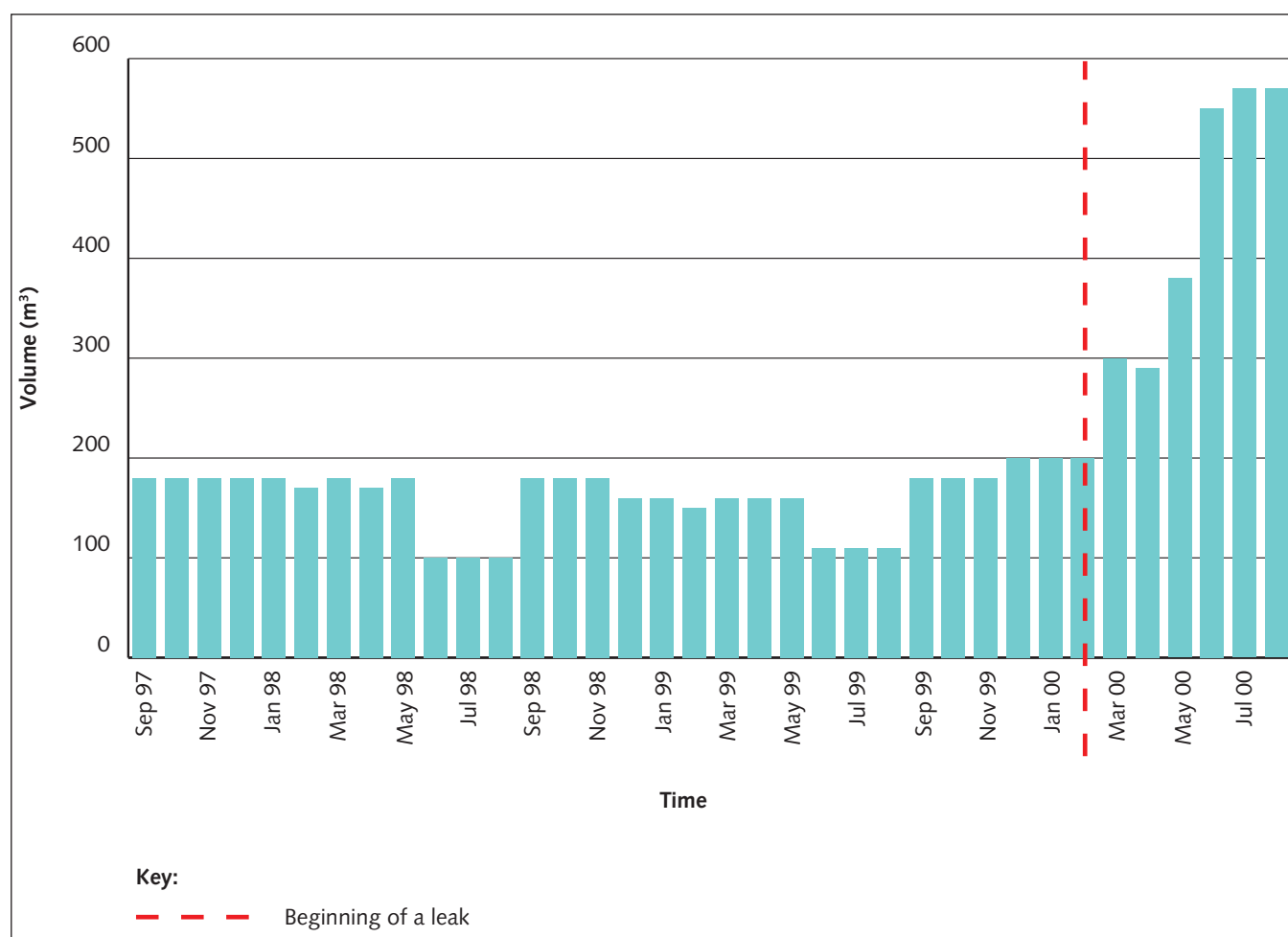


Figure 7 Example of annual consumption for a hospital



water audit should be circulated to staff, and an opportunity to discuss the most appropriate actions provided.

- 5.42 Once a picture of water use and wastage emerges, the costs of each type of water should be calculated; this will indicate potential volumes and cost savings associated with water-efficiency options (outlined in [Chapter 6](#)).
- 5.43 The next action is to assess the capital costs of implementing changes to reduce wastage. Capital costs can then be compared against operational savings; this should provide a hierarchy of water-saving actions based on whole-lifecycle costs.
- 5.44 In making final decisions on water conservation actions, other factors should be taken into account, such as infection control, health and safety, staff acceptability, environmental costs and benefits, the implications for sewerage, and any energy savings or costs associated with the water-saving measures. When choosing the appropriate technology, it is important to consult with staff and the control of

infection team in order to identify any health risks or patients' needs that may be relevant.

- 5.45 A plan should consist of a clear, measurable set of key objectives that can be easily monitored and updated.

Note

The formulation of an action plan is considered best practice. It is not mandatory.

Implementation

Outreach

- 5.46 Once an audit is produced or a strategy is in place, it should be disseminated. A strategy should seek to empower and engage staff and patients, as half of all water savings can be generated through behaviour change, which can be free if the right atmosphere is created. Some suggestions for outreach are:

- an information pack or other communication that highlights the importance and value of efficient water use both in and out of the workplace;
- management rewards and ring-fencing of water savings;
- signs and notices on appropriate use next to water-using appliances; and
- informing local media (via a healthcare organisation's communications manager) of the new plan to raise the profile of water efficiency and local environmental policy.

Procurement and installation

- 5.47 Information on water-efficient devices is included in **Chapter 10**. When corresponding with contractors and consultants, water efficiency should be stressed as a priority.

Monitoring and maintaining standards

Benchmarking: hospital water consumption

- 5.48 Benchmarking helps to inform a manager about appropriate parameters for water efficiency.
- 5.49 As the size, design and use of healthcare facilities will vary considerably, a means of normalising water consumption across buildings is necessary. Normalisation may be achieved by calculating water consumed:
- per square metre of floor space (Table 2);

- per bed day (Table 3); or
- by person type (Table 4).

- 5.50 In each case, it may also be necessary to distinguish between building types in order to achieve a more realistic benchmark. It is recommended that benchmarking be used as a guideline for management rather than a stringent target.

Table 2 Hospital water use (expressed in cubic metres per square metre of floor area per year)

Type of hospital	Typical use	Best practice benchmarks
Small acute or long-stay hospitals without personal laundry	1.17	0.90
Small acute or long-stay hospitals with personal laundry	1.56	1.24
Large acute/teaching hospital	1.66	1.38

Source: Water UK (2003)

Recommended benchmarks

- 5.51 Table 2 reflects the findings of a Water UK study conducted in 2003, in which cubic metres of water per square metre of floor space per year was found to most accurately reflect data analysis. It was also found that the only activity within hospitals which significantly influenced consumption was laundry washing.

Table 3 Hospital water use (by patient bed days)

Type of hospital	Water per patient bed-day (m ³)			
	Very poor	Poor	Average	Good
Acute (>100 beds)	1.138	0.711–1.137	0.531–0.710	<0.530
Long-stay (>25,000 patient days per year)	0.690	0.412–0.689	0.331–0.411	<0.330
Long-stay (<25,000 patient days per year)	0.380	0.298–0.379	0.218–0.297	<0.217

Source: Audit Commission (1993)

Table 4 Hospital water use (expressed in litres per person per day)

Person type	Litres per person per day
Employee (full-time without canteen)	25–50
Employee (full-time with canteen)	40–90
Resident employee	180
Hospital patient (in-patient)	450

Source: Audit Commission (1993)

Other benchmarks

5.52 The benchmarks in Tables 3 and 4 are provided for information purposes only. However, if data necessary for calculating water consumption according to Table 2 (for instance total floor space) is not available, they may be used as guidance for water management.

Benchmarking: water consumption in healthcare facilities other than hospitals

5.53 The benchmarks given in Tables 2–4 may not be appropriate for other types of healthcare facility. Where the facilities are largely used for office work, it is advisable that building managers use the current government performance target of 4 m³ per employee per year (CIRIA, 2006).

5.54 In other instances, data for water consumption per square metre of floor space (collected through a recent Estates Return Information Collection (ERIC) survey) may help to indicate an appropriate consumption level.

Northern Ireland and Scotland have similar data-gathering systems.

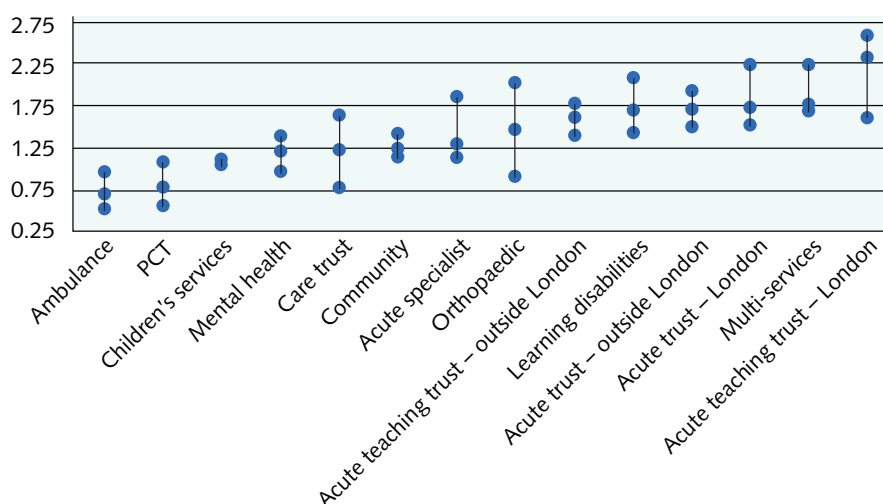
5.55 Table 5 and Figure 8 provide figures for a number of healthcare facilities. Data is given according to upper and lower quartiles and median values. These values should be taken as indicators only.

Table 5 Annual water consumption (litres per occupied floor area)

Building type	Consumption (m ³ per m ² per year)		
	Q1	Median	Q2
Ambulance	0.969	0.716	0.535
PCT	1.092	0.798	0.567
Children's services	1.116	1.088	1.053
Mental health	1.39	1.222	0.973
Care trust	1.636	1.227	0.776
Community	1.412	1.248	1.135
Acute specialist	1.844	1.29	1.128
Orthopaedic	2.018	1.458	0.902
Acute teaching – outside London	1.771	1.596	1.39
Learning disabilities	2.072	1.682	1.422
Acute – outside London	1.906	1.7	1.499
Multi-service	2.219	1.702	1.492
Acute teaching – London	2.213	1.74	1.656
Acute – London	2.554	2.298	1.591

Source: Estates Return Information Collection (ERIC) (2005/2006)

Figure 8 Annual water consumption (litres per occupied floor area)



Source: Estates Return Information Collection (ERIC) (2005/2006)

6 Suggested components of a water strategy

Boilerhouses

- 6.1 Optimising boiler performance and maintaining the system can save large amounts of water. This can be very cost-effective and will have a significant impact on reducing a facility's carbon footprint, since hot water and steam have a great deal of embedded energy.
- 6.2 When making any changes to boiler management or alterations to design, suitably trained personnel or companies must be employed.
- 6.3 In addition to manufacturers' instructions, the Health and Safety Executive's (HSE) Guidance Note PM5 – 'Automatically controlled steam and hot water boilers' should be consulted prior to any action.

Boiler feed-water pre-treatment

- 6.4 Feed-water entering the boiler will frequently need to be demineralised in order to reduce solid deposits in the system. This process often involves the use of ion-exchange beds. These beds require frequent regeneration, typically through the use of hydrochloric acid or caustic soda. Water is used to flush the regeneration agents from the beds and is then considered effluent.
- 6.5 Water may be conserved by conducting the regeneration process only when needed, rather than at regular daily intervals. Trigger levels for regeneration can be defined either by volume of water treated or by monitored conductivity breakthrough of the bed.

Boiler blowdown

- 6.6 Throughout operation, boiler units gradually build up concentrations of total dissolved solids (TDS). At sufficient concentrations, these TDS precipitate from the water and form solid material in the boiler unit, impairing efficiency and heat transfer. In order to avoid the water reaching high concentration of TDS, water should occasionally be dumped from the boiler; this is called "blowdown".

- 6.7 Older models of boiler may continuously remove water from the top of the water tank or they may flush the system out at predetermined intervals. A blowdown system that is activated only when TDS concentration exceeds a certain threshold may provide significant energy and water savings. Calculations and decisions should be made by a competent person.

Steam losses, leaks and condensate recovery

- 6.8 As steam travels through the outlet pipes of a boiler, its temperature decreases and water condenses in the pipes. This condensate can be collected and recycled into the boiler system, reducing energy and water consumption as well as slowing the build-up of TDS (as the condensed water tends to have a much lower TDS content).
- 6.9 The energy required to produce steam is extremely high. Approximately 80% of the energy used in a boiler is used in providing the necessary latent heat to produce steam, with only 20% attributed to raising water to boiling point; care should be taken to prevent steam losses from the system and to ensure that the necessary safety precautions are in place.
- 6.10 Installing heat exchangers (sealed thermal units) should be considered, as this will reclaim otherwise lost heat and will help to curb the risk of *Legionella* growth.

Cooling towers

- 6.11 Cooling towers are used to transport heat from processes within the building to the roof. The process involves pumping water to holding tanks on the roof where water is allowed to evaporate – cooling the remaining water. In a similar manner to boilers, as water is lost through evaporation, the concentration of TDS grows. In order to prevent the build-up of solid materials in the tower, water must occasionally be bled from the system and make-up water introduced.

- 6.12 Alternatives to using cooling towers for temperature control are outlined in the Building Research Energy Conservation Support Unit's (BRESCU) General Information Report 85 (GIR085) – 'New ways of cooling: information for building designers'. (See also the Health and Safety Executive's (2000) 'Approved Code of Practice: Legionnaires' disease – the control of legionella bacteria in water systems'.)

Cycles of concentration

- 6.13 The rate at which water is replaced in cooling towers is determined by the "cycles of concentration" (CoC) value. This value describes the acceptable ratio between the TDS bled from the cooling tower system and those introduced. Systems at lower CoC will use more water to maintain the required TDS value. Calculations and decisions should be made by a competent person.

Additional losses

- 6.14 Losses due to factors other than evaporation and bleed water can be calculated using the following equation:

$$\left(\frac{\text{Make-up water}}{\text{Cycles of concentration (CoC)}} \right) \times \text{Bleed water}$$

Catering department

- 6.15 The catering department constitutes a significant portion of total water consumption in healthcare facilities, and may benefit from being submetered for monitoring purposes. Reducing water waste in this department requires a combination of behavioural change in staff and appropriate changes to technology. Suggestions for informing staff on how to conserve water are outlined below, followed by technical advice.

Washing and preparing food

- 6.16 Staff awareness concerning efficient use of water in food preparation should be raised on the following points:
- **Taps:** A running tap can typically consume 12 L/min. An effort not to leave unused taps running should be made – signs next to taps may be effective. Technology such as flow restrictors and automatic shut-off mechanisms will also reduce waste.
 - **Defrosting:** Defrosting food under running hot water should be avoided when possible.

Changing management of frozen foods to avoid using hot water for defrosting will save water and may be more energy-efficient.

Waste disposal

- **Recycling:** When preparing packaging for recycling, the recycling authority should be consulted on whether it is necessary to wash/rinse packaging.
- **Automatic potato peelers:** Peelers often require a water supply to flush out potato peelings. Flows should be set at the minimum amount required. A flow-restricting valve can be used to achieve this.
- **Food waste disposal channels:** Larger kitchens occasionally use channels of water running through the facility to transport organic waste to a macerator, which is then released into the sewers. If an alternative method of collecting food waste cannot be implemented, channels should be managed with the following in mind:
 - channels should only flow when the kitchen is in use and there is a need for them;
 - the number of channels should be kept to a minimum;
 - flow rates in the channel should be regulated and kept to a minimum.
- **Reducing waste:** Where the amount of waste entering the sewerage system is significant, water companies may charge an additional "trade effluent" charge. Reducing the amount of waste entering the sewerage system will help to reduce or remove such charges where present.

Washing

- **Dishwashing and laundry:** Daily uses should be evaluated for dishwashers and washing machines, and a washing routine which ensures that machines are completely full before turning them on should be established. When replacing machines, water-efficient models should be selected. In larger facilities, industrial-standard machines will be required, and procurement should be based on the most efficient model, taking into account whole-life costings.

In the case of smaller estates where domestic (as opposed to industrial) washers are used, a database of domestic dishwashers and their efficiency ratings is available from the Waterwise website.

- **Washing food-preparation areas:** In larger kitchens, surfaces and equipment are often washed down using a hose. If hoses are used, there is a need to reduce the risk of aerosol formation.

Sanitary appliances

- 6.17 Non-process uses of water are commonly referred to as “domestic”. Domestic appliances consist of WCs, urinals, taps, baths and showers. It is likely that domestic uses will be the most cost-effective area for water efficiency as they constitute a large portion of water consumption in hospitals and other healthcare facilities. This section outlines options for upgrading technology and changing staff behaviour and the resulting water savings.
- 6.18 The use of water-efficient fittings and appliances may not be appropriate to the needs of the patient and may adversely affect the incidence and propagation of infections (see Health Technical Memorandum 00 and Health Building Note 00-02 for further guidance). Managers are also advised to refer to the control of infection team before any measures are taken (see also Health Technical Memorandum 04-01).

WCs

- 6.19 Water consumption per flush for WCs will depend on the age of the model, as will options for upgrading or retrofitting. Often WCs are the first choice for water efficiency, as they constitute a large portion of domestic use. Older models may use as much as 12 L per flush, whereas newer models consume around 4–6 L. The Water Supply (Water Fittings) Regulations 1999 (Water Byelaws in Scotland; Water Regulations in Northern Ireland) require any new WC installations to use a maximum of 6 L per flush (7.5 L in Northern Ireland) (see Health Technical Memorandum 00 and Health Building Note 00-02 for further guidance).

Cistern displacement devices (CDDs)

- 6.20 A cistern displacement device (CDD) may be used to displace a set volume of water inside the WC

cistern, saving water on each flush. CDDs typically save around 1 L of water per flush.

- 6.21 Care should be taken to install a CDD appropriate for the WC model and that still provides an adequate flush volume. CDDs offer a simple low-cost method of reducing WC flush volumes; however, consideration should be given as to whether it is better to use CDDs or to upgrade WCs to low-flush models, which may also be easier to maintain and ergonomically better to use.
- 6.22 Generally, CDDs may be useful for clinics and WCs in GP surgeries, but large-scale use of CDDs in a hospital may indicate the need to refurbish the WCs.

Retrofitting flush mechanisms

- 6.23 As mentioned in paragraph 6.19, WCs manufactured after 2001 are subject to regulations enforcing a maximum flush of 6 L. Older WCs that consume as much as 12 L per flush can be retrofitted with flushing mechanisms that allow the user to vary the flush volume. Depending on the age of the WC, water savings of up to 5 L per flush are possible. Users control the flush either through a choice between a full and a half-flush (dual flush) or through releasing the flush handle to cut the flow of water (variable flush). If such a device is installed, clear instructions on its use should be displayed near the WC.

Installing new water-efficient WCs

- 6.24 When installing a new WC, it should be confirmed that the model has been approved by WRAS. WRAS-approved WCs consume as little as 4 L per flush and 2.6 L per reduced flush. When upgrading WCs, a dual-flush water-efficient model should be considered (see Health Technical Memorandum 00). Drainage facilities for new sanitary equipment should be designed to cope with the maximum expected production of waste.

Urinals

- 6.25 Urinals are often controlled through an automatic flush system which is triggered at regular intervals. A typical system will flush volumes of approximately 7.5–12 L of water at 20-minute intervals. This can amount to as much as 197 m³ per year per urinal, resulting in unnecessary water and sewerage charges. Installing passive infrared detectors in urinals typically reduces water consumption by 60%. Costs stand at £120–£150,

but payback is rapid. Further options include installing more water-efficient models when upgrading, or considering waterless urinals for certain areas; however, the infection control team should be consulted before installing waterless urinals (see Health Technical Memorandum 00 and Health Building Note 00-02 for further guidance).

Note

With regard to waterless urinals, there may be issues over perception and maintenance, as cleaning staff may not be familiar with these types of urinal. It is recommended that the use of waterless urinals is discussed with medical and cleaning staff before a decision on installation is made. There are also ultra-low-flush urinals available that may overcome any perceived hygiene issues.

Some waterless urinals use disposable cartridges or other devices, which need changing routinely. The system also needs to be flushed occasionally to remove any debris. Both of these tasks will need to be accounted for in an agreed maintenance contract, which must then be evaluated in terms of additional costs introduced versus the water savings, as well as the appropriate levels of maintenance necessary to ensure good hygiene.

Taps

Leakage

6.26 Taps are prone to leakage. It is estimated that a dripping tap may consume around 15 L per day. Staff should be informed of the importance of reporting leakage and a reporting system should be put in place.

Design

- The uses of taps should be considered before reducing flow rates. In some cases, reducing flow rates may be inappropriate. For instance, where taps are used to fill containers, reducing flow rates will only increase the time taken and will have little effect on efficiency. In other cases, where the risk of spread of infection is particularly high (for example surgical scrubbing), sensor-, lever- or foot-operated taps may be most appropriate.
- Taps typically use about 9 L of water per minute, but may use as much as 18 L per

minute. Staff should be informed of the importance of using taps appropriately.

- Sensor (non-touch) taps may in some cases be ideal, as they both conserve water and reduce the risk of infections spreading.
- The fitting of non-concussive self-closing taps can also reduce unnecessary flow.
- Flow regulators may also be fitted to taps, as appropriate.

See Health Technical Memorandum 00 for guidance on the appropriate types of tap for use in healthcare facilities.

Baths and showers

6.27 Baths typically use around 80 L per event and showers around 9 L per minute. Where possible, showers should be favoured over baths; however, the care needs of patients must take priority. Reducing the water used for showers and baths may also potentially reduce energy bills due to a reduction in hot water used.

Shower technology

- Flow restrictors may be used to reduce the flow rate of water in showers.
- Shower location and design can significantly reduce the amount of water wasted due to waiting for showers to reach the desired temperature. In addition, in healthcare facilities there is a risk of scalding for vulnerable patients, the very young, older people and patients with mental-health illnesses. Upgrading to thermostatic mixing valves will minimise this risk (see Health Technical Memorandum 04-01 and Health Technical Memorandum 00).
- Fitting water-efficient showerheads may reduce water consumption significantly.
- There should be efficient ventilation to control aerosol dispersion.

Medical activities

Surgical scrubbing

6.28 The NHS carries out about 7 million operations a day; each one will require a minimum of two staff to scrub. Scrub taps are generally lever- or sensor-operated. This is an essential area of water use;

reduced flow taps should not be used (see also Health Technical Memorandum 00).

Dialysis unit

- 6.29 In a renal unit, water quality should meet the recommendations specified by the European Renal Association-European Dialysis and Transplant Association's (ERA-EDTA) 'European best practice guidelines for haemodialysis'. To ensure purity, water is passed through a reverse osmosis (RO) unit. This means that water can be reused (for WC flushing, for instance) as the RO unit can remove almost any level of contamination (see also "Example 4" after paragraph 4.7).

Patient care

- 6.30 Patient bathing, WC use, washing and drinking can use a large amount of water. However, the best way to reduce waste is by ensuring all the appliances used by patients are efficient. Indeed, patients should be encouraged to use more water through good hydration and personal washing. All hospitals should provide easy access to drinking water for patients, and the promotion of good hydration should be stated in any water management plan.

Laser cooling

- 6.31 Medical lasers are generally water-cooled. Owing to the cost and sensitivity of the equipment, water efficiency should be a secondary consideration after ensuring water purity (to prevent corrosion) and cooling efficiency. Depending on the type of laser, it may be possible to use thermoelectric cooling or air cooling, but water efficiency should not be a driving factor in choosing cooling systems.

Hydrotherapy pools and swimming pools

- 6.32 Hydrotherapy is a therapeutic whole-body treatment that involves moving and exercising in water – physiotherapy in a pool. Hydrotherapy pools are usually different from ordinary pools – the temperature and movement of water is controlled and changed according to who is using the pool and why. Pool covers can reduce evaporation losses. Filtration units can be used to recirculate water. This is common on modern pools, but is expensive to retrofit; however, the Health Protection Agency's (1999) 'Hygiene for hydrotherapy pools' states that most pools should have a filter.

Birthing pools

- 6.33 Birthing pools can use around 500 L of water per use. For hygiene reasons, the water cannot be reused without extensive treatment. The only way to increase water efficiency is through the shape of the pools; however, medical and comfort considerations should take priority over water efficiency. If considering installing birthing pools, there are three points to take into account:
1. They will use a great deal of water.
 2. They are very heavy – therefore, the structural integrity of the building should be considered if a number of pools are situated in the same area of a floor.
 3. They require a great deal of cleaning, which will use much water.
- 6.34 Some hospitals may also have mobile birthing pools.

Decontamination

Endoscopy

- 6.35 This is an area where water efficiency is unlikely to be acceptable from a clinical perspective and where water reuse may pose an infection threat. For further guidance on decontamination in endoscopy, see Health Technical Memorandum 01-06 – 'Decontamination of flexible endoscopes'.

Sterile services departments

- 6.36 It is very difficult to improve water efficiency in essential support services such as sterile services. While trying to promote water-efficiency measures, it is important to remember that the decontamination process should not be compromised in any way.
- 6.37 However, it is recommended that:
- all decontamination equipment (washer-disinfectors and sterilizers) operates with full loads;
 - wash cycles are evaluated for water-use efficiency.

Outdoor use

- 6.38 Few healthcare facilities have considered the amount or type of water used for outside watering, or the selection of plants. Given that a single water sprinkler may consume as much as 900 L of water

an hour, the costs of outdoor use are potentially large. Consider the following solutions to reducing outdoor use:

- **Rainwater harvesting:** this may be ideal for plant watering, as the collected water requires little or no treatment (see [paragraphs 7.9–7.11](#)).
- **Plant choice:** consideration should be given to installing drought-resistant or perennial plants in estate grounds; these will need little water and will add diversity.
- **Sprinkler timings:** sprinkler timings should be adjusted such that they are active in the early morning or late afternoon; this will reduce water loss due to evaporation.
- **Mulching:** mulch and bark should be used in flower and tree beds; this will reduce the loss of water through evaporation by up to 70%.

7 Whole building concerns

- 7.1 Achieving good water management in healthcare facilities will demand that decisions about issues such as security of supply, water quality and flood risk are assessed in terms of impacts on the entire building (see also Health Technical Memorandum 00 and Health Technical Memorandum 04-01 for further guidance).

Alternative supply sources

Boreholes/private supplies

- 7.2 The use of water abstracted from private sources may be feasible in some circumstances.
- 7.3 Where water quality is not required to be at a potable standard (for instance in cooling equipment or flushing urinals and WCs), it may be possible to use water directly abstracted from a borehole.
- 7.4 Where water is to be used for human consumption or cleaning, filtration and/or further treatment may be necessary to comply with the Private Supplies Regulations 1991 and Water Industry Act 1999.

In Northern Ireland, this is covered by the Water and Sewerage Services Order 2006, and in Scotland by the Water Supply (Water Quality) Regulations 2001.

- 7.5 Boreholes are drilled through underground strata that contain water (known as aquifers). Water is then abstracted through a submersible pump at depths varying from 20 to 200 m. The water is then stored in a holding tank on the surface.
- 7.6 In each case, feasibility of abstraction will depend on the availability and quality of groundwater, which can be established through a preliminary survey. Once this has been verified, abstraction will require a licence.

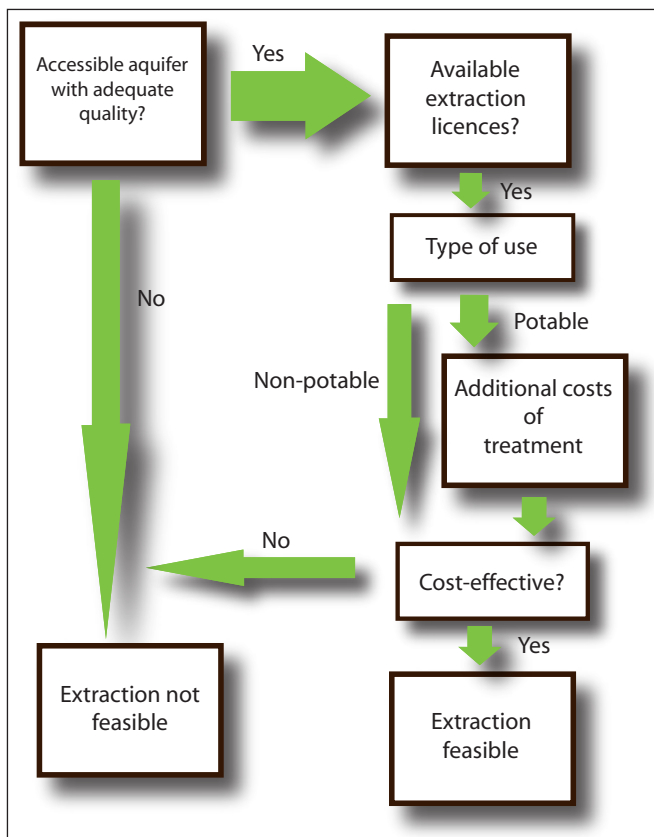
In England and Wales, licences are managed by the Environment Agency and often depend on the density of abstractors in the area, managed through local CAMS. In the case of Scotland, abstraction licences are provided by the Scottish Environment Protection Agency, and in Northern Ireland by the Department of Environment.

- 7.7 There are potentially large financial savings to be made through private abstraction; however, the long-term costs of water supply from water companies must be balanced against the following:
- the capital costs of the construction of works, mains, plumbing, treatment plant etc;
 - the operational costs of electricity for pumping, water treatment chemicals, direct and indirect maintenance, and associated management costs.
- 7.8 Once all factors are taken into account, a decision to develop a private water supply can be made. **Figure 9** is an example of a decision tree outlining the key factors.

Rainwater harvesting

- 7.9 Harvesting rainwater that falls on property roofs may be economically feasible for larger buildings. Water collected from roofs may be used for low-quality purposes such as laundries and WC/urinal flushing. The payback period will vary depending on the size of the roof and annual rainfall values.
- 7.10 Systems supplied should have an alternative automatic supply (for instance where rainfall is insufficient).
- 7.11 Depending on where the water is harvested from, there may be issues with water quality (bird droppings and pesticide deposits are commonly present on roofs). It should always be presumed that rainwater is non-potable, and it should not be used where ingestion is a possibility.

Figure 9 Decision tree for establishing a private water supply



At the time of writing this guidance, industry standards for rainwater and greywater harvesting have not yet been developed, but a British Standard is in preparation.

Visit the UK Rainwater Harvesting Association's website for further information.

Greywater reuse

7.12 Greywater and rainwater are often discussed together. Greywater is water that has been previously used and is almost certainly contaminated.

7.13 Greywater should not be used in healthcare premises. However, there may be circumstances where its use may be acceptable on a case-by-case basis. Where greywater is to be considered, a risk assessment should be undertaken that considers all the potential microbiological risks that may result from such a change of use. This assessment should involve a microbiologist and infection-control staff.

7.14 Technology for greywater reuse is advancing very quickly and there may be certain circumstances where the type of greywater or the certainty of the

technology can allow greywater reuse. Each case should be judged on its merits, balancing risks and benefits, and should be discussed fully with staff before implementation. Any implementation should also ensure that all pipes and equipment carrying or using greywater are clearly labelled.

Water security

7.15 To guard against an interruption in supply, Health Technical Memorandum 04-01 stipulates that at least 12 hours' supply of cold water should be stored on site. Guidelines also state that a maximum of 24 hours' supply of water should be stored in order to avoid stagnation of water in supply tanks and the resulting risk of *Legionella* growth and transmission.

7.16 Where actions are taken to reduce water consumption in existing buildings, the amount of water required to supply the building for 12 hours will reduce, as will the turnover rate of water in the storage tank. Where it is calculated that a building has significantly reduced the amount of water used per day, the possibility of reducing storage tank sizes should be investigated.

7.17 The required storage volume should be calculated for a 12-hour demand scenario, including peak periods of demand. Similar calculations should be made if there is a reduction in turnover times for wall-mounted calorifiers, with a maximum of two hours' storage time available, including peak demand.

7.18 In addition, the turnover rate of water in all pipes within the building should be considered. The risk of water remaining stagnant in the distribution pipes will rise – particularly in deadlegs.

7.19 Where fixtures are rarely used, the possibility of removing the fixture and any deadlegs supplying it should be considered.

7.20 A water management strategy should consider the logistics of ensuring water supply. The following questions should be addressed:

- In the case of a "boil water" notice from the local water company, how will water be boiled and distributed around the site?
- In the case of interruption to the supply, where are the connection points for water supplied by a tanker?

7.21 It may be necessary to have arrangements for bringing in drinking water to ensure patients

do not dehydrate (see also Health Building Note 00-07 – ‘Resilience planning for the healthcare estate’).

Water quality

- 7.22 In all circumstances, water efficiency should not compromise water quality and safety requirements. Issues relating to these requirements are discussed below.

***Legionella* and internal hot and cold distribution networks**

- 7.23 Related to the issue of security of supply is the overall risk of *Legionella* growth. High-risk scenarios of *Legionella* growth include those where water remains stagnant in tanks and distribution pipes for extended periods of time, particularly under favourable temperatures. For cold water supplies, water temperature should not exceed 20°C and should aim to be no more than 2°C warmer than the temperature recorded at the main supply pipe. For hot water supplies, flow temperatures should be set to 60°C, and a minimum of 55°C should be maintained at all points in the network (see Health Technical Memorandum 04-01 for further guidance).

Water hardness

- 7.24 Water hardness is expressed in terms of milligrams per litre of calcium carbonate (CaCO₃). The hardness of water supplies will depend largely on the region in which the water is abstracted.

For a map of hardness, see the report ‘Water hardness in the British Isles’ on the Waterwise website.

- 7.25 Higher hardness levels may adversely affect equipment – as water is heated, its capacity to carry dissolved salts decreases, leading to calcium deposits on pipe walls and heating elements, thus decreasing efficiency. It may therefore be appropriate in some cases to install water softeners for certain uses. Possible uses that may benefit from softening are:
- boilers and hot-water supply systems – to prevent sludge and limescale build-up;
 - mixing devices and blending valves – to avoid clogging of control ports and showerheads by limescale;
 - laundries – water hardness leads to high maintenance costs and the uneconomic use of soap detergents.

- 7.26 In the case of drinking water, epidemiological studies have shown that the incidence of cardiovascular disease tends to be higher in areas of soft-water supplies than in areas with hard water. The association is clearest in supplies which contain less than 150 mg/L. The explanation is not known, but it is advised that where water is used for drinking supplies, it should not be softened.

Metal contamination

Water softness and monitoring

- 7.27 Where water is acidic and particularly soft, its capacity to dissolve metals is higher. In such cases, regular sampling through the building should be conducted to identify possible contamination from the original source or the internal distribution network.

Lead

- 7.28 The Water Supply (Water Quality) Regulations 2000 stipulate an upper limit of 0.01 mg/L to be achieved in all supply by 2013; this value is likely to be exceeded if lead pipework or solder containing lead has been used in building plumbing systems. Should a value higher than 0.01 mg/L be detected, remedial action should be taken.

Copper

- 7.29 Copper concentrations above 1 mg/L may cause staining of laundry and sanitaryware and increase the corrosion of galvanised iron and steel fittings. While the maximum allowable copper concentration in water supply is 2 mg/L, a typical supply will be below 1 mg/L.

Specialist units

- 7.30 In general, the supply of water to certain specialist units such as maternity departments, neo-natal units, children’s units and renal dialysis areas should be monitored to ensure that water quality is within acceptable limits. Epidemiological advice should be sought concerning the exact water quality requirements for each specialist unit.

Wastewater and sewage

Sewage

- 7.31 Sewage accounts for over 50% of water and sewage costs to the NHS. Unlike water, which is metered, sewage bills are normally based on water use.
- 7.32 Standing charges for sewage depend on the size of the incoming water meters and the volume of water consumed.
- 7.33 It is possible to negotiate an allowance with water or sewerage companies for water that is not returned to the sewer. For clinics and GP surgeries, where water use is domestic, sewage rates are based on 95% return, but hospitals have higher evaporation losses, and returns to sewer could be as low as 70%.
- 7.34 Once an audit has been carried out or the water balance has been assessed, a rebate with the water or sewerage company should be negotiated. In some areas, water and sewerage are provided by a single company; in others, there may be two separate companies.
- 7.35 Water and sewerage companies classify effluent discharges as either domestic or trade. Most healthcare facilities' wastewater is classified as domestic. However, parts of certain sites, such as laundries or laboratories, could possibly be classified as trade. The classification varies between water companies.
- 7.36 Charges for trade effluent depend on the toxicity of the wastewater. If a healthcare facility has a trade tariff, it should contact its local water or sewerage provider about how to reduce toxicity and thus reduce charges.
- 7.37 The volume flow of effluent is the most important factor in determining the bill. However, it is very common for trade effluent flows not to be measured. In such circumstances, the volume of effluent is assumed to be the same as the volume of water purchased, as recorded on the site's incoming water meter. This figure may be used as it stands or after some modification for losses as steam or in product use.
- 7.38 In general, what is going into the drains at the facility should be assessed. Increasing water efficiency will reduce sewage bills as well as water bills, and it will also highlight areas where wastewater can be reused. As the level of wastewater

reuse increases, consideration should be given to opportunities to renegotiate the sewage return rate.

- 7.39 It is therefore very important to take all steps to reduce water consumption and, where practical, to measure or make a reliable estimate of the flow of effluent that enters the sewer. The flow of water and effluent through the premises should be mapped and analysed; all opportunities for reducing water use should be noted. It should be determined whether any cooling water or rainwater that flows to sewer would be sufficiently clean for direct discharge to a ditch; this may require discharge consent from the Environment Agency (England and Wales).

In Northern Ireland, discharge consent is given by the Department of Environment, and in Scotland by the Scottish Environment Protection Agency.

- 7.40 It is also worth monitoring the contents of wastewater; this will enable a reduction of the contaminants in sewage and will enable optimised chemical use in certain processes. A reduction in contaminants may also reduce trade effluent charges.

Sustainable urban drainage systems (SUDS)

- 7.41 Discharge of clean wastewater or drainage water to a soakaway, swale or infiltration area is often classified as a sustainable urban drainage system (SUDS). This method can reduce sewage or drainage bills, but may require discharge consent from the Environment Agency.

In Northern Ireland, discharge consent is given by the Department of Environment, and in Scotland by the Scottish Environment Protection Agency.

- 7.42 When designing new buildings, re-landscaping or adding car parking, a SUDS should always be considered. Well-designed drainage systems can reduce landscape watering requirements, add biodiversity through the creation of wetland areas, reduce drainage charges, and – if the water is captured in rainwater tanks – provide water for irrigation, WC flushing and fire-fighting. However, water quality should be assessed before using rainwater or greywater inside any healthcare facility (see also [paragraphs 7.9–7.14](#)).

Hospital sources of sewage pollution

7.43 Freshwater quality in healthcare facilities is paramount; however, the contamination of wastewater should not be overlooked. Reducing contaminants released into the sewerage system will significantly contribute to improving the natural environment, into which the contaminants could otherwise be released (see Table 6).

- It can cause or exacerbate leakage.
- It causes a higher flow-rate of water through appliances.

Calculating changes in flow rate due to water pressure

7.46 In general, the following approximation for change in flow rates due to a change in pressure can be used to determine the effects on taps, showers, hoses etc.

$$\text{New flow rate} = \text{Old flow rate} \times \sqrt{\left(\frac{\text{New pressure}}{\text{Old pressure}}\right)}$$

Equation (1)

Discharges to sewers: red list chemicals

7.44 The chemicals shown in Table 7 must not be discharged to sewer.

Water pressure

Effects of high pressure

7.45 Excessive water pressure can contribute to waste in the following ways:

- It places additional and unnecessary wear and tear on the distribution system.

See also Figure 10, which shows an example calculation for a tap with a base flow of 8 L per minute at 1 bar pressure.

Table 6 Possible contaminants to the sewerage system from hospital sources

Source	Main contaminants	Officer responsible
X-ray	Photographic fixer	Superintendent/senior radiographer
Nuclear medicine	Aqueous radioactive isotopes	Medical physicist
Pathology laboratories	• Aqueous radioactive isotopes • Solvents • Heavy-metal compounds • Tissues: human/animal	Laboratory manager
Dental departments	Mercury	Chief dental technician
Dispensing pharmacy	Drugs	Chief pharmacist
Manufacturing pharmacy	Batch failures of products	Chief pharmacist
Medical illustration	• Photographic fixer • Photographic developer	Chief technician
Laundry	• Detergents • Contaminants on laundry	Laundry manager
Sterile services department, endoscopy unit	• Detergents • Disinfectants • Microbial contaminants	Unit manager
Catering	• Cleaning agents • Macerated food	Catering manager
Incinerators	Ash	Estates manager
Domestic maintenance	Cleaning agents	Domestic services manager
Vehicle maintenance	Spent oil	Transport manager
Grounds maintenance	• Pesticides • Nitrate fertilisers	Grounds manager
Blood transfusion centre	• Aqueous radioactive isotopes • Crushed glass	Unit manager

Table 7 Red list chemicals

All flammable and water-immiscible substances
1,2-Dichloroethane
Aldrin
Atrazine
Azinphos-methyl
Cadmium and its compounds
Dichlorodiphenyltrichloroethane (DDT)
Dichlorvos
Dieldrin
Endosulfan
Endrin
Fenitrothion
Gamma-hexachlorocyclohexane
Hexachlorobenzene
Hexachlorobutadiene
Malathion
Mercury and its compounds
Pentachlorophenol and its compounds
Polychlorinated biphenyls
Simazine
Tributyltin compounds
Trichlorobenzene
Trifluralin
Triphenyltin compounds

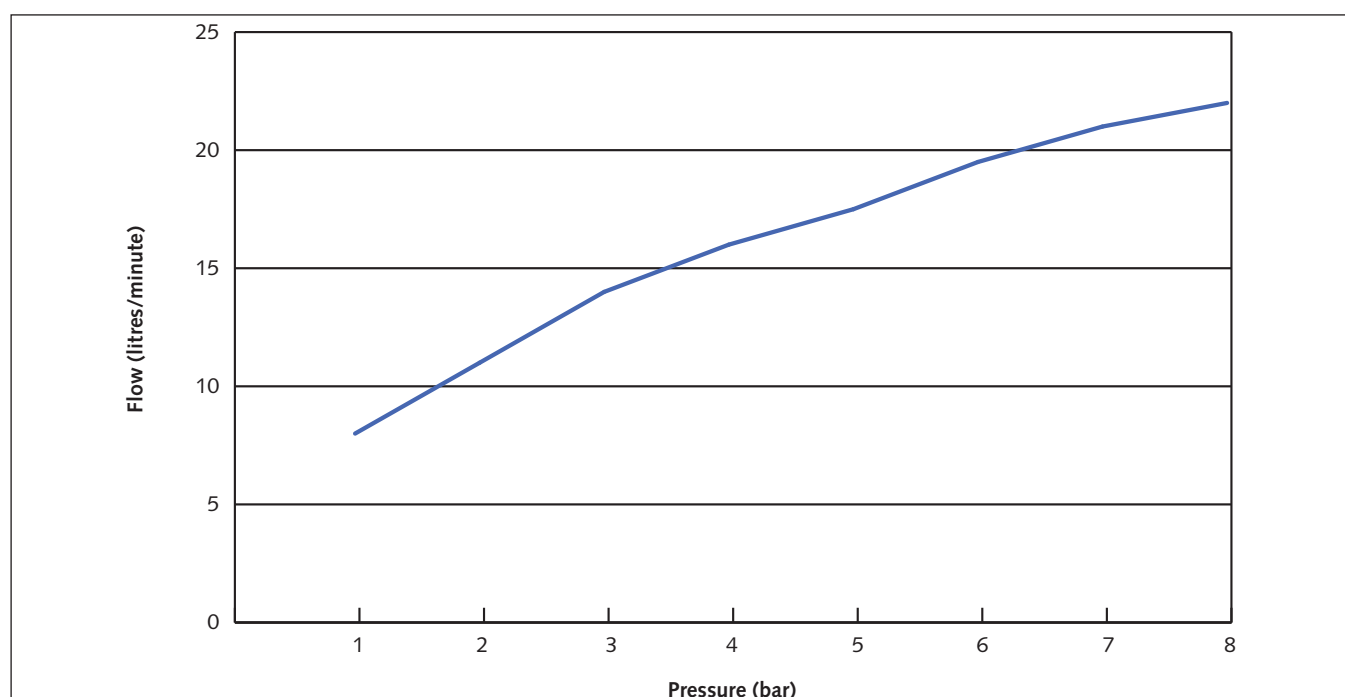
Sources of high pressure

- 7.47 Water is supplied according to minimum flow and pressure regulations, typically at around 2–4 bar; however, maximum pressure would not typically exceed 10 bar. High pressure supplies may occur where buildings are located down-gradient from storage reservoirs (for example when a reservoir is located on top of a hill and the building is in a neighbouring valley).
- 7.48 High pressures may also occur due to building design. Lower floors of multi-storey buildings in which water is supplied under gravity from a break tank in the roof may experience high pressures. High pressure may also occur when water is delivered via booster pumps inside the building.

Managing water pressure

- 7.49 Pressure-reducing valves (PRVs) can act as pre-set or adjustable pressure controls. Typically a valve can accept up to 25 bar pressure, and control this to a delivered 1.5–6 bar.
- 7.50 Valves can be installed in incoming mains pipes and are also commonly used to regulate supply pressure on each floor of a building in gravity-fed or pumped systems.
- 7.51 When selecting the size and setting of PRV, input and output pressures should be taken into consideration. The valve should be suited to the

Figure 10 An example calculation for a tap with base flow of 8 L per minute at 1 bar pressure (with further flow rates calculated using Equation (1))



level of incoming pressure and should ensure an adequate flow rate for all appliances it supplies. This is particularly the case for mixer taps and showers (see Health Technical Memorandum 04-01).

Water temperature

7.52 Owing to the risk of *Legionella* growth, hot and cold water supply temperatures should be closely monitored and maintained (see [paragraph 7.23](#)). Insulating distribution pipes will help to maintain

stable temperatures and will reduce waste by decreasing the waiting time for water to reach the desired temperature in taps and showers.

7.53 When designing new buildings, efforts should be made to reduce the length of hot-water supply pipes to fixtures, as this will reduce the time allowed for heat to dissipate through pipes. Point-of-source heating may be appropriate where there is a particularly large lag-time in water temperatures (see Health Technical Memorandum 04-01).

8 Flood risk

- 8.1 The water strategy should contain contingencies for flooding. Flooding can be coastal flooding, river flooding, localised flooding due to high rainfall, or groundwater flooding where water seeps up from below.
- 8.2 In addition to the immediate threat of flood waters, flooding may disrupt water supplies through contamination of the mains supply or damage to pumping stations. Contamination of water within the building's own system is also a risk.
- 8.3 Guidelines on developing new build and extending existing building in the context of flood risk are provided in the Department for Communities and Local Government's Planning Policy Statement 25 – 'Development and flood risk'.

In Northern Ireland, guidance is provided in Planning Policy Statement 15 – 'Planning and flood risk'.

Mitigating flood risk

- 8.4 When designing new buildings or extensions to existing buildings, the following should be taken into account.
 - **Consult the flood risk maps:** flood risk maps are available from the Environment Agency (England and Wales), Department of Environment (Northern Ireland), or the Scottish Environment Protection Agency, and will provide initial guidance on appropriate construction sites for new build. These maps can be found at:
 - www.environment-agency.gov.uk/homeandleisure/37837.aspx (England and Wales).
 - **Design to reduce risk:** both new buildings and refurbishments will alter surface shape and permeability, affecting the dynamics of flood risk in terms of timing, volume and areas of accumulation. Designs should adhere to the principles of SUDS, in which the principal aim

is to mimic as closely as possible the natural drainage dynamics of an area in order to reduce the risk of flooding to buildings nearby. Approaches include improving drainage through semi-permeable surfaces in areas such as car parks and channelling flood paths away from high-risk areas into "sacrificial land", in which water is allowed to collect and drain away.

- **Direct flood defence:** bunding walls can be installed to redirect flood waters. This is a more traditional approach; however, efforts to reduce risk should be made before conventional flood defences are installed.

- 8.5 However, in mitigating flood risk to one site, it should not be passed on to create flood risk at another vulnerable site (see Health Technical Memorandum 07-07 – 'Sustainable health and social care buildings').

Responding to flooding

- 8.6 Contingency plans for flooding should be drawn up and should include the following:
 - options for securing alternative supplies for essential water uses;
 - screening back-up-generator power supplies for resilience to flooding;
 - a full citing of patients, equipment, power lines and communications cables that are at risk from flooding;
 - options for evacuation of patients and staff, including routes, assembly points and responsibilities;
 - accessibility for services to get to the site.

See also the Department of Health's "preparedness for floods" website.

9 Responsible bodies in water management

Consumer councils

Consumer Council for Water (CCWater)

The Consumer Council for Water (CCWater) is the industry watchdog, set up to represent customers of water and sewerage companies in England and Wales, and provides a national voice for consumers.

www.ccwater.org.uk/

Department for Environment, Food and Rural Affairs (Defra)

The Department for Environment, Food and Rural Affairs (Defra) is a governmental organisation responsible for water supply and resources, regulatory systems for the water industry and environmental protection.

www.defra.gov.uk/

Drinking water regulators

Drinking Water Inspectorate (DWI)

The Drinking Water Inspectorate (DWI) is responsible for ensuring that water companies and suppliers in England and Wales meet their statutory duties in relation to drinking water quality. The Inspectorate does this through a programme of technical audit to ensure that water companies are taking appropriate actions to safeguard drinking water quality. The Inspectorate can call on powers of enforcement and (where appropriate) prosecution to legally enforce the requirements of the legislation.

www.dwi.gov.uk/

Economic regulators

Water Services Regulation Authority (Ofwat)

The Water Services Regulation Authority (Ofwat) is the government-appointed economic regulator of the private water industry in England and Wales. Its remit is to protect the interests of water-company customers while ensuring water companies are able to properly finance and carry out their functions. It determines prices through periodic reviews of water-company expenditures and future plans.

www.ofwat.gov.uk/

UK environmental regulatory authorities

Environment Agency

The Environment Agency is responsible for the protection and preservation of the natural environment in England and Wales. Its role in the water industry is to ensure that water-company operations do not adversely affect the water environment and are sustainable in the long term. As well as reviewing water-company plans, it regulates abstraction licences and is responsible for flood risk management.

www.environment-agency.gov.uk/default.aspx

Water UK

Water UK represents the private water industry in the UK. It actively seeks to develop policy and improve understanding in areas that involve the industry, its customers and stakeholders.

www.water.org.uk/

10 How to find water-efficient products

Bathroom Manufacturers Association

The Bathroom Manufacturers Association (BMA) is the lead trade association for manufacturers of bathroom products in the UK and has launched a “water-efficient product” labelling scheme. The scheme acts as a guide to selecting products for use in bathrooms.

<http://water-efficiencylabel.org.uk/default.asp>

Enhanced Capital Allowances Scheme: the Water Technology List

The Enhanced Capital Allowance (ECA) Scheme enables businesses to claim 100% first-year capital allowances on investments in technologies and products that encourage sustainable water use. Businesses are now able to write off the whole cost of their investment against their taxable profits for the period during which they make the investment. As part of this scheme, a list of water-efficient technologies that qualify can be found on the ECA water technology list website.

www.eca-water.gov.uk/

Water Regulations Advisory Scheme (WRAS)

The Water Regulations Advisory Scheme (WRAS) is the UK water industries’ scheme to promote knowledge of

UK water regulations and byelaws and approve fittings and appliances that comply with these. It encourages consistent interpretation and enforcement for the prevention of waste, undue consumption, misuse, erroneous measurement or contamination of water.

All WRAS-approved products or materials (which will normally bear the “WRAS-Approved Product” or “WRAS-Approved Materials” logos) have been tested and have been found to comply with the Water Supply (Water Fittings) Regulations 1999 (as amended) and the Scottish Water Byelaws 2004.

WRAS approval should be sought on all procured fixtures and fittings.

www.wras.co.uk/

Waterwise

Waterwise is an independent, not-for-profit organisation that receives funding from the UK water industry and from sponsorship and consultancy work. In England, it sits on the Government’s Water Saving Group alongside the water industry and regulators. Waterwise’s website provides guidance on water-efficient appliances, including a database of water-efficient washing-machines and dishwashers. Waterwise also awards the Waterwise Marque to products which are deemed to save water.

www.waterwise.org.uk/



11 Available support for auditing

Advanced Demand Side Management (ADSM)

OGCbuying.solutions (an executive agency of the Office of Government Commerce (OGC) in the Treasury) has negotiated a framework contract with ADSM.

ADSM can assist with the following:

- Compare a facility's water usage with that of similar organisations.
- Obtain help and advice to reduce consumption.
- Implement water-saving measures.
- Have the facility's entire water system and bills monitored and managed.
- Fast-track savings and meet government environmental targets.

www.adsm.com/

Envirowise

Envirowise delivers a government-funded programme of free, confidential advice to UK businesses. This assistance enables companies to increase profitability and reduce environmental impact.

www.enviro-wise.co.uk/site/uk/content-folder/homepage

National Water Conservation Group

The mission of the NWCG is to stimulate and inform debate about how to achieve the efficient use of water in the UK.

www.waterwise.org.uk/pages/national-water-conservation-group.html

Water UK

Water UK is the representative body for the UK water industry. It can advise on which water and sewerage companies provide local services.

www.water.org.uk/

12 Audit structures

GPs' surgeries and health clinics

In almost all cases, water use in GPs' surgeries and health clinics will be domestic. Normally there will be WCs, basin taps, a kitchen tap and a dishwasher. In some cases, there may also be a shower, a urinal and fittings for outside use (for example, water for a garden).

The following steps should be considered in a water management plan:

Note

These are best practice guidelines only.

- **Choose a designated water champion.** This should be someone with an overview of the building's facilities, someone in charge of financial management or someone who is keen on the subject.
- **Communicate with all staff (including contract cleaners and washroom maintenance contractors).** Communication could be written or ideally face-to-face, and should explain that a water management plan is being established and that all staff will be kept informed and are also welcome to contribute.
- **Gather information.** This should include plans of the building showing plumbing and fixtures, water and sewerage bills, how water is used in the building (who waters the plants, how often is the dishwasher used, does anyone use the shower, where do the cleaners fill their buckets etc), and any alternative sources of water (bottled water for catering, a water cooler in the waiting room, rainwater butt for the garden).
- **Carry out a water audit.**
- **Assess other water issues** such as what the level of flood risk is, how to deal with flooding, and what to do if the water supply is interrupted.
- **Draw up a management plan.** This should include plans of where all water fittings, plumbing and drains are. It should list all appliances and fittings with a guide to their water consumption (WC flush volume, dishwasher usage per wash etc). It should then suggest actions such as fitting cistern displacement devices or sourcing flood-prevention measures, with an outline of potential costs and savings.
- **Discuss the management plan** with all staff and take action where appropriate.
- **Keep the plan up to date.**

Hospitals

- **Choose a designated water champion.** This should be someone with an overview of the building's facilities, someone in charge of financial management or someone who is keen on the subject. This person should have the support of the senior management.
- **Communicate with all staff (including clinicians, contract cleaners and washroom maintenance contractors).** Communication could be written or ideally face-to-face, and should explain that a water management plan is being established and that all staff will be kept informed and are also welcome to contribute.
- **Gather information.** This should include plans of the site showing water meters, plumbing and fixtures, water and sewerage bills, the main areas of water use and drainage. It should include any existing water reports, input from staff who use water, and copies of contracts that specify water use for landscape maintenance or cleaning.
- **Walk the site** to check information and plans against reality.
- **Carry out a water and wastewater audit.**
- **Assess other water issues** such as what the level of flood risk is, how to deal with flooding and what to do if water supply is interrupted.
- **Draw up a management plan.** This should include plans of where all water fittings, plumbing and drains are. It should provide a breakdown of water and wastewater issues for each part of the site, allocating a reference code to each piece of water-using equipment and providing details of its water use, its condition and information on what it does. The plan should

then suggest actions for each area of the site with an outline of potential costs and savings.

- **Keep the plan up to date.**
- **Discuss the management plan** with all staff and take action where appropriate.

13 Case Study 1: Gwent Healthcare NHS Trust: water-leakage detection initiative

The energy team at Gwent Healthcare NHS Trust, South Wales, manages over 70 properties including nine hospitals, among them being the Royal Gwent (600 beds) and Nevill Hall (400 beds). The Trust spends over £4 million per year on electricity, gas and water, which is billed from over 300 meter points.

Managers at County Hospital, Griffithstown, had long suspected there might have been a water leak on the site, as the water bills appeared excessive compared to hospitals of a similar size. As a result, they decided to install a water-leakage detection system. This involved the use of a meter logger and Internet-based water-meter monitoring and analysis, which helped to track water usage.

When the results were analysed using the water-meter-monitoring website, they discovered that there was a very high level of water consumption during the early hours of the morning – a period when water demand should have been low.

It soon became apparent there was a leak of 4 m³ per hour on the site. Trial holes were excavated at positions where the leak was thought to be. Because of the high number of unrecorded service tees off the site's water main, the leak initially proved difficult to locate. When it was eventually found and repaired, water demand on the site was reduced by a factor of 10.

This initiative has saved the Gwent Healthcare NHS Trust over £66,000 on its annual water bill. It will receive an additional £66,000 in sewerage rebates from its water supplier for the last two years. These savings will be used to invest in additional energy-saving technology.

Internet-based metering services can analyse and identify abnormal utility consumption, correct excessive usage or leakage and provide daily reporting to facilities management. In most cases, the payback period is less than two years. In the case of Griffithstown, payback was less than one month, with immediate positive cash-flow benefit from the second month onwards in reduced water charges.

14 Case study 2: St Thomas' Hospital water audit

Introduction

There are seven strategic health authorities within the Thames Water area and numerous hospitals of differing types and sizes. Thames Water carried out a thorough water review at each of the seven largest London hospitals to understand where water savings could be achieved, estimate how much water these actions could save, and identify the best location and type of water savings devices to be installed.

The following summarises the findings of Thames Water's water audit of St Thomas' Hospital.

St Thomas' Hospital

St Thomas' Hospital is part of the Guy's and St Thomas' NHS Trust. The individual buildings range considerably in age.

Trending

The hospital has put in place some good water management practices (for example the closed-loop cooling of MRI scanners), and St Thomas' water consumption appears to be better than average.

The hospital has lower than average consumption of around 342,500 m³/year when compared with its expected use of between 247,500 m³ and 517,500 m³ of water per annum (based on the benchmarking data given in [Tables 2–4](#) of Chapter 5, and assuming there will be 750,000 patient contacts per year).

Periodic checks of actual normalised consumption against benchmarking data and the previous year's performance are worthwhile completing. Without monitoring and comparing water consumption against historical levels and consumption patterns, it is impossible to know whether current consumption is typical or excessive, or whether the hospital is getting more or less efficient. Trending also allows the unusual to be rapidly identified – particularly leaks or losses.

Guidance on how to trend a site's water consumption is given in 'Steps to sustainable water use'.

Cost

St Thomas' is currently on the Thames Water major-user tariff and is charged with a separate volumetric rate for water supply and wastewater disposal.

Water use at the time of the audit cost the hospital approximately £206,860 and £116,826 for water and wastewater volumetric charges, respectively, and an additional £47,444 in standing charges – a total of £371,130 per annum.

Given the large losses of steam and water from evaporation in the cooling towers (estimated at 30,000 m³/year and 9000 m³/year, respectively), the 10% non-return-to-sewer allowance currently assumed appeared low. However, no accurate data existed on which to base any correction. Thames Water recommended that flowmeters be inserted at relevant points so that non-return-to-sewer could be more accurately evaluated.

Water distribution plan

It was recommended that the site's water distribution plan be maintained and developed to show meters, submeters and valve work in order to assist in water management and provide a process-mapping tool to understand water use on site.

Recommendations to reduce water use

Pressure

There is a variable pressure supply throughout one of the buildings – the lower the floor, the greater the water pressure. With an estimated 4 m between floors, the static head from the 13 floors to the ground floor is some 50 m or 5 bar. Several taps were tested (mixer tap, full-bore cold supply) in the building as follows:

- upper floor – 15 L/min;
- lower floor – 40 L/min;
- basement – 60 L/min.

Apart from the flow on the top floor, the flows through other taps are excessive.

Even though taps are not often used fully open, any overpressure results in unnecessary water consumption by taps (and showers).

It was recommended that pressure-reducing valves be fitted to reduce pressure to points of use to the more usual 1.5–2.5 bar. However, because of the pipework configuration, it was acknowledged that this could prove to be difficult. An alternative could be to restrict the maximum flow by adjusting the isolation ball-valves to taps, where they are fitted.

Leakage

As the site is fed by multiple water mains and has a large network of internal and underground pipes, a leakage survey was undertaken. The only significant water leak identified during the water review was estimated at around 120 L per hour (over 1000 m³/year).

Steam loss

Several significant steam releases were occurring across the site. It was thought that traps or steam-release valves were not seating correctly. Apart from the obvious water loss, the value of this loss is really in the treatment of, and energy in, the steam.

An approximate assessment of its value can be made at £1 per cubic metre for the raw water (including softening and boiler water treatment costs) and approximately £11 in energy costs (assuming 732 kWh to raise 1 m³ water from 15°C to 100°C, and converting it to steam with useful energy at 1.5p per kWh). This gives a value of approximately £12 per cubic metre of water used for steam generation – the cost of a steam loss is therefore reasonably high.

Evaporation from the hydrotherapy pool

The hydrotherapy pool is approximately 18 m³. The water temperature is held at 35°C and has a pH value of 7.28 during sessions. It is not equipped with a cover.

Evaporation losses from this pool are typically around 5–10 mm per day – hence, annual evaporation loss may be 22–44 m³/year. While this may not appear much water, its value is high because of the energy loss. Each litre of water that evaporates wastes 1.3 kWh of energy; assuming useful energy costs at 1.5p per kWh, this represents a loss of £21 per cubic metre.

Fitting a pool cover will virtually eliminate evaporation when the pool is unoccupied, saving water and energy. Assuming this is 16 hours per day, savings will be around £300–£600 per annum.

Baths/showers

It was recommended that, when showers are provided, high-performance low-flow types are used and that, to avoid water running to waste while the correct temperature is obtained (and for safety), thermostatic controls are used. Apart from the savings in water, there are also significant energy savings, as most of the water saved will be hot or warm.

WCs

The volume of water used for flushing can be minimised by adjusting the internal ball-cock to reduce filling volume to a minimum, fitment of a cistern volume adjuster (cistern devices) or replacement of the toilet (new units have a maximum flush of 6 L).

Urinals

It was recommended that the urinals be fitted with a passive infrared (PIR) automatic sensor flush control of the “cumulative” type – that is, it counts the number of people using the facility and flushes after, for example, 25 users. Such a device would eliminate flushing during low use, weekends and at night (except a hygiene flush) such that the amount of water saved will be approximately 1051 m³ per annum.

Savings can be notable, with payback for each unit generally obtained within 9–12 months.

It was also recommended that all urinals fitted during refurbishment be specified with PIR-type flush controls.

Taps

By far the greatest problem was the excessive flow due to high pressure on lower floors (see above). Tap regulators can be fitted to reduce the flow of water. In the case of hot water taps, energy savings will also result. Regulators can reduce the flow of water by up to 50%.

Break tanks and overflows

Overflows from break tanks and toilet cisterns should be visible so that if an overflow occurs it is easy to detect – a hidden overflow could be running for years without detection. A minor overflow (estimated as a 3 mm stream) will lose approximately 350 m³ water per year.

Potential savings

There are still several opportunities to reduce water consumption, some of which will also reduce energy consumption, allowing significant financial savings to be made.

Practical actions to achieve water savings have been identified in Table A1.

Table A1 Potential savings

Opportunity		Action	Potential saving (m ³ /annum)	Cost saving ^a (£/annum)	Estimated payback
Immediate low-cost actions	Hydrotherapy pool	Minimise evaporation by fitting simple cover when not in use	33	450	Moderate
	Urinal flush control	Fit sensor-type flush control to existing urinals	2,180	2,137	9–12 months
	Toilet cistern flush	Adjust ball-cock to reduce flush by 250 ml (or more)	500	489	Immediate
	Leaking taps	Repair leaking tap in the sterile services department	1,000	980	Immediate
	Steam losses	Maintain/repair release valves, traps etc	2,242	26,846	Rapid
	Endoscopy RO overflow	Replace two small ball-cock units with one larger one to avoid jamming of floats	1,576	1,544	Immediate
	Condensate losses	Fix leaks (appeared to require simple gland tightening)	30	75	Immediate
	Leaking pipes	Investigate and repair leak	1,000	980	Immediate
	Reduce distribution pressure	Install pressure-reducing valves (PRVs) as appropriate (or adjust isolation/flow regulation valves to taps)	8,076 ^b	7,915	Not calculated
Medium-term actions	Still cooling water	Replace once-through softened water with recirculating chiller or cooling-tower feed water. Alternatively, buy in distilled water	585	570	Moderate or intermediate
	Condensate return	Investigate current efficiency and improve collection and return	5,800	14,500	High
	Blowdown cooling	Cool blowdown via a heat exchanger – not simple dilution cooling with fresh water	182	450	Immediate
	Reuse reverse osmosis reject	Investigate scope for collecting reject water from boiler water RO unit (and others), storing it and using for a low-grade use	700	15,386	High but long-term
Total			15,828	72,322	

Notes:

Savings are combined estimations from separate building audits, summarised as net potential savings for the entire hospital.

a. Annualised cost estimated based on current tariffs. Note these are also year-on-year savings.

b. This figure could well be much higher than this

15 References

Acts and regulations

Pollution Prevention and Control Act 1999. HMSO, 1999.

Pollution Prevention and Control (England and Wales) Regulations 2000. SI 2000 No 1973.

Private Water Supplies Regulations 1991. SI 1991 No 2790. HMSO, 1991.

Water Act 2003. HMSO, 2003.

Water Industry Act 1999. HMSO, 1991.

Water Supply (Water Fittings) Regulations 1999. SI 1999 No 1148. HMSO, 1999.

Water Supply (Water Quality) Regulations 2000. SI 2000 No 3184. HMSO, 2000.

European legislation

Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy. Official Journal of the European Communities. No L372, 22.12.2000, p. 01.

Department of Health publications

Health Building Note 00-02 – Sanitary spaces. The Stationery Office, 2008.

Health Building Note 00-07 – Resilience planning for the healthcare estate. The Stationery Office, 2007.

Health Technical Memorandum 00 – Policies and principles of healthcare engineering. DH, 2013.

Health Technical Memorandum 04-01 – The control of *Legionella*, hygiene, “safe” hot water, cold water and drinking water systems. The Stationery Office, 2006.

Health Technical Memorandum 01-06 – Decontamination of flexible endoscopes. The Stationery Office (forthcoming).

Health Technical Memorandum 2005 – Building management systems. The Stationery Office, 1996.

Health Technical Memorandum 07-07 – Sustainable health and social care buildings. The Stationery Office, 2009.

Health Facilities Note 30 – Infection control in the built environment. The Stationery Office, 2002.

The NHS Healthcare Cleaning Manual. 2004.

The Health Act 2006: Code of practice for the prevention and control of healthcare associated infections. DH, 2008.

Department for communities and local government (CLG) publications

Planning Policy Statement 25 – Development and flood risk. 2006.

Defra publications

Conserving water – advice for government departments. 1999.

Future water: the Government’s water strategy for England. 2008.

Government response to consultation on water metering in areas of serious water stress between 31 January and April 2007. 2007.

Other publications

Audit Commission. **Untapped savings: water charges in the NHS (NHS Occasional Papers).** Audit Commission, London (ISBN 978-0118860789), 1993.

Building Research Energy Conservation Support Unit. **General Information Note 85: New ways of cooling – information for building designers.** BRESCU, London, 2001.

Carbon Trust. **New practice case study 120 (NPCS120) – Energy and cost savings through the installation of low maintenance steam traps.** Carbon Trust, London, 2000.

Construction Industry Research and Information Association (CIRIA). **Water – key performance indicators**

and benchmarks for offices and hotels (C657). CIRIA, 2006.

Environment Agency (2005). *Creating a better place: the Environment Agency water efficiency awards 2005*. Environment Agency, Bristol, 2005.

European Renal Association-European Dialysis and Transplant Association (ERA-EDTA). *European best practice guidelines for haemodialysis – Part 1. Nephrology Dialysis Transplant*. Vol 17 Supplement 7, 2002, pp 45–62.

Health & Safety Commission. **Approved Code of Practice, Legionnaires' disease: the control of legionella bacteria in water systems (L8)**. HSE Books, 2000.

Health & Safety Executive (HSE). **Guidance Note PM5 – Automatically controlled steam and hot water boilers**. HSE Books, 1989.

Health Protection Agency (HPA). **Hygiene for hydrotherapy pools**. HPA, London, 1999.

Thames Water. *Using water wisely*.

Water UK. *Sustainability indicators 2006/07*. Water UK, London, 2007.

Water UK. *Water efficient hospitals: efficient use of water could save your hospital money*. Water UK, London, 2003.

Water hardness in the British Isles. Waterwise.

Websites

BREEAM Healthcare.

Code for Sustainable Homes.

Estates Return Information Collection (ERIC).

Good Corporate Citizenship.

Scottish Building Standards Agency.

OFWAT.

Water for Health.

Waterwise.

UK Rainwater Harvesting Association.

Department of Health's "preparedness for floods" website.



Water Systems Safety Policy

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Approved By	NHSGGC Corporate Management Team
Responsible Director	Director of Estates & Facilities
Lead Manager	Assistant Director of Estates & Facilities
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Appendix 1 - Roles and Responsibilities

Appendix 2 - Statutes and Guidance

Appendix 3 - Definitions and Acronyms

Appendix 4 – Governance Structure

1.0 Application of the Policy

1.1 Application

The Water Systems Safety Policy shall apply to all Domestic Hot Water, (DHW) and Domestic Cold Water, (DCW) systems, Water-Dispensing Equipment as well as defined, 'At Risk Water-carrying Systems' across all NHSGGC Premises, (hereafter referred to as 'Water Systems' in this Policy).

1.2 Objective

The objective of this policy is to ensure safe and effective control of Water Systems throughout NHSGGC Premises in order to minimise the risk from water borne Pathogens and maintain water quality in all NHSGGC Premises.

2.0 Introduction

2.1 Pathogens

Most microorganisms are harmless to healthy individuals and are commonly found on people, in the environment and in water supplies or on birds and other animals in the vicinity of NHSGGC Premises. As these microorganisms are 'naturally occurring'; they can readily find their way into Water Systems. Some of these microorganisms however, if given the appropriate conditions, can cause, or lead to, infections that may put some people at risk of serious harm.

2.2 Statutory Instruments and Mandatory Guidance

The variety and extent of water-related Statutory Instruments, mandatory and other approved Guidance, Policies, Operational Procedures/Protocols and good industry practice (Hereafter referred to as 'Statutory Instruments & Mandatory Guidance' in this Policy), emphasises the essential nature of safely managing Water Systems. The applicable Statutes and Guidance are referenced in Appendix 2.

2.3 Statutory Responsibilities

NHSGGC has a statutory obligation to identify and effectively control risks to protect patients, Staff and members of the public arising from Water Systems within NHSGGC Premises.

2.4 Competence

NHSGGC will maintain a formal training programme for nominated key staff to ensure those appointed to devise strategies and carry out control measures are appropriately informed, instructed, trained and assessed to competently undertake their Roles & Responsibilities (See Appendix 1).

2.5 Penalties for Compliance Failures

Failures in compliance with 'Statutory Instruments & Mandatory Guidance' responsibilities may attract prosecution by Enforcing Authorities, (e.g. The Health & Safety Executive). Prosecutions may be 'Corporate', against the organisation, but

could also be 'Personal', brought against individual members of Staff. Penalties for prosecution may take the form of fines and/or imprisonment.

NHSGGC take their Statutory and Mandatory responsibilities and over-arching duty of care to its patients, staff and others seriously and will employ appropriate measures and sanctions where required to address failures to meet these duties in line with existing policy arrangements.

3.0 Duty of Care

3.1 Awareness of Responsibilities

NHSGGC recognises that it has a moral and ethical duty of care for the safety of patients and others, particularly those whom may have an elevated susceptibility to infection because of their increased vulnerability caused by underlying health factors and/or the suppression of their personal immune defences caused by their illness.

3.2 Discharging NHSGGC's Duty of Care

NHSGGC will discharge its Duty of Care through rigorous compliance with all relative 'Statutory Instruments & Mandatory Guidance'.

3.3 Essential Participation in Water Safety

Water safety within NHSGGC can only be achieved by every member of Staff actively contributing to a concerted 'team effort' and the risk to patients' safety will be compromised by people failing in their statutory responsibilities, by not following, or incorrectly applying the 'Statutory Instruments & Mandatory Guidance'.

It is essential therefore, that each Staff group and every individual in NHSGGC actively participates and applies procedures designed to reduce risks arising from Pathogens in Water Systems in NHSGGC.

4.0 Roles and Responsibilities

4.1 General Responsibilities

The active participation of all NHSGGC Staff members is essential to protect patients, Staff and members of the public from risks arising from Water Systems.

4.2 Key Personal Responsibilities

The 'Statutory Instruments & Mandatory Guidance' relating to water safety, identifies key roles with specific responsibilities to ensure the effective application of recommended and mandatory procedures.

Specific individual and group responsibilities of each of these key roles, along with nominated posts for each of these key roles, are provided in Appendix 1 of this Policy. Named individuals appointed to these roles are detailed in the respective site procedures and Written Scheme(s). Each named individual or group must familiarise

themselves with the dimensions of their specific and corporate responsibilities relating to water safety in NHSGGC.

It should be noted that the responsibilities noted in this policy may not be exhaustive and it is recommended that individuals refer to the 'Statutory Instruments & Mandatory Guidance' at Appendix 2 for a deeper understanding of their responsibilities.

5.0 Reporting

5.1 Monitoring & Review

Control Measures relating to water safety in NHSGGC shall be systematically examined, monitored and reviewed by designated teams and individuals carrying specific or delegated managerial responsibilities.

5.2 Formal Periodic Reports

Formal periodic reports on Water Systems will be presented by:

- I. Various Sector-located Groups and appointed key individuals, (e.g. RPs(W)) to their respective Sector Water Systems Safety Groups (SWSSG);
- II. Groups and appointed key individuals within the Sector management structure of The Health and Safety Department, the E&F and Infection Prevention & Control Service via the SWSSG to the NHSGGC Board Water Systems Safety Group (BWSSG);
- III. Either or both co-Chairs of the BWSSG, on behalf of the Group, to the Board Infection Control Committee (BICC) and the Health & Safety Forum;
- IV. The Chair of the BICC on behalf of the BICC to the Corporate Management Team (CMT) (including the Chief Executive, (CE)).

5.3 Governance Structure

The Governance Structure is shown in Appendix 4 of this policy.

6.0 Risk Reduction

6.1 Assessment

Following any assessment of the risks arising from Water Systems, Control Measures will be implemented, when appropriate and reasonably practicable.

6.2 Risk Reduction

Control Measures may include Risk Reduction Strategies to reduce the likelihood and/or severity of patient infections.

SWSSGs are responsible for ensuring that a multi disciplinary approach is taken to risk reduction within the Board at local level.

7.0 Operational Arrangements

7.1 Written Scheme & Operational Procedures

Control measures are set out in NHSGGC's Water Safety Written Scheme and Operational Procedures, designed to establish a system of control which shall be rigorously applied by specifically trained staff within a recommended, formally appointed structure for the safe management and governance oversight of Water Systems. The Written Scheme and operational procedure records are held in the Board's smart sheet document management service and are available for review on request.

7.2 Planned Maintenance

Water Systems throughout NHSGGC are subject to a routine planned maintenance system, managed and controlled via NHSGGC's proprietary Computer Aided Facilities Management (CAFM) System, FMfirst ®, by designated Maintenance Supervisors.

8.0 Testing

In keeping with the current HSE guidance, testing for Legionella will be carried out within NHSGGC as follows:-

8.1 High Risk Clinical Areas

A list of High Risk Clinical Areas, where immuno-compromised patients may be cared for, has been determined by the NHSGGC Lead Infection Control Doctor, (ICD), and these are designated as 'high-risk clinical areas'. This list can be found at Appendix 3, clause A.3.8.

Clinical High Risk Areas will be specifically identified within the various site-specific Written Schemes.

8.2 Engineering Risk Areas

Due to the 'age' of some of NHSGGC's current property portfolio, it is recognised that there are some installations that may present a high risk of contamination by Pathogens due to the Water System's distribution configuration. Where this is the case, the system will be defined as an Engineering High Risk and a testing programme will be implemented and rigorously maintained.

The Engineering High Risk areas and Other High Risk Areas can be found at Appendix 3 – clauses A3.1.5 & A.3.11 and will be specifically identified within the various site-specific 'Written Schemes'.

9.0 Pseudomonas

9.1 Pseudomonas Guidance

NHSGGC will seek to reduce the risk from Pseudomonas in its Water Systems by complying with the Water (Scotland) Group's guidance document titled, 'Guidance for Neonatal Units, (NNUs) (levels 1, 2 & 3), adult and paediatric Intensive Care Units, (ICUs), in Scotland to minimise the risk of Pseudomonas Aeruginosa infection from water', (version 2.3 dated May 2018), produced by Health Facilities Scotland, Health Protection Scotland.

10.0 Action on Identification or Incident

10.1 Action if an environmental organism is identified as a source of an infection incident (not Legionella);

Guidance as per the NHS GGC IPC Environmental Organisms Standard Operating Procedure (SOP) (<https://www.nhsggc.org.uk/media/253288/environmental-organisms-in-high-risk-areas-sop-final-v1-november-2018.pdf>) and the Pseudomonas SOP (<https://www.nhsggc.org.uk/media/255146/sop-pseudomonas-aeruginosa-v3-amended-july-2019.pdf>) will be followed to assess and action incidents involving these water related organisms.

Where an incident team is set up to investigate a trigger, the Outbreak SOP (https://www.nhsggc.org.uk/media/245201/outbreak-sop-final-version-oct-2017-_2_.pdf) will be followed.

10.2 Action if Legionella Bacteria is Identified in Water Systems;

If a water sample, a reading of Legionella bacteria is shown to be present routine precautions and control measures designed to eliminate the Legionella bacteria will be applied. If there is still Legionella bacteria detected in a follow-up sample still, then a record of this incident will be made on NHSGGC's Datix reporting and recording system in line with the NHSGGC's Incident Management Policy and Procedure.

The RP(W) and AP(W) in the Directorate of E&F must be copied into all Datix reported incidents.

10.3 Action if Legionella Bacteria is the Source of an Infection Incident

When it can be demonstrated that an infection incident has originated in a Water System, the AP(W) must ensure that a review and investigation is carried out and formally recorded and reported to the RP(W) and ICD.

These incidents should be reviewed as a 'significant adverse event' as per the Incident Management Policy and Procedure.

10.4 Review of Infection Incident Reports

In order to ensure the implementation and effectiveness of this policy all incident reports relating to water management should be reviewed regularly by the Sector Estates Manager, RP(W), and the site ICD and periodically reported to, and reviewed by, the SWSSG.

10.5 Clinical Incident

In the event that two or more clinical cases are potentially linked to water quality, a problem assessment group or IMT will be initiated by the nominated ICD. In certain circumstances, e.g. Legionella serogroup 1, a single hospital acquired case would warrant an IMT.

10.6 Outbreak

Where water quality is confirmed as the source of clinical cases and the IMT assess the incident using the Hospital Infection Incident Assessment Tool (HIIAT) as HIIAT red or amber, this will be reported to HPS using the Hospital Infection Incident Reporting Template, (HIIORT) and recorded on the service risk register by the nominated ICD.

11.0 Audit

11.1 Monitoring of Policy Effectiveness

The application and effectiveness of this policy throughout the organisation shall be monitored by the Health and Safety Department reporting via the BWSSG and the Estates & Facilities Senior Management Team (SMT).

11.2 Policy Review

This Policy will normally be reviewed annually, but certainly within every 3 year period. The Policy will be revised at the time of review or as a result of any changes in or to the 'Statutory Instruments & Mandatory Guidance'.

Appendix 1A1 Roles and ResponsibilitiesA1.1 Chief Executive – Duty Holder (Water) (DH(W)).

The Chief Executive has overall executive responsibility with accountability to NHSGGC's Board for all safety, health and risk matters in NHSGGC. The Chief Executive, (CE), is the designated Duty Holder (Water) (DH(W)), for NHSGGC.

The responsibilities of the DH(W) include:

- Assuring NHSGGC's Board, via the Board's Corporate Management Team (CMT), that the Board's statutory responsibilities relating to Water Systems are being safely and appropriately discharged;
- Participate in a recommended training programme to maintain personal knowledge and a level of expertise allowing the efficient discharge of the DH(W) responsibilities;
- Ensuring the provision of adequate resources to safely maintain and to effectively manage and control identified risks arising from the Water Systems in the NHSGGC estate to an appropriate level;
- Ensuring the implementation of and adherence to the NHSGGC Water Systems Safety Policy at all levels within the organisation;
- Formally appointing the Designated Person (Pseudomonas) and Designated Person (Water) (and their deputies) to assist in the execution of these responsibilities, who for NHSGGC are respectively, the Infection Control Manager and the Director of Estates & Facilities.

A1.2 Board Corporate Management Team (CMT).

The CMT will have managerial oversight of water-related issues and responsibility for communication in sufficient detail to NHSGGC Health Board, giving assurance that Water Systems are being safely and effectively managed and that the Board's related Statutory obligations are being appropriately discharged.

The CMT membership is:

CEO (CHAIR);
 Medical Director (BICC Chair);
 COO – Acute;
 Corporate Communications;
 Chief Officer– HSCP;
 Director of Public Health;
 Director of eHealth;
 Directors of HSCPs;
 Director of HR;
 Co – Partnerships;
 Employee Director;
 Director of Nursing;
 Co HSCP;
 Director of Estates & Facilities;
 Head of Corporate Governance;
 Director of Finance;

Executive Director HSCP Glasgow.

The water-related responsibilities of the CMT include:

- Having managerial oversight of, and assuring NHSGG&C Health Board that the Board's statutory responsibilities relating to Water Systems are being safely and appropriately discharged;
- Individually participate in appropriate periodic training to establish and maintain personal knowledge and a level of expertise allowing the efficient discharge responsibilities related to this Policy;
- Ensuring, through the Board's management structure, the implementation of all 'Statutory Instruments & Mandatory Guidance' related to Water Systems examples 'Guidance' at 3 and adherence to the NHSGGC Water Systems Safety Policy at all levels within NHSGGC;
- Liaising with the DP(P) and the DP(W) to ensure the Boards Water Systems Policy is understood and applied across all areas of the Board;
- With support from the DP(P) and the DP(W), formulate a Water Systems Safety Compliance Programme, (for both passive and active measures) in existing properties and for new capital projects;
- Performing governance oversight on behalf of the Board by reviewing the effectiveness of operational arrangements. The CMT will be advised on this by the BICC with contributions from the DP(P) and the DP(W) via the BWSSG.

A1.3 Director of Estates & Facilities, (DE&F) – Designated Person (Water) (DP(W)).

The DE&F has delegated executive responsibility with accountability to DH(W) for all safety, health and risk matters relating to Water Systems in NHSGGC, with the exception of the responsibilities delegated to the Designated Person (Pseudomonas), at clause A1.4 . The DE&F is the DP(W) for NHSGGC.

The Responsibilities of the DP(W) include:

- Identify and ensure the efficient formal record of Water System risks and raising those considered appropriate from the BWSSG to the CMT via the BICC;
- Provide formal reports from the BWSSG to assure the Health Board via the CMT that the Board's statutory responsibilities relating to Water Systems are being safely and appropriately discharged;
- Participate in a recommended training programme to maintain personal knowledge and a level of expertise allowing the efficient discharge of the DP(W) responsibilities;
- Identify to the CMT a risk-based prioritisation of necessary resources required to effectively manage and control water system risks arising from the Water Systems in the NHSGGC estate, to an acceptable level;
- Effectively manage the resources provided to safely maintain and to manage and control identified risks, to an acceptable level, as far as reasonably practicable;
- Ensuring the implementation of all 'Statutory Instruments & Mandatory Guidance' related to Water Systems, (see examples in section, 'Guidance', in this Policy), and adherence to the NHSGGC Water Systems Safety Policy at all levels within the Directorate of E&F;
- Ensuring that E&F Staff, through the Directorate management structure, are fully aware and appropriately trained in the Statutory and Mandatory

requirements and standards for the provision and maintenance of Safe Water Systems;

- Ensuring, with the RP(P), that the Water System Safety Policy is regularly reviewed and updated;
- Co-Chair the NHSGGC BWSSG;
- Formally appoint a 'Deputy Designated Person (Water)', (DDP(W)), who will deputise for the DP(W) as required, undertaking delegated responsibilities;
- Formally appoint (or delegate the responsibility) the Responsible Person (Water) at sector level (Sector Estates Manager), Deputy Responsible Person(s) (Water) at site level (Site Maintenance/Estates Manager) and the Authorised Person (Water), (AP(W)), at site level within the E&F Directorate management structure.

A1.4 Infection Control Manager – Designated Person (Pseudomonas) (DP(P)).

The ICM has delegated executive responsibility with accountability to DH(W) for all Pseudomonas related safety, health and risk matters in Water Systems within NHSGGC premises. The ICM is the Designated Person (Pseudomonas), (DP(P)), and will be supported by the Board's designated ICD.

The DP(P) shall be responsible for:

- Identifying and ensuring the efficient, formal record of Water System risks related to Pseudomonas and raising those considered appropriate from the BWSSG to the CMT via the BICC;
- Provide formal reports to assure the CMT that the Board's statutory responsibilities relating to the control of Pseudomonas, (and other Pathogens), in Water Systems are being safely and appropriately discharged;
- Participate in a training programme to maintain personal knowledge and a level of expertise allowing the efficient discharge of the DP(P) responsibilities;
- Identify to the CMT a risk-based prioritisation of necessary resources required to effectively manage and control water system risks arising from the Water Systems in the NHSGGC Premises to an acceptable level;
- Effectively use the resources provided to manage and control identified risks arising from the control of Pseudomonas, (and related pathogenic bacteria), in Water Systems in the NHSGGC Premises, to an acceptable level, as far as reasonably practicable;
- Ensuring the implementation of all 'Statutory Instruments & Mandatory Guidance' related to the control of Pseudomonas, (and related pathogenic bacteria), in Water Systems, examples of, 'Guidance' in Appendix 3, in particular, the 'Guidance for Neonatal Units (NNU's) (levels 1, 2 & 3) adult and paediatric Intensive Care Units ICU's in Scotland', and adherence to the NHSGGC Water Systems Safety Policy at all levels in Infection Control Teams in all NHSGGC Premises;
- Ensuring that Infection Control Teams, (ICTs), are fully aware of, and are appropriately trained in statutes and appropriate guidance on Legionella control matters and the minimisation of the risk of Pseudomonas Aeruginosa, (and other Pathogens), infection arising from Water Systems in NHSGGC Premises;
- Ensuring, with the DP(W) that the Water System Safety Policy is regularly reviewed and updated;
- Co-Chair the BWSSG;

- Formally appoint a 'Deputy Designated Person (Pseudomonas)', who will deputise for the DP(P) as required, undertaking delegated responsibilities;
- Appointing in writing the Responsible Person(s) (Pseudomonas) at sector level. These shall be the relevant ICDs.

A1.5 Assistant Director of Estates & Capital Planning, (ADE&CP) – Deputy Designated Person (Water) (DDP(W)).

The ADE&CP will be appointed by the DE&F and in his absence has delegated executive responsibility with accountability to DH(W) for all safety, health and risk matters relating to Water Systems in NHSGGC, with the exception of the responsibilities delegated to the Designated Person (Pseudomonas), at clause A1.4 .

He will carry out all the duties and responsibilities of the DP(W) as stated in clause A1.3 above.

A1.6 Head of Corporate Estates (HCE) – Senior Corporate Responsible Person (Water) (SCR(P(W))).

The Head of Corporate Estates (HCE) has responsibilities delegated by the DP(W) with accountability to the DDP(W) and the DP(W) for all safety, health and risk matters relating to Water Systems across NHSGGC Premises involved in minor works. The HCE is also the lead in ensuring SCART compliance, audits and training is in place with respect to Water Safety.

The SCR(P(W)) is responsible for:

- Identifying and ensuring the efficient formal record of Sector related Water System risks and raising those considered appropriate to the DDP(W) & DP(W) and the BWSSG;
- Provide formal compliance reports to the BWSSG assuring the DDP(W) & DP(W) that the Board's statutory responsibilities relating to Water Systems, in respective Sectors, are being safely and appropriately discharged;
- Supporting the HOE in the production of policies & procedures to ensure the quality of water in NHSGGC Premises is safely maintained;
- Appoint a Water Safety Authorising Engineer (AE) to support NHSGG&C on all issues relating to Water;
- Working with the AE(W) and SORP appoint Responsible Persons Water (RP(W)) across all sectors;
- Appoint Authorised Persons Water (AP(W)) across NHSGG&C on the recommendation of the Authorising Engineer Water (AE(W));
- Participate in a recommended training programme to maintain personal knowledge and a level of expertise allowing the efficient discharge of the RP(W) responsibilities;
- Ensuring the implementation of all 'Statutory Instruments & Mandatory Guidance' related to Water Systems and adherence to the NHSGGC Water Systems Safety Policy at all levels within the Sector of the Directorate of E&F;
- Ensuring that Corporate estates staff are fully aware and appropriately trained in the 'Statutory Instruments & Mandatory Guidance' and standards for the provision and maintenance of safe Water Systems;
- Ensure that adaption's and modifications to installations in NHSGGC Premises are not implemented without prior review and formal, prior approval by the

RP(W), AP(W) and/or AE(W) as required relating to the scale, complexity and/or associated risk;

- Liaise closely with other professionals to ensure consistency in application of Control Measures and other procedures designed to allow legislative and statutory compliance, comprehensively in all NHSGGC Premises.
- Compliance Audit Duties;
 - Ensuring a robust annual water audit regime is in place;
 - Ensuring that Written Schemes and Risk Assessments are in place and reviewed regularly;
 - Ensure the e-SCART tool is populated and updated regularly with action plans in place, where required;
 - Ensuring operational procedures are carried out and appropriately recorded;
 - Ensuring formal records are kept of all Water Systems and their purpose;
 - Ensure an Annual report on Water Compliance across NHSGG&C is delivered to the DP(W).

A1.7 Head of Operational Estates (HOE) – Senior Operational Responsible Person (Water) (SORP(W)).

The Head of Operational Estates (HOE) has responsibilities delegated by the DP(W) with accountability to the SORP(W) & DP(W) for all safety, health and risk matters relating to Water Systems across NHSGGC Premises.

The SORP(W) is responsible for:

- Identifying and ensuring the efficient formal record of Sector related Water System risks and raising those considered appropriate to the DDP(W) DP(W) and the BWSSG;
- Provide formal reports to the BWSSG assuring the DDP(W) & DP(W) that the Board's statutory responsibilities relating to Water Systems, in respective Sectors, are being safely and appropriately discharged
- Participate in a recommended training programme to maintain personal knowledge and a level of expertise allowing the efficient discharge of the RP(W) responsibilities;
- Identify to the BWSSG a risk-based prioritisation of necessary resources required to effectively manage and control water system risks arising from the Water Systems to an acceptable level;
- Effectively manage and control the resources provided to safely maintain and to effectively manage and control identified risks arising from the Water Systems in the Sector of the NHSGGC Premises, to an acceptable level, as far as reasonably practicable;
- Ensuring the implementation of all 'Statutory Instruments & Mandatory Guidance' related to Water Systems and adherence to the NHSGGC Water Systems Safety Policy at all levels within the Sector of the Directorate of E&F;
- Ensuring that Sector estates staff, through the Directorate management structure, are fully aware and appropriately trained in the 'Statutory Instruments & Mandatory Guidance' and standards for the provision and maintenance of safe Water Systems;
- Ensuring the effective maintenance of engineering controls installed for the purposes of controlling water systems;

- Ensuring that Written Schemes and risk assessments are in place and reviewed regularly;
- Devising and maintaining procedures to ensure the quality of water in NHSGGC Premises is safely maintained;
- Ensuring operational procedures are carried out and appropriately recorded;
- Ensuring formal records are kept of all Water Systems and their purpose, giving locations recording and maintaining within the Board's CAFM System;
- Ensure that adaption's and modifications to installations in NHSGGC Premises are not implemented without prior review and formal, prior approval by the RP(W), AP(W) and/or AE(W) as required relating to the scale, complexity and/or associated risk;
- Liaise closely with other professionals to ensure consistency in application of Control Measures and other procedures designed to allow legislative and statutory compliance, comprehensively in all NHSGGC Premises.

A1.8 Assistant Head of Operational Estates – Responsible Person (Water) (RP(W)).

The Assistant Head of Operational Estates (AHOE) has responsibilities delegated by the DP(W) with accountability to the SORP(W) & DP(W) for all safety, health and risk matters relating to Water Systems in their respective Sectors of NHSGGC Premises.

The RP(W) is responsible for:

- Identifying and ensuring the efficient formal record of Sector related Water System risks and raising those considered appropriate to the SORP(W) & DP(W) and the BWSSG;
- Provide formal reports to the BWSSG assuring the SORP, DDP(W) & DP(W) that the Board's statutory responsibilities relating to Water Systems, in respective Sectors, are being safely and appropriately discharged
- Participate in a recommended training programme to maintain personal knowledge and a level of expertise allowing the efficient discharge of the RP(W) responsibilities;
- Identify to the BWSSG a risk-based prioritisation of necessary resources required to effectively manage and control water system risks arising from the Water Systems to an acceptable level;
- Effectively manage and control the resources provided to safely maintain and to effectively manage and control identified risks arising from the Water Systems in the Sector of the NHSGGC Premises, to an acceptable level, as far as reasonably practicable;
- Ensuring the implementation of all 'Statutory Instruments & Mandatory Guidance' related to Water Systems and adherence to the NHSGGC Water Systems Safety Policy at all levels within the Sector of the Directorate of E&F;
- Ensuring that Sector estates staff, through the Directorate management structure, are fully aware and appropriately trained in the 'Statutory Instruments & Mandatory Guidance' and standards for the provision and maintenance of safe Water Systems;
- Ensuring the effective maintenance of engineering controls installed for the purposes of controlling water systems;
- Ensuring that Written Schemes and risk assessments are in place and reviewed regularly;
- Devising and maintaining procedures to ensure the quality of water in NHSGGC Premises is safely maintained;

- Ensuring operational procedures are carried out and appropriately recorded;
- Ensuring formal records are kept of all Water Systems and their purpose, giving locations recording and maintaining within the Board's CAFM System;
- Ensure that adaptations a modifications to installations in NHSGGC Premises are not implemented without prior review and formal, prior approval by the RP(W), AP(W) and\or AE(W) as required relating to the scale, complexity and\or associated risk;
- Liaise closely with other professionals to ensure consistency in application of Control Measures and other procedures designed to allow legislative and statutory compliance, comprehensively in all NHSGGC Premises.

A1.9 Authorising Engineer (Water), (AE(W)).

The AE(W), is appointed in writing by the SCRP and is employed independently of NHS Boards. The AE(W) acts as an independent professional advisor to NHSGGC with a brief to provide services in compliance with relative 'Statutory Instruments & Mandatory Guidance', and particularly with Scottish Health Technical Memoranda (SHTM) 04-01, mandatory guidance for the NHS in Scotland.

The AE(W) will have specialist knowledge of large scale domestic and commercial hot and cold water services installations including incoming supplies and Other Risk Systems as detailed in Appendix 3 and in particular, those installations for which an Authorised Person (Water) will assume responsibility for.

The AE(W) is free to comment on the organisational risk base and give guidance on the numbers of AP(W) required across all NHSGGC properties.

The AE(W)'s main duties will include:

- To be a formal Assessor, making recommendations to the SCRP(W) for the appointment of AP(W) in terms of skills, training and site familiarity;
- Formally monitoring the performance of NHSGGC against 'Statutory Instruments & Mandatory Guidance', particularly, ACoP L8, HSG274 (Parts 1,2 & 3), and SHTM 04-01 guidance;
- The provision of a formal, annual 'L8 Audit' to the SCRP(W).

A1.10 Senior General Manager – Property and Capital Planning – Deputy Responsible Person (Water), (DRP(W)).

The Senior General Manager – Property & Capital Planning, (P&CP), will be formally appointed as a DRP(W), at Board level by the SCRP(W);

The DRP(W) responsibilities include the following within any Capital Projects:

- Identifying and ensuring the efficient formal record of any related Water System risks and raising those considered appropriate to the RP, SCRP(W) & SCRP(W);
- Provide formal reports where required assuring the SORP(W), SCRP(W) & DP(W) that the Board's statutory responsibilities relating to extensions to, and refurbishments of Water Systems, are being safely and appropriately discharged;

- Participate in a recommended training programme to maintain personal knowledge and a level of expertise allowing the efficient discharge of the DRP(W) responsibilities;
- Identify to the SORP(W), SCRP(W) & DP(W) a risk-based prioritisation of the necessary resources required to effectively manage and control identified risks arising from the need to safely design, manufacture, install, alter or develop Water Systems in all new works in NHSGGC Premises, to an acceptable level;
- Effectively manage and control the resources provided to control risk in Water Systems in all new works in NHSGGC Premises, to an acceptable level, as far as reasonably practicable;
- Ensuring the implementation of all 'Statutory Instruments & Mandatory Guidance' related to Water Systems, (see examples in section, 'Guidance', in this Policy), and adherence to the NHSGG&C Water Systems Safety Policy at all levels within the P&CP, section of the Directorate of E&F, particularly those related to guidance in SHTM 04-01, HSG274 Parts 1, 2 & 3 and ACoP L8 and compliance to this guidance shall be formally certified by the design engineer;
- Ensuring that P&CP Staff, are fully aware and appropriately trained in the statutory and mandatory requirements and standards for the design and provision of safe Water Systems;
- Ensuring that any new works undertaken or refurbishment within existing NHSGGC Premises shall comply with the requirements of this Policy and the Written Scheme and Operational Procedures for managing water safety including particularly, The Control of Legionella, Hygiene, 'Safe' Hot Water, Cold Water and Drinking Water Systems';
- Ensuring that installations, adaptations a modifications carried out under capital project developments are approved and signed off by the AE(W), & respective senior AP(W);
- Ensuring all works are formally commissioned and handed over to the respective Site Manager Operational Estates (SMOE) in compliance with the handover protocol for water as identified in the Written Scheme;
- Ensuring that all physical and control interfaces with existing Water Systems for new and refurbishment works shall be safely designed, installed, commissioned in a pre-planned, safe and effective manner and formally agreed and signed off by the RP(W) and AP(W), particularly any derogations or deviations from applicable Guidance;
- Ensuring that any works which will affect an operational water service will be discussed and formally agreed with the estates AP(W) prior to arranging that work.

A1.11 Site Manager Operational Estates (SMOE) – Deputy Responsible Person (Water), (DRP(W)).

The Site Manager Operational Estates shall be formally appointed in writing by the SCRP(W).

The DRP(W) responsibilities include:

- Identifying and ensuring the efficient formal record of relative Water System risks and raising those considered appropriate to the RP(W) and the SWSSG;
- Provide formal reports to the SWSSG assuring the RP(W) that the Board's statutory responsibilities relating to Water Systems, in relative NHSGGC Premises, are being safely and appropriately discharged;

- Participate in a recommended training programme to maintain personal knowledge and a level of expertise allowing the efficient discharge of the DRP(W) responsibilities;
- Identify to the SWSSG a risk-based prioritisation of necessary resources required to effectively manage and control risks arising from the management of Water Systems to an acceptable level;
- Effectively manage and control identified risks arising from the Water Systems in the relative locations of the NHSGG&C Premises, to an acceptable level, as far as reasonably practicable;
- Ensuring the implementation of all 'Statutory Instruments & Mandatory Guidance' related to Water Systems, (see examples in section, 'Guidance', in this policy), and adherence to the NHSGG&C Water Systems Safety Policy at all levels within the relative locations of the Directorate of E&F;
- Ensuring that E&F Staff, managed by the DRP(W), through the Directorate management structure, are fully aware of their personal roles and responsibilities and appropriately trained in the statutory and mandatory requirements and standards for the management of safe Water Systems;
- Ensuring Water Systems are operated in accordance with the current guidance, and with the assessed risk of the individual systems under the control of the DRP(W);
- Ensuring water system maintenance records are maintained and kept up-to-date;
- Regularly checking maintenance records;
- Ensuring all work is completed in accordance with the NHSGGC Operational Procedures.

A1.12 Acute Services Directors, HSCP Directors and Corporate Division Directors.

NHSGGC Directors and Senior Managers, play an essential role in the safe management of Water Systems, actively ensuring and demonstrating that water safety is embedded within the culture of the organisation.

The responsibilities of Directors and Senior Managers include:

- Identifying and ensuring necessary formal records are maintained relating to Policies and Operational Procedures for Water Systems and raising any potential risks relating to Water Systems to the RP(W) and the SWSSG;
- Participate in training to maintain personal knowledge and a level of expertise allowing the efficient discharge of Director and Senior Manager responsibilities;
- Effectively manage and control identified risks arising from the Water Systems in the relative NHSGGC Premises areas of responsibility, to an acceptable level, as far as reasonably practicable;
- Ensuring the implementation of all 'Statutory Instruments & Mandatory Guidance' and Operational Procedures related to Water Systems, (see examples in section, 'Guidance', in this Policy), and adherence to the NHSGG&C Water Systems Safety Policy at all levels within the relative NHSGGC Premises areas of responsibility;
- Ensuring that Staff, managed by the Director and Senior Manager are fully aware of their personal roles and responsibilities and appropriately trained in the statutory and mandatory requirements and standards for the management and operation of safe Water Systems;

- Facilitating Staff to allow their timely attendance at Water Safety training at the appropriate frequency, as per the NHSGGC Water Safety Policy and Operational Procedures which underpin this Policy;
- Ensuring Water Systems are operated in accordance with the current guidance, and NHSGGC Operational Procedures;
- Ensuring Water Systems records, including Staff training records, are monitored and kept up-to-date;
- Supporting the DP(W) and DP(P) in the development of the Board's overall strategy in relation to the safe management and operation of NHSGGC Water Systems and for ensuring and demonstrating implementation within their areas of responsibility;
- Monitor and actively and effectively correct situations where inaction or actions by Staff put themselves and/or others at risk from actual or potential water safety incidents.

A1.13 Heads of Service (HoS), Departmental Managers (DMs), Clinical Managers (CMs) and Senior Charge Nurses (SCNs)

All managers and SCNs have a responsibility in the safe management of Water Systems, actively ensuring and demonstrating that water safety is sufficiently embedded in their departments, and for the safe, day to day management of facilities, Staff or services, and/or premises.

Water safety responsibilities that include:

- Familiarise themselves with the NHSGGC Water Safety Policy and local control measures including any water risk assessments for their area(s) of responsibility;
- Ensuring that persons in the department, clinic or ward are fully aware of their responsibilities and duties in respect of Water Safety, in particular, the action required of them should the area be defined as High Risk, listed in the site-specific Water Safety Written Scheme and Operational Procedures;
- Ensure that persons in the department, clinic or ward are fully aware of the 'Infrequently Used Outlets' definitions and Operating Procedure which underpins the NHSGGC Water Safety Policy;
- Actively promoting Water Safety within the department or ward by maintaining good housekeeping within the department or ward at all times, ensuring that any flushing or documentation as described in the Water Safety Written Scheme and Operational Procedures documentation is completed on time ;
- Responding appropriately to any water safety concerns of persons in the department, clinic or ward;
- Encouraging their staff and themselves to promptly report any breaches in the water system, such as water ingress, leaks etc. to estates;
- Nominating a responsible person to complete the Monthly 'Infrequently Used Outlets' Audit for each area, forwarding a copy to the Site Maintenance/Estates Manager, thereby assisting NHSGGC to consistently comply with its statutory and mandatory obligations;
- Ensuring that action is taken on a daily basis to address any access issues identified within the Cleaning Compliance Checklist Sign Off documentation retained in the Facilities Folder;
- Liaising with the Estates Department as required.

A1.14 Authorised Person (Water) (AP(W)).

The AP(W), has the key operational role and will be specifically qualified, trained and experienced to allow the efficient discharge of their responsibilities. AP(W) will be recommended by the AE(W) for appointment by the SCRP(W).

Important elements of an AP(W) role are the comprehensive maintenance of formal records and the necessary quality of service and maintenance of systems to ensure their safety and integrity.

The AP(W) will also be responsible for establishing and formally appointing a sufficient number of Competent Persons (Water), (CP(W)), to carry out maintenance and operational Procedures on Water Systems.

The AP(W) will ensure all CPs(W) managed by the AP(W) are suitably trained, competent NHSGGC employees or formally engaged competent contractor(s).

Larger sites may require more than one AP(W). Where more than one AP(W) is operating on a site, the SCRP(W) will appoint one AP(W) to take a lead role, ensuring effective, clear, unambiguous communications, with the purpose of safely discharging responsibilities and avoiding confusion and duplication.

The responsibilities of the AP(W) include:

- Identifying and ensuring the efficient formal record of relative Water System risks and raising those considered appropriate to the RP(W);
- Provide formal reports to the RP(W) assuring the SORP, SCRP & DP(W) that the Board's statutory responsibilities relating to Water Systems, in relative locations, are being safely and appropriately discharged;
- Participate in a recommended training programme to maintain personal knowledge and a level of expertise allowing the efficient discharge of the AP(W) responsibilities;
- Identify to the RP, SORP & SCRP a risk-based prioritisation of necessary resources required to effectively manage and control water system risks arising from the Water Systems to an acceptable level;
- Effectively manage and control identified risks arising from the Water Systems in the relative locations of the NHSGGC Premises, to an acceptable level, as far as reasonably practicable;
- Ensuring the implementation of all 'Statutory Instruments & Mandatory Guidance' related to Water Systems, (see examples in section, 'Guidance', in this Policy), and adherence to the NHSGGC Water Systems Safety Policy at all levels within the relative locations of the Directorate of E&F;
- Ensuring that estates staff, managed by the AP(W), through the Directorate management structure, are fully aware and appropriately trained in the 'Statutory Instruments & Mandatory Guidance' and standards for the provision and maintenance of safe Water Systems;
- The AP(W) will also be able to demonstrate:
 - Their application through familiarisation with the system(s) they are responsible for and the successful completion of an appropriate professional course;
 - A sufficient level of professional experience;
 - Evidence of knowledge and skills relating to Water Systems;

- Review and formally approve all new minor installations, adoptions and modifications prior to implementation, engage with RP (W), and/or AE(W) as required with respect to the scale, complexity and/or associated risks.

A2.0 Statutes & Guidance

Compliance with Statutory Instruments, (SIs), is Compulsory and will take primacy. The SIs and Mandatory Guidance, (listed below), should be consulted for more comprehensive information and guidance.

- Health & Safety at Work, etc. Act 1974
- The Management of Health and Safety at Work Regulations 1999 & (Amendment) Regulations 2006
- The Control of Substances Hazardous to Health Regulations (COSHH) 2002 7 (Amendment) Regulations 2004
- Health & Safety Commission's Approved Code of Practice & Guidance L8, (ACOP L8), 'Legionnaires' disease: The control of Legionella bacteria in water systems'. (Forth Edition 2014)
- Public Health (Infectious Diseases) Regulations 1998 si1988 No 1550 (s.155)
- NHS Estates - Scottish Health Technical Memoranda 04-01 (SHTM 04-01)
- The Chartered Institute of Building Services Engineers (CIBSE) - Technical Memorandum (TM13), Minimising the Risk of 'Legionnaires' Disease'
- Water Regulations Advisory Scheme - Water Supply (Water Fittings) Regulations 1999
- Water Regulations Advisory Scheme (WRAS 2005) - Water Fittings and Materials Directory
- The Water Supply (Water Fittings) (Scotland) Byelaws 2014
- Water Supplies (Scotland) Regulations 2014
- Food Safety Act 1990
- BS 8580: 2019 Water quality. Risk assessments for Legionella control. Code of practice
- BS 6700; 2006, 'Design, Installation, Testing & Maintenance of services supplying water for domestic use within buildings & their cartilages - Specification'
- BS EN 806-1; (2012) 'Specification for installations inside buildings conveying water for human consumption'
- BS 1710; 2014 Specification for Identification of Pipelines and Services
- BS EN 12671: 2009 Chemicals used for treatment of water intended for human consumption. Chlorine dioxide. British Standards Institution, 2009
- Thermostatic Mixing Valve Manufacturers Association - Recommended Code of Practice for Safe Water Temperatures
- Guidance for neonatal units (NNU's) (levels 1, 2 & 3) adult and paediatric intensive care units ICU's in Scotland to minimise the risk of Pseudomonas aeruginosa infection from water
- HSG274 Legionnaires' Disease Technical Guidance
- Date of publication: 2014 ISBN: 978 0 7176 6635 5 Series code: HSG274
- HSG274 is split into three distinct parts as follows:
- HSG274 Legionnaires' disease: Technical guidance Part 1:
- The control of legionella bacteria in evaporative cooling systems
- HSG274 Legionnaires' disease: Technical guidance Part 2:
- The control of legionella bacteria in hot and cold water systems
- HSG274 Legionnaires' disease: Technical guidance Part 3:
- The control of legionella bacteria in Other Risk Systems

- CEL 08 (2013) water sources and potential risk to patients in high risk units – revised guidance

A 3.0 Definitions and Acronyms

A3.1 Definitions

A3.1.1 Cleaning Compliance Checklist

A formal checklist of cleaning within the ward or department, signed off by the person in charge of the area confirming satisfaction of compliance with cleaning standards

A3.1.2 Control Measures

Considered, deliberate strategies, actions and activities employed, or stopped, which are designed to remove, reduce or mitigate risks that may diminish the ability to deliver safe and effective healthcare

A3.1.3 Domestic Cold Water

Cold potable water, either from water mains or storage systems, used by people for washing and drinking etc.

A3.1.4 Domestic Hot Water

Tempered Water for use by people for washing and bathing

A3.1.5 Engineering High Risk areas

The 'Engineering High Risk areas' are:

- In Water Systems treated with biocides, e.g. CLO₂;
- Where water is stored;
- In water systems where the control levels of the treatment regime, e.g. temperature or disinfectant concentrations are not being consistently achieved or frequently vary from recommended levels;
- In water systems suspected or identified in a case or outbreak of Legionellosis where it is probable the Incident Control Team will require samples to be taken for analysis;
- In water systems suspected or identified in a case or outbreak linked to other potential water borne Pathogens where it is probable the Incident Control Team will require samples to be taken for analysis;
- In areas which have been identified within the current Water Safety Risk Assessment as being of a risk.

A3.1.6 Facilities Folder

A folder, held as documentary evidence and a formal record of procedures at ward / department level.

A3.1.7 Guidance / Mandatory Guidance

Guidance, policies, operational procedures/protocols and good industry practice etc. Guidance can be varied if the variation can be defended. Where Guidance is 'mandated' within general industry and in the NHS in Scotland, it becomes 'Mandatory Guidance' and may be referred to within Statutory Instruments as an 'Approved Code of Practice (ACOPs).

A3.1.8 High Risk Clinical Areas

The list of High Risk Clinical Areas determined by the NHSGGC Lead ICD, where immuno-compromised patients may be cared for, are as follows;

- Transplant units
- ICU\PICU
- NICU\SCBU
- Haemato-oncology units
- Cardiology
- Coronary Care

A3.1.9 Infrequently Used Outlets

Water Systems' appliances that are used infrequently, as defined in 'Infrequently Used Outlets' definitions and Operating Procedure.

A3.1.10 NHSGGC Premises

All Hospitals, Health Centres, Clinics and other Properties, General Practice, Dental and other Surgeries, owned and or operated by NHSGGC where healthcare is delivered/provided to patients.

A3.1.11 Other Risk Systems

The following locations, systems and items of plant will have specific Control Measures applied to reduce the risk of infection.

- ultrasonic humidifiers/foggers
- spray humidifiers
- air washers, wet scrubbers, particle and trivial gas scrubbers
- water softeners
- emergency showers, eyebaths and face wash fountains
- sprinkler and hose reel systems
- spa pools
- whirlpool baths
- hydrotherapy pools
- birthing pool
- horticultural misting systems
- vehicle washers including automatic washers for cars, buses, lorries and railway rolling stock
- powered dental equipment
- fountains and decorative water features including those on display for sale
- non-disposable nebulisers used for respiratory therapy
- industrial effluent treatment plants
- irrigation systems
- fire, dust and odour suppression systems
- clinical wash-handbasins, drain outlets and connections
- wet drainage sump
- chilled beams
- cardiac heaters / coolers
- ECMO

A3.1.12 Outbreak SOP

The NHS GGC Outbreak SOP is a document which provides a definition of an outbreak /incident and recommended actions. The actions include when to set up an incident meeting, who should be invited (including external expertise) and a sample agenda. It also provides guidance on communications within the HB and to the Scottish Government.

A3.1.13 Pathogens

Microorganisms that are, or may become, harmful to people.

A3.1.14 Risk Reduction Strategies

Risk Reduction strategies/procedures can include, but are not limited to:

- Policy awareness and implementation;
- Risk assessment both generic and specific;
- Training, e.g. WH001 Legionella Management HTM 04-01 and WH003 Legionella Control within Hot and Cold Water Systems used in NHSGGC for APs(W), DRP(W), RP(W) etc.;
- The development, approval and implementation of local procedures;
- Reporting and recording;
- Evaluating effectiveness of risk reduction strategies/procedures;
- Reviewing in the light of experience, e.g. looking at incident investigations and inspection reports. Do they show improvement?;
- Re-train Staff if required, reading available policies, strategies and procedures;
- Review clinical and workplace risk assessments after reports of any adverse events;
- Implementation of risk reduction strategies as defined by the findings of the risk assessment for the NHSGGC buildings;
- Implementation of a formal review and/or audit process of the risk reduction procedures;
- Implementation of contractor audit and review procedures;
- Review and update Written Scheme and water action plan every 2 years or following material system amendments/change of use.

A3.1.15 Sector

A designated area of NHGGC that is a recognised Sector of NHSGGC Premises.

A3.1.16 Staff

People employed by NHSGGC on various contracts and will include locum, bank, volunteers etc.

A3.1.17 Statutory Instruments

Laws, regulations etc. that have legal standing and are applied by enforcing authorities.

A3.1.18 Water Systems

All domestic hot and cold water systems, water-dispensing equipment as well as defined, 'at risk' water-carrying systems across all NHSGGC premises.

A3.1.19 Water Dispensing Equipment

Equipment or machinery dispensing water, in all forms and states, for consumption and or use by people, e.g. Water coolers, Ice-making machines etc.

A3.1.20 Written Scheme & Operational Procedures

A document written to record and communicate, in detail, how responsibilities relating to the safe operation and management of Water Systems will be discharged and will describe who will have responsibilities for their safe and effective implementation

A3.2 Acronyms:

ACoP

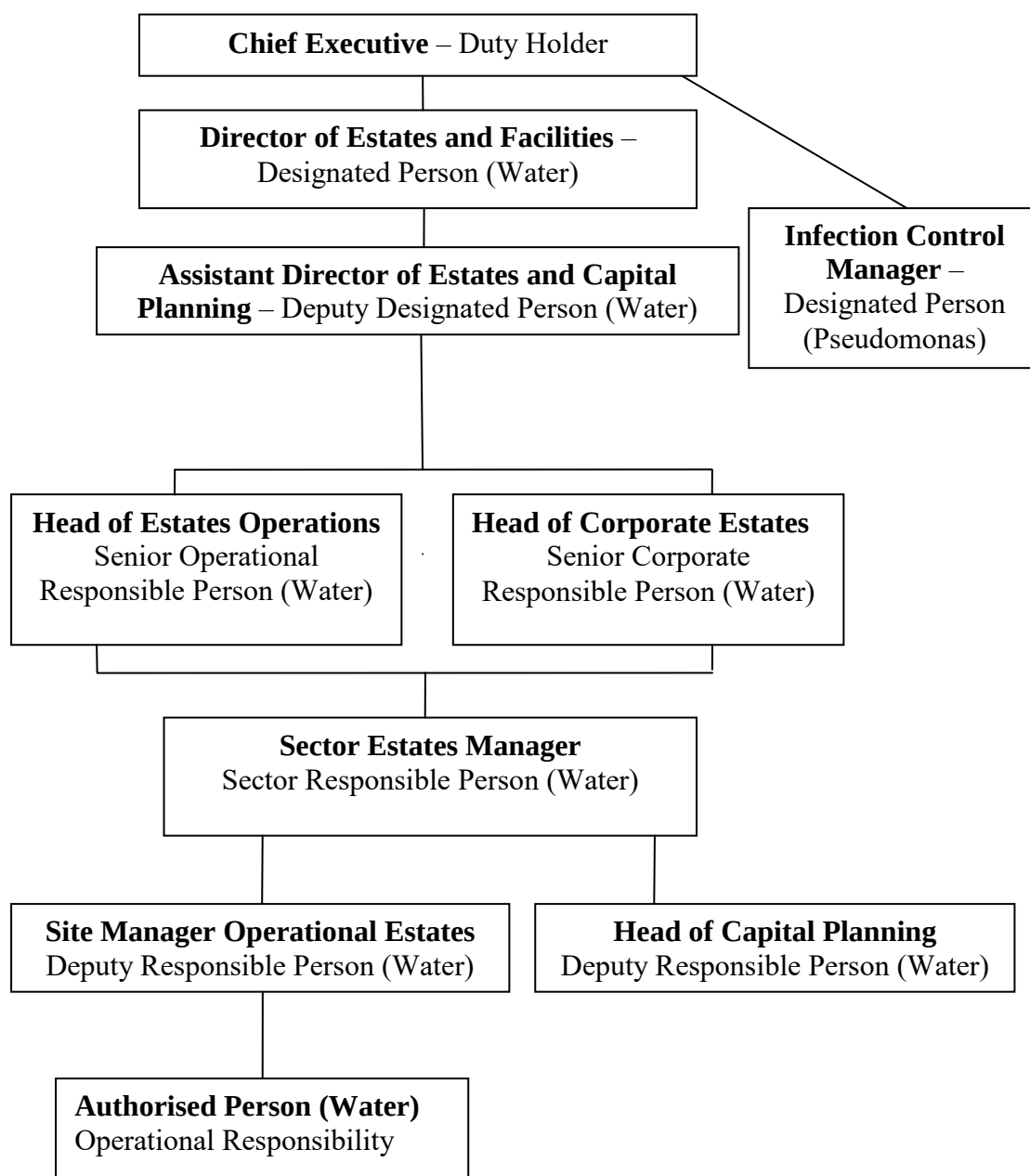
Approved Code of Practice

ADP(W)

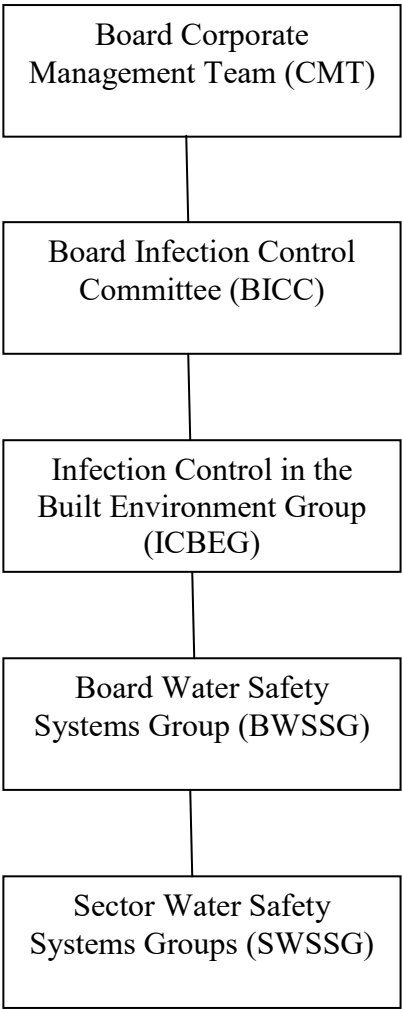
Acting Designated Person (Water)

AE(W)	Authorising engineer (Water)
AP(W)	Authorised Person (Water)
BWSSG	NHSGGC Water Systems Safety Group
BICC	Board Infection Control Committee
BS	British Standards
CAFM	Computer Aided Facilities Management
CE	Chief Executive
CIBSE	Chartered Institute of Building Services Engineers
CHP	Community Health Partnership(s)
CMT	Corporate Management Team
COSHH	Control of Substances Hazardous to Health
CP(W)	Competent Person (Water)
DCW	Domestic Cold Water
DDP(W)	Deputy Designated Person (Water)
DDP(P)	Deputy Designated Person (Pseudomonas)
DE&F	Director of Estates & Facilities
DHW	Domestic Hot Water
DH(W)	Duty Holder (Water)
DP(P)	Designated Person (Pseudomonas)
DP(W)	Designated Person (Water)
DRP(W)	Deputy Responsible Person (Water)
E&F	Estates & Facilities
ECMO	Extracorporeal Membrane Oxygenation
HIIAT	Hospital Infection Incident Assessment Tool
HIORT	Hospital Infection Incident Reporting Template
HPS	Health Protection Scotland
HSE	The Health & Safety Executive
ICD	Infection Control Doctor
ICM	Infection Control Manager
ICT	Infection Control Team
IMT	Incident Management Team
NHS	National Health Service
NHSGGC	NHS Greater Glasgow & Clyde Health Board
P&CP	Property & Capital Planning
RP(W)	Responsible Person (Water)
RP(P)	Responsible Person (Pseudomonas)
SHTM	Scottish Health Technical Memoranda
SI	Statutory Instruments
SMT	Estates & Facilities Senior Management Team
SWSSG	Sector Water Systems Safety Groups
TM	Technical Memorandum

A4.0 - Governance Structure (by designation)



A4.1 - Governance Structure (by governance groups)





Water Systems Safety Policy

Produced By	NHSGGC Board Water Safety Group
Approved By	NHSGGC Corporate Management Team
Responsible Director	Director of Estates & Facilities
Lead Manager	Assistant Director of Estates
Date Approved	November 2023
Review Date	Annual Review January 2025 Policy Term Expiry November 2026

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1.0 Application of the Policy

1.1 Application

The Water Systems Safety Policy shall apply to all Domestic Hot Water, (**DHW**) and Domestic Cold Water, (**DCW**) systems, Water-Dispensing Equipment as well as defined, 'At Risk Water-carrying Systems' across all NHSGGC Premises, (hereafter referred to as 'Water Systems' in this Policy).

1.2 Objective

The objective of this policy is to ensure safe and effective control of Water Systems throughout NHSGGC Premises in order to minimize the risk from water borne Pathogens and maintain water quality in all NHSGGC Premises.

2.0 Introduction

2.1 Pathogens

Most microorganisms are harmless to healthy individuals and are commonly found on people, in the environment and in water supplies or on birds and other animals in the vicinity of NHSGGC Premises. As these microorganisms are 'naturally occurring'; they can readily find their way into Water Systems. Some of these microorganisms however, if given the appropriate conditions, can cause, or lead to, infections that may put some people at risk of serious harm.

2.2 Statutory Instruments and Mandatory Guidance

The variety and extent of water-related Statutory Instruments, mandatory and other approved Guidance, Policies, Operational Procedures/Protocols and good industry practice (Hereafter referred to as 'Statutory Instruments & Mandatory Guidance' in this Policy), emphasise the essential nature of safely managing Water Systems. The applicable Statutes and Guidance are referenced in **Appendix 1**.

2.3 Statutory Responsibilities

NHSGGC has a statutory obligation to identify and effectively control risks to protect patients, Staff and members of the public arising from Water Systems within NHSGGC Premises.

2.4 Competence

NHSGGC will maintain a formal training programme for nominated key staff to ensure those appointed to devise strategies and carry out control measures are appropriately informed, instructed, trained and assessed to competently undertake their Roles & Responsibilities **Appendix 2**.

2.5 Penalties for Compliance Failures

Failures in compliance with 'Statutory Instruments & Mandatory Guidance' responsibilities may attract prosecution by Enforcing Authorities, (e.g. The Health & Safety Executive). Prosecutions may be 'Corporate', against the organisation, but could also be 'Personal', brought against individual members of Staff. Penalties for prosecution may take the form of fines and/or imprisonment.

NHSGGC take their Statutory and Mandatory responsibilities and over-arching duty of care to its patients, staff and others seriously and will employ appropriate measures and sanctions where required to address failures to meet these duties in line with existing policy arrangements.

3.0 Duty of Care

3.1 Awareness of Responsibilities

NHSGGC recognises that it has a moral and ethical duty of care for the safety of patients and others, particularly those whom may have an elevated susceptibility to infection because of their increased vulnerability caused by underlying health factors and/or the suppression of their personal immune defences caused by their illness.

3.2 Discharging NHSGGC's Duty of Care

NHSGGC will discharge its Duty of Care through rigorous compliance with all relative 'Statutory Instruments & Mandatory Guidance'.

3.3 Essential Participation in Water Safety

Water safety within NHSGGC can only be achieved by every member of Staff actively contributing to a concerted 'team effort' and the risk to patients' safety will be compromised by people failing in their statutory responsibilities, by not following, or incorrectly applying the 'Statutory Instruments & Mandatory Guidance'.

It is essential therefore, that each Staff group and every individual in NHSGGC actively participates and applies procedures designed to reduce risks arising from Pathogens in Water Systems in NHSGGC.

4.0 Roles and Responsibilities

4.1 General Responsibilities

The active participation of all NHSGGC Staff members is essential to protect patients, Staff and members of the public from risks arising from Water Systems.

4.2 Key Personal Responsibilities

The 'Statutory Instruments & Mandatory Guidance' relating to water safety, identifies key roles with specific responsibilities to ensure the effective application of recommended and mandatory procedures.

Specific individual and group responsibilities of each of these key roles, along with nominated posts for each of these key roles, are provided in [Appendix 2](#) of this Policy. Named individuals appointed to these roles are detailed in the respective site procedures and Written Scheme(s). Each named individual or group must familiarise themselves with the dimensions of their specific and corporate responsibilities relating to water safety in NHSGGC.

It should be noted that the responsibilities noted in this policy may not be exhaustive and it is recommended that individuals refer to the 'Statutory Instruments & Mandatory Guidance' in [Appendix 1](#) for a deeper understanding of their responsibilities.

5.0 Reporting

5.1 Monitoring & Review

Control Measures relating to water safety in NHSGGC shall be systematically examined, monitored and reviewed by designated teams and individuals carrying specific or delegated managerial responsibilities.

5.2 Formal Periodic Reports

Formal periodic reports on Water Systems will be presented by:

- I. Various Sector-located Groups and appointed key individuals, (e.g. **RP(W)**) to their respective Sector Water Systems Safety Groups (**SWSSG**);
- II. Groups and appointed key individuals within the Sector management structure of The Health and Safety Department, Estates, Facilities and Infection Prevention & Control Service via the **SWSSG** to the NHSGGC Board Water Systems SafetyGroup (**BWSSG**) e.g minutes from **SWSSG** to **BWSSG** and **AICC**;
- III. Either or both co-Chairs of the **BWSSG**, on behalf of the Group, to the Board Infection Control Committee (**BICC**) and the Health & Safety Forum;
- IV. The Chair of the **BICC** on behalf of the **BICC** to the Corporate Management Team (**CMT**) (including the Chief Executive, (**CE**)).
- V. Local monthly minuted meetings between Estates and Microbiology should be arranged to review 'out of specs'.

6.0 Risk Reduction

6.1 Assessment

Following any assessment of the risks arising from Water Systems, Control Measures will be implemented, when appropriate and reasonably practicable. The water safety risk assessment program will be reviewed at each Board Water Safety Group Meeting. All new or refurbished properties will have a full Risk Assessment undertaken. NHSGG&C Acute sites (including our large partnership/HSCP) sites where there are in/outpatients will be risk assessed every 2 years and all other sites shall be risk assessed every 5 years unless there has been modifications carried out to the water installation or a significant change in the use of the building. Compliance will maintain this list.

6.2 Control Measures

Control Measures may include Risk Reduction Strategies to reduce the likelihood and/or severity of patient infections. SWSSGs are responsible for ensuring that a multi disciplinary approach is taken to risk reduction within the Board at local level.

As part of the risk of the risk reduction process, Infection Control will consider the permanent fitting of point of use filters in specific areas as per SHTM04-01

7.0 Operational Arrangements

7.1 Written Scheme & Operational Procedures

The Written Scheme and operational procedure records for each site are designed to establish a system of control which shall be rigorously applied by specifically trained staff within a recommended, formally appointed structure for the safe management and governance oversight of Water Systems. The Written Scheme and operational procedure records for each site are held in the Board's smart sheet document management service and are reviewed annually.

7.2 Planned Maintenance

Water Systems throughout NHSGGC are subject to a routine planned maintenance system, managed and controlled via NHSGGC's proprietary Computer Aided Facilities Management (CAFM) System, FMfirst ®, by designated Estates Supervisors and Managers.

8.0 Testing

In keeping with the current HSE guidance, testing for Legionella will be carried out within NHSGGC as follows:-

8.1 High Risk Clinical Areas

A list of High Risk Units at risk of legionella or pseudomonas and where immuno-compromised patients may be cared for, has been determined by ARHAI Scotland Guidance and these are designated as 'high-risk clinical areas'. This list can be found in **Appendix 3**, clause A.3.1.8.

Clinical High Risk Areas in relation to water will be specifically identified within the various site-specific Written Schemes.

8.2 Other sampling

Based on risk assessment and agreed through appropriate water management governance for operational, capital or minor works projects there may be a requirement for the sampling of other bacteria and a specific thresholds which are acceptable for these. There may be also a requirement agreed for ongoing monitoring.

8.3 Engineering Risk Areas

Due to the 'age' of some of NHSGGC's current property portfolio, it is recognised that there are some installations that may present a high risk of contamination by Pathogens due to the Water System's distribution configuration. Where this is the case, the system will be defined as an Engineering High Risk and a testing programme will be implemented and rigorously maintained.

The Engineering High Risk areas and Other High Risk Areas can be found in **Appendix 3** – clauses A3.1.5 & A.3.11 and will be specifically identified within the various site-specific 'Written Schemes'.

8.4 Governance Structure

The Governance Structure is shown in **Appendix 4** of this policy.

9.0 Pseudomonas

9.1 Pseudomonas Guidance

NHSGGC will seek to reduce the risk from Pseudomonas in its Water Systems by complying with the Water (Scotland) Group's guidance document titled, 'Guidance for Neonatal Units, (NNUs) (levels 1, 2 & 3), adult and paediatric Intensive Care Units, (ICUs), in Scotland to minimise the risk of Pseudomonas Aeruginosa infection from water', (version 2.3 dated May 2018), produced by Health Facilities Scotland, Health Protection Scotland.

10.0 Action on Identification of bacteria in a water system or Clinical Incident

10.1 Action above agreed thresholds

Reference of full details can be found in the GG&C Sampling Procedure. If bacteria is shown to be present above thresholds routine precautions and control measures designed to eliminate the bacteria will be applied. An incident record form (004) will be created listing actions taken and by whom. Sampling will be carried out as per agreed sampling procedure e.g. minimum of 3 not detected or within parameters for the specific bacteria. **ICD** will consider other precautions e.g. outlet to be placed out of use, patient moved etc.

The **LAP(W)** should provide at minimum monthly summary of current out of specs and actions taken to the **RP(W)**, **DRP(W)**, **Microbiology** and **ICD** colleagues and supply full details within an agreed Teams folder.

10.2 Action if an environmental organism is identified as a source of an infection

Guidance as per the NHS GGC IPC Environmental Organisms Standard Operating Procedure (SOP) (<https://www.nhsggc.org.uk/media/253288/environmental-organisms-in-high-risk-areas-sop-final-v1-november-2018.pdf>) and the Pseudomonas SOP (<https://www.nhsggc.org.uk/media/255146/sop-pseudomonas-aeruginosa-v3-amended-july-2019.pdf>) will be followed to assess and action incidents involving these water related organisms.

Where an incident team is set up to investigate a trigger, outbreak SOP [Incident Management Process Framework V1 - NHSGGC](#) will be followed. Any incidents **HIAT** assessed will be reported nationally as per chapter 3 **NIPCM** as well as part of the reporting requirements for **IPCT**.

In the event of clinical cases are potentially linked to water quality, which is determined by ICD's as per Chapter 3 NIPCM, a problem assessment group or **IMT** will be initiated by the nominated **ICD**. In certain circumstances, e.g. Legionella serogroup 1, a single hospital health care associated case would warrant an **IMT** (refer to Chapter 3 NIPCM and the Incident Management Process Framework).

Where water quality is confirmed as the source of clinical cases and the **IMT** assess the incident using the Hospital Infection Incident Assessment Tool (**HIAT**) as **HIAT** red, amber or green this will be reported to **ARHAI** using the Hospital Infection Incident Reporting online reporting tool, (**HIORT**) and recorded on the service risk register by the nominated Clinical Service. Any that score red, amber or green in the **HIAT** assessment will be reported in the **HAIRT** which goes to clinical and care governance group, in addition a summary **HAIRT** is presented each time the NHS Board meets.

When it can be demonstrated that an infection incident has originated in a Water System, the **AP(W)** must ensure that a review and investigation is carried out and formally recorded and reported to the **RP(W)** and **ICD**. These incidents should be reviewed as a 'significant adverse event' as per the Incident Management Policy and Procedure.

11.0 Audit

11.1 Monitoring of Policy Effectiveness

The application and effectiveness of this policy throughout the organisation shall be monitored by the Health and Safety Department reporting via the **BWSSG** and the Estates & Facilities Senior Management Team (**SMT**).

11.2 Policy Review

This Policy will normally be reviewed annually, but certainly within every 3 year period. The Policy will be revised at the time of review or as a result of any changes in or to the 'Statutory Instruments & Mandatory Guidance'.

12.0 Appendices

Appendix 1 – A1.0 Statutes & Guidance

Compliance with Statutory Instruments, (SIs), is Compulsory and will take primacy. The SIs and Mandatory Guidance, (listed below), should be consulted for more comprehensive information and guidance **including but not limited to :-** .

- Health & Safety at Work, etc. Act 1974
- The Management of Health and Safety at Work Regulations 1999 & (Amendment) Regulations 2006
- The Control of Substances Hazardous to Health Regulations (COSHH) 2002 7(Amendment) Regulations 2004
- Health & Safety Commission's Approved Code of Practice & Guidance L8, (ACOP L8), 'Legionnaires' disease: The control of Legionella bacteria in water systems'.
- Public Health (Infectious Diseases) Regulations 1998 si1988 No 1550 (s.155)
- NHS Estates - Scottish Health Technical Memoranda 04-01 (SHTM 04-01)
- The Chartered Institute of Building Services Engineers (CIBSE) - Technical Memorandum (TM13), Minimising the Risk of 'Legionnaires' Disease'
- Water Regulations Advisory Scheme - Water Supply (Water Fittings) Regulations 1999
- Water Regulations Advisory Scheme (WRAS 2005) - Water Fittings and Materials Directory
- The Water Supply (Water Fittings) (Scotland) Byelaws 2014
- Water Supplies (Scotland) Regulations 2014
- Food Safety Act 1990
- BS 8580: 2019 Water quality. Risk assessments for Legionella control. Code of practice
- BS 6700; 2006, 'Design, Installation, Testing & Maintenance of services supplying water for domestic use within buildings & their cartilages - Specification'
- BS EN 806-1; (2012) 'Specification for installations inside buildings conveying water for human consumption'
- BS 1710; 2014 Specification for Identification of Pipelines and Services
- BS EN 12671: 2009 Chemicals used for treatment of water intended for human consumption. Chlorine dioxide. British Standards Institution, 2009
- Thermostatic Mixing Valve Manufacturers Association - Recommended Code of Practice for Safe Water Temperatures
- Guidance for neonatal units (NNU's) (levels 1, 2 & 3) adult and paediatric intensive care units ICU's in Scotland to minimise the risk of Pseudomonas aeruginosa infection from water
- HSG274 Legionnaires' Disease Technical Guidance Date of publication: 2014 ISBN: 978 0 7176 6635 5 Series code: HSG274
 - o Legionnaires' disease: Technical guidance Part 1: Control of legionella bacteria in evaporative cooling systems
 - o Legionnaires' disease: Technical guidance Part 2: The control of legionella bacteria in hot and cold water systems
- Legionnaires' disease: Technical guidance Part 3: The control of legionella bacteria in Other Risk Systems.
- CEL 08 (2013) water sources and potential risk to patients in high risk units –revised guidance.

Appendix 2 – A2.0 Roles and Responsibilities

A2.1 Chief Executive – Duty Holder (Water) DH(W)

The Chief Executive has overall executive responsibility with accountability to NHSGGC's Board for all safety, health and risk matters in NHSGGC. The Chief Executive, (**CE**), is the designated Duty Holder (Water) **DH(W)**, for NHSGGC.

The responsibilities of the **DH(W)** include:

- Assuring NHSGGC's Board, via the Board's Corporate Management Team (**CMT**), that the Board's statutory responsibilities relating to Water Systems are being safely and appropriately discharged;
- Participate in a **Compliance defined** training programme **for this role** to maintain personal knowledge and a level of expertise allowing the efficient discharge of the **DH(W)** responsibilities;
- Ensuring the provision of adequate resources to safely maintain and to effectively manage and control identified risks arising from the Water Systems in the NHSGGC estate to an appropriate level;
- Ensuring the implementation of and adherence to the NHSGGC Water Systems Safety Policy at all levels within the organisation;
- Formally appointing the Designated Person (Pseudomonas) **DP(P)** and Designated Person (Water) **DP(W)** (and their deputies) to assist in the execution of these responsibilities, who for NHSGGC are respectively, the Infection Control Manager and the Director of Estates.

A2.2 Board Corporate Management Team (CMT)

The CMT will have managerial oversight of water-related issues and responsibility for communication in sufficient detail to NHSGGC Health Board, giving assurance that Water Systems are being safely and effectively managed and that the Board's related Statutory obligations are being appropriately discharged.

Refer to CMT ToR for full membership.

The water-related responsibilities of the **CMT** include:

- Having managerial oversight of, and assuring NHSGG&C Health Board that the Board's statutory responsibilities relating to Water Systems are being safely and appropriately discharged;
- Individually participate in appropriate periodic training to establish and maintain personal knowledge and a level of expertise allowing the efficient discharge responsibilities related to this Policy;
- Ensuring, through the Board's management structure, the implementation of all 'Statutory Instruments & Mandatory Guidance' related to Water Systems examples 'Guidance' at 3 and adherence to the NHSGGC Water Systems Safety Policy at all levels within NHSGGC;
- Liaising with the **DP(P)** and the **DP(W)** to ensure the Boards Water Systems Policy is understood and applied across all areas of the Board;
- With support from the **DP(P)** and the **DP(W)**, formulate a Water Systems Safety Compliance Programme, (for both passive and active measures) in existing properties and for new projects;
- Performing governance oversight on behalf of the Board by reviewing the effectiveness of operational arrangements. The **CMT** will be advised on this by the **BICC** with contributions from the **DP(P)** and the **DP(W)** via the **BWSSG**.

A2.3 Director of Estates and Facilities (DE) – Designated Person (Water) DP(W)

The **DP(W)** has delegated executive responsibility with accountability to **DH(W)** for all safety, health and risk matters relating to Water Systems in NHSGGC, with the exception of the responsibilities delegated to the Designated Person (Pseudomonas) **DP(P)**.

The Responsibilities of the **DP(W)** include:

- Identify and ensure the efficient formal record of Water System risks and raising those considered appropriate from the **BWSSG** to the **CMT** via the **BICC**;
- Provide formal reports from the **BWSSG** to assure the Health Board via the **CMT** that the Board's statutory responsibilities relating to Water Systems are being safely and appropriately discharged;
- Participate in a Compliance defined training programme for this role to maintain personal knowledge and a level of expertise allowing the efficient discharge of the **DP(W)** responsibilities;
- Identify to the **CMT** a risk-based prioritisation of necessary resources required to effectively manage and control water system risks arising from the Water Systems in the NHSGGC estate, to an acceptable level;
- Effectively manage the resources provided to safely maintain and to manage and control identified risks, to an acceptable level, as far as reasonably practicable;
- Ensuring the implementation of all 'Statutory Instruments & Mandatory Guidance' related to Water Systems, (see examples in section, 'Guidance', in this Policy), and adherence to the NHSGGC Water Systems Safety Policy at all levels within the Directorate of Estates;

Ensuring that Estates, through the Directorate management structure, are fully aware and appropriately trained in the Statutory and Mandatory requirements and standards for the provision and maintenance of Safe Water Systems;

- Ensuring, with the **RP(P)**, that the Water System Safety Policy is regularly reviewed and updated;
- Chair the NHSGGC **BWSSG (or nominated deputy)** as per SHTM requirements ;
- Formally appoint a **DDP(W)**, who will deputise for the **DP(W)** as required, undertaking delegated responsibilities;
- Formally appoint (or delegate the responsibility) to **RP(W)** at sector level, **DRP(W)** and **AP(W)** at site level and on larger sites also **LAP(W)**.

A2.4 Infection Control Director (ICD) – Designated Person (Pseudomonas) DP(P)

The Infection Control Director has delegated executive responsibility with accountability to **DH(W)** for all Pseudomonas related safety, health and risk matters in Water Systems within NHSGGC premises. The **ICD** is the Designated Person (Pseudomonas), **DP(P)**, and will be supported by the Board's designated **LICD**.

The **DP(P)** responsibilities are outlined in the pseudomonas guidance and include :

- Include *P. aeruginosa* from a blood culture as an alert organism via IC net from an adult or paediatric patient. Also include *P. aeruginosa* from any clinical specimen in a neonatal unit/Adults ICU as an alert organism via ICnet. IPCTs when assessing alert organisms be mindful that *P. aeruginosa* can be selected for by prior antibiotic usage.
- Ensure they can detect in real time any possible outbreak early through effective local surveillance and monitoring of numbers of cases over time. e.g automatic trigger alerts as defined by the NHSGGC Surveillance Review Group.
- Be able to facilitate early identification of possible source in collaboration with colleagues in estates and microbiology.
- Have a contingency plan for NNUs and ICUs to enable safe patient care to continue without direct patient/water contact, e.g. use of patient wipes and sterile water in neonatal units.
- Any local outbreak or incident should be assessed using the Hospital Infection Incident Assessment Tool (HIIAT) and reported to ARHAI if amber or red. In addition, if there is an active ongoing clinical incident, where the source is considered to be tap water, then ARHAI should also be informed regardless of the HIIAT.
- An assessment of the clinical practice and ongoing care of invasive devices, cleaning of patient equipment and usage of hand wash stations that could compromise patients during incidents or outbreaks.
- Review of cases each year to inform decision making around high risk areas and update the pseudomonas risk assessment yearly.
- Instruct at the discretion of the ICD/IMT water testing during incidents or outbreaks.
- Ensuring the implementation of all Guidance' related to the control of Pseudomonas, in particular, the 'ARHAI(2018) Guidance for Neonatal Units (NNU's) (levels 1, 2 & 3) adult and Paediatric Intensive Care Units ICU's in Scotland', and adherence to the NHSGGC Water Systems Safety Policy at all levels in Infection Control Teams in all NHSGGC Premises;
- Participate in a Compliance defined training programme for this role to maintain personal knowledge and a level of expertise allowing the efficient discharge of the **DP(P)** responsibilities;

A2.5 Assistant Director of Operational Estates, (ADOE) – Deputy Designated Person (Water) DDP(W)

The **DDP(W)** will be appointed by the **DP(W)** and in their absence have delegated executive responsibility with accountability to **DP(W)** for all safety, health and risk matters relating to Water Systems in NHSGGC, with the exception of the responsibilities delegated to the **DP(P)**., at **A2.4** .

The **DDP(W)** will carry out all the duties and responsibilities of the **DP(W)** as stated in **A2.3** above.

A2.6 Head of Corporate Estates (HCE) – Corporate Responsible Person (Water) CRP(W)

The Head of Corporate Estates (**HCE**) has responsibilities delegated by the **DP(W)** with accountability to the **DDP(W)** for all safety, health and risk matters relating to Water Systems across NHSGGC Premises involved in minor works. The HCE is also the lead in ensuring SCART compliance, audits and training is in place with respect to Water Safety.

The **CRP(W)** is responsible for:

- Identifying and ensuring the efficient formal record of Sector related Water System risks and raising those considered appropriate to the **DDP(W)** & **DP(W)** and the **BWSSG**;
- Identifying and ensuring the efficient formal record of any related Water System risks due to minor works projects and raising those considered appropriate to the **RP(W)**, **AE(W)** and **DDP(W)**.
- Unknown risks not apparent to design teams `during Minor Works Projects should also be highlighted during project scoping involving **AP(W)**'s and **AE(W)**.
- Provide formal compliance reports to the **BWSSG** assuring the **DDP(W)** & **DP(W)** that the Board's statutory responsibilities relating to Water Systems, in respective Sectors, are being safely and appropriately discharged;
- Supporting the **DP(W)** and **DDP(W)** in the production of policies & procedures to ensure the quality of water in NHSGGC Premises is safely maintained;
- Appoint a Water Safety Authorising Engineer **AE(W)** to support NHSGG&C on all issues relating to Water;
- Working with the **AE(W)** and **DDP(W)** appoint Responsible Persons Water **RP(W)** across all sectors;
- Appoint Authorised Persons Water **AP(W)** across NHSGG&C on the recommendation of the Authorising Engineer Water **AE(W)**;
- Participate in a Compliance defined training programme for this role to maintain personal knowledge and a level of expertise allowing the efficient discharge of the **DRP(W)** responsibilities;
- Ensuring that Corporate staff, are fully trained as **AP(W)** to ensure that delegated projects comply with all NHSGG&C policy and procedures. This is to ensure that those working on water systems, **AP(W)** are appropriately trained in the statutory and mandatory requirements and standards for the design and provision of safe Water Systems including :-
- Ensuring that any new works undertaken or refurbishment within existing NHSGGC Premises shall comply with the requirements of this Policy and the Written Scheme and Operational Procedures for managing water safety including particularly, The Control of Legionella, Hygiene, 'Safe' Hot Water, Cold Water and Drinking Water Systems';
- Ensuring all works are formally commissioned and handed over to the respective **LAP(W)** in compliance with the handover protocol for water as identified in the Written Scheme including but not limited to drawings, changes to schematics, WRAS approval documentation and modified or new risk assessment;
- Ensuring that all physical and control interfaces with existing Water Systems for new and refurbishment works shall be safely designed, installed, commissioned in a pre-planned, safe and effective manner particularly any derogations or deviations from applicable guidelines;

- Ensure, as **DRP(W)** that Corporate Estates modifications to installations in NHSGGC Premises can only be implemented following completion of **Form (025)**. This form should be completed by the Designer and then signed by **Designer, AP(W)P, DRP(W)P and LAP(W)**;
 - Formal handover to **LAP(W)** should be implemented via **Form (029)** Record form for acceptance of work to be conducted and confirmation of work completed on a water system; This form should be completed by **AP(W)P** and signed as accepted by **DH(W)** for **AP(W)P** and **LAP(W)**.
 - Included in **Form (029)** is the requirement to complete the Confirmation of work completed and acceptance section. This section should be signed by the **Designer, AP(W)P and LAP(W)**.
 - Liaise closely with other professionals to ensure consistency in application of Control Measures and other procedures designed to allow legislative and statutory compliance, comprehensively in all NHSGGC Premises;
-
- Compliance Audit Duties;
 - o Ensuring a robust annual water audit regime is in place;
 - o Ensuring that Written Schemes and Risk Assessments are in place and reviewed regularly;
 - o Ensure the e-SCART tool is populated and updated regularly with action plans in place, where required;
 - o Ensuring operational procedures are carried out and appropriately recorded;
 - o Ensuring formal records are kept of all Water Systems and their purpose;
 - o Ensure an Annual report on Water Compliance across NHSGG&C is delivered to the **DDP(W)** and **DP(W)**.

A2.7 Assistant Head of Operational Estates – Responsible Person (Water) RP(W)

The Assistant Head of Operational Estates (**AHOE**) has responsibilities delegated by the **DP(W)** and **DDP(W)** with accountability to the **DDP(W)** & **DP(W)** for all safety, health and risk matters relating to Water Systems in their respective Sectors of NHSGGC Premises. They will be nominated in writing by the **CRP(W)** and signed by the **DP(W)** and/or **DDP(W)** ;

The **RP(W)** is responsible for:

- Identifying and ensuring the efficient formal record of Sector related Water System risks and raising those considered appropriate to the **DDP(W)** & **DP(W)** and the **BWSSG**;
- Identifying and ensuring the efficient formal record of any related Water system risk due to Operational Estates projects and raising those considered appropriate to the **RP(W)**, **AE(W)** and **DDP(W)**.
- Unknown risks not apparent to design teams `during Minor Works Projects should also be highlighted during project scoping involving **AP(W)**'s and **AE(W)**.
- Provide formal reports to the **BWSSG** assuring the **CRP(W)**, **DDP(W)** & **DP(W)** that the Board's statutory responsibilities relating to Water Systems, in respective Sectors, are being safely and appropriately discharged
- Participate in a Compliance defined training programme for this role to maintain personal knowledge and a level of expertise allowing the efficient discharge of the **RP(W)** responsibilities;
- Identify to the **BWSSG** a risk-based prioritisation of necessary resources required to effectively manage and control water system risks arising from the Water Systems to an acceptable level;
- Effectively manage and control the resources provided to safely maintain and to effectively manage and control identified risks arising from the Water Systems in the Sector of the NHSGGC Premises, to an acceptable level, as far as reasonably practicable;
- Ensure risk assessments, schematics and drawing are supplied to **LRP(W)** to effectively manage and control the resources provided to control risk in Water Systems in all new works in NHSGGC Premises, to an acceptable level, as far as reasonably practicable;
- Ensuring the implementation of all 'Statutory Instruments & Mandatory Guidance' related to Water Systems, (see examples in section, 'Guidance', in this Policy), and adherence to the NHSGG&C Water Systems Safety Policy at all levels within Corporate Estates, particularly those related to guidance in SHTM 04-01, HSG274 Parts 1, 2 & 3 and ACoP L8 and compliance to this guidance shall be formally certified by the Designer;
- Ensuring the implementation of all 'Statutory Instruments & Mandatory Guidance' related to Water Systems and adherence to the NHSGGC Water Systems Safety Policy at all levels within the Sector of the Directorate of Estates & Facilities;
- Ensuring that Sector estates staff, through the Directorate management structure, are fully aware and appropriately trained in the 'Statutory Instruments & Mandatory Guidance' and standards for the provision and maintenance of safe Water Systems;
- Ensuring the effective maintenance of engineering controls installed for the purposes of controlling water systems;

- Ensuring that Written Schemes and risk assessments are in place and reviewed regularly;
- Devising and maintaining procedures to ensure the quality of water in NHSGGC Premises is safely maintained;
- Ensuring operational procedures are carried out and appropriately recorded;
- Ensuring formal records are kept of all Water Systems and their purpose, giving locations recording and maintaining within the Board's CAFM System;
- Ensuring that all physical and control interfaces with existing Water Systems for new and refurbishment works shall be safely designed, installed, commissioned in a pre-planned, safe and effective manner particularly any derogations or deviations from applicable
- Liaise closely with other professionals to ensure consistency in application of Control Measures and other procedures designed to allow legislative and statutory compliance, comprehensively in all NHSGGC Premises;

A2.8 Authorising Engineer (Water), AE(W)

The **AE(W)**, is appointed in writing by the **CRP(W)** and is employed independently of NHS GG&C. The **AE(W)** acts as an independent professional advisor to NHSGGC with a brief to provide services in compliance with relative 'Statutory Instruments & Mandatory Guidance', and particularly with Scottish Health Technical Memoranda (SHTM) 04-01, mandatory guidance for the NHS in Scotland.

The **AE(W)** will have specialist knowledge of large scale domestic and commercial hot and cold water services installations including incoming supplies and Other Risk Systems as detailed in **Appendix 3** and in particular, those installations for which an Authorised Person (Water) will assume responsibility for.

The **AE(W)** is free to comment on the performance of the organization against the operational risk base.

The **AE(W)**'s main duties will include:

- To be a formal Assessor, making recommendations to the **CRP(W)** for the appointment of **AP(W)** in terms of skills, training and site familiarity;
- Formally monitoring the performance of NHSGGC against 'Statutory Instruments & Mandatory Guidance', particularly, ACoP L8, HSG274 (Parts 1,2 & 3), and SHTM 04-01 guidance;
- The provision of a formal, annual L8 Audit at all NHSGGC Acute sites including our large hospitals where there are in/outpatients and an audit every 3 years for all remaining sites.
Reporting of potential risks (operational and through potential improvements).

A2.9 Head of Capital Projects or nominated person/persons in Capital – Deputy Responsible Person (Water), DRP(W)P

The Head of Capital Projects or Deputy be formally appointed as a **DRP(W)**, by the **DP(W) or DDP(W)**. They will be nominated in writing by the **CRP(W)** and signed by the **DP(W)** and/or **DDP(W)**;

The **DRP(W)P** responsibilities include the following within any Infrastructure, Planning and Delivery (IPD) projects:

- Identifying and ensuring the efficient formal record of any related Water System risks due to projects and raising those considered appropriate to the **RP(W)**, **DP(W)** & **CRP(W)**;
- Unknown risks not apparent to design teams during Projects should also be highlighted during scoping involving **AP(W)'s and AE(W)**.
- Provide formal reports where required assuring the **RP(W)**, **DDP(W)** & **CRP(W)** that the Board's statutory responsibilities relating to extensions to, and refurbishments of Water Systems, are being safely and appropriately discharged;
- Participate in a Compliance defined training programme for this role to maintain personal knowledge and a level of expertise allowing the efficient discharge of the **DRP(W)** responsibilities;
- Ensuring that Property and Capital Planning Staff, are fully trained as **AP(W)P** to ensure that delegated projects comply with all NHSGG&C policy and procedures. This is to ensure that those working on water systems, **AP(W)P** are appropriately trained in the statutory and mandatory requirements and standards for the design and provision of safe Water Systems including :-
- Ensure risk assessments, schematics and drawing are supplied to **LRP(W)** to effectively manage and control the resources provided to control risk in Water Systems in all new works in NHSGGC Premises, to an acceptable level, as far as reasonably practicable;
- Ensuring the implementation of all 'Statutory Instruments & Mandatory Guidance' related to Water Systems, (see examples in section, 'Guidance', in this Policy), and adherence to the NHSGG&C Water Systems Safety Policy at all levels within Capital, particularly those related to guidance in SHTM 04-01, HSG274 Parts 1, 2 & 3 and ACoP L8 and compliance to this guidance shall be formally certified by the Designer;
- Ensuring that any new works undertaken or refurbishment within existing NHSGGC Premises shall comply with the requirements of this Policy and the Written Scheme and Operational Procedures for managing water safety including particularly, The Control of Legionella, Hygiene, 'Safe' Hot Water, Cold Water and Drinking Water Systems';
- Ensuring all works are formally commissioned and handed over to the respective **LAP(W)** in compliance with the handover protocol for water as identified in the Written Scheme including but not limited to drawings, changes to schematics, WRAS approval documentation and modified or new risk assessment;
- Ensuring that all physical and control interfaces with existing Water Systems for new and refurbishment works shall be safely designed, installed, commissioned in a pre-planned, safe and effective manner particularly any derogations or deviations from applicable guidelines;
- Ensure, as **DRP(W)P** that Capital works modifications to installations in

NHSGGC Premises can only be implemented following completion of **Form (025)**. This form should be completed by the Designer and then signed by **Designer, AP(W)P, DRP(W)P** and **LAP(W)**.

- Formal handover to **LAP(W)** should be implemented via **Form (029)** Record form for acceptance of work to be conducted and confirmation of work completed on a water system; This form should be completed by **AP(W)P** and signed as accepted by **DH(W)** for **AP(W)P** and **LAP(W)**.
- Included in **Form (029)** is the requirement to complete the Confirmation of work completed and acceptance section. This section should be signed by the **Designer, AP(W)P** and **LAP(W)**.
- Liaise closely with other professionals to ensure consistency in application of Control Measures and other procedures designed to allow legislative and statutory compliance, comprehensively in all NHSGGC Premises;

A2.10 Site Manager Operational Estates (SMOE) – Deputy Responsible Person(Water), DRP(W)

The Site Manager Operational Estates RP role shall be formally appointed in writing by the **CRP(W)**. They will be nominated in writing by the **CRP(W)** and signed by the **DP(W)** and/or **DDP(W)**;

The **DRP(W)** responsibilities include:

- Identifying and ensuring the efficient formal record of relative Water System risks and raising those considered appropriate to the **RP(W)** and the **SWSSG**;
- Provide formal reports to the **SWSSG** assuring the **RP(W)** that the Board's statutory responsibilities relating to Water Systems, in relative NHSGGC Premises, are being safely and appropriately discharged;
- Participate in a Compliance defined training programme for this role to maintain personal knowledge and a level of expertise allowing the efficient discharge of the **DRP(W)** responsibilities;
- Identify to the **SWSSG** a risk-based prioritisation of necessary resources required to effectively manage and control risks arising from the management of Water Systems to an acceptable level;
- Effectively manage and control identified risks arising from the Water Systems in the relative locations of the NHSGG&C Premises, to an acceptable level, as far as reasonably practicable;
- Ensuring the implementation of all 'Statutory Instruments & Mandatory Guidance' related to Water Systems, (see examples in section, 'Guidance', in this policy), and adherence to the NHSGG&C Water Systems Safety Policy at all levels within the relative locations of the Directorate of E&F;
- Ensuring that Estates & Facilities Staff, managed by the **DRP(W)**, through the Directorate management structure, are fully aware of their personal roles and responsibilities and appropriately trained in the statutory and mandatory requirements and standards for the management of safe Water Systems;
- Ensuring Water Systems are operated in accordance with the current guidance, and with the assessed risk of the individual systems under the control of the **DRP(W)**;
- Ensuring water system maintenance records are maintained and kept up-to-date;
- Regularly checking maintenance records;
- Ensuring all work is completed in accordance with the NHSGGC Operational Procedures.

A2.11 Acute Services Directors, HSCP Directors and Corporate Division Directors

NHSGGC Directors and Senior Managers, play an essential role in the safe management of Water Systems, actively ensuring and demonstrating that water safety is embedded within the culture of the organisation. **CRP(W)** will arrange awareness and responsibility training.

The responsibilities of Directors and Senior Managers include:

- Identifying and ensuring necessary formal records are maintained relating to Policies and Operational Procedures for Water Systems and raising any potential risks relating to Water Systems to the **RP(W)** and the **SWSSG**;
- Participate in training to maintain personal knowledge and a level of expertise allowing the efficient discharge of Director and Senior Manager responsibilities;
- Effectively manage and control identified risks arising from the Water Systems in the relative NHSGGC Premises areas of responsibility, to an acceptable level, as far as reasonably practicable;
- Ensuring the implementation of all 'Statutory Instruments & Mandatory Guidance' and Operational Procedures related to Water Systems, (see examples in section, 'Guidance', in this Policy), and adherence to the NHSGGC Water Systems Safety Policy at all levels within the relative NHSGGC Premises areas of responsibility;
- Ensuring that Staff, managed by the Director and Senior Manager are fully aware of their personal roles and responsibilities and appropriately trained in the statutory and mandatory requirements and standards for the management and operation of safe Water Systems;
- Facilitating Staff to allow their timely attendance at Water Safety training at the appropriate frequency, as per the NHSGGC Water Safety Policy and Operational Procedures which underpin this Policy;
- Ensuring Water Systems are operated in accordance with the current guidance, and NHSGGC Operational Procedures;
- Ensuring Water Systems records, including Staff training records, are monitored and kept up-to-date;
- Supporting the **DP(W)** and **DDP(W)** in the development of the Board's overall strategy in relation to the safe management and operation of NHSGGC Water Systems and for ensuring and demonstrating implementation within their areas of responsibility;
- Monitor and actively and effectively correct situations where inaction or actions by Staff put themselves and/or others at risk from actual or potential water safety incidents.

A2.12 Heads of Service (HoS), Departmental Managers (DMs), Clinical Managers (CMs) and Senior Charge Nurses (SCNs)

All managers and SCNs have a responsibility in the safe management of Water Systems, actively ensuring and demonstrating that water safety is sufficiently embedded in their departments, and for the safe, day to day management of facilities, Staff or services, and/or premises. **CRP(W)** will arrange awareness and responsibility training.

Water safety responsibilities that include:

- Familiarise themselves with the NHSGGC Water Safety Policy and local control measures including any water risk assessments for their area(s) of responsibility;
- Ensuring that persons in the department, clinic or ward are fully aware of their responsibilities and duties in respect of Water Safety, in particular, the action required of them should the area be defined as High Risk, listed in the site-specific Water Safety Written Scheme and Operational Procedures;
- Ensure that persons in the department, clinic or ward are fully aware of the 'Infrequently Used Outlets' definitions and Operating Procedure which underpins the NHSGGC Water Safety Policy;
- Actively promoting Water Safety within the department or ward by maintaining good housekeeping within the department or ward at all times, ensuring that any flushing or documentation as described in the Water Safety Written Scheme and Operational Procedures documentation is completed on time ;
- Responding appropriately to any water safety concerns of persons in the department, clinic or ward;
- Encouraging their staff and themselves to promptly report any breaches in the water system, such as water ingress, leaks etc. to estates;
- Nominating a responsible person to complete the Monthly 'Infrequently Used Outlets' Audit for each area, forwarding a copy to the Site Maintenance/Estates Manager, thereby assisting NHSGGC to consistently comply with its statutory and mandatory obligations;
- Ensuring that action is taken on a daily basis to address any access issues identified within the Cleaning Compliance Checklist Sign Off documentation retained in the Facilities Folder;
- Liaising with the Estates Department as required and in particular when outlets cannot be flushed e.g. broken so actions can be taken promptly.
- Ensure a flushing regime is place in accordance with specific duties under SHTM Guidelines (e.g. Clinical, Non-Clinical, Facilities, Domestics etc.)
Ensure part empty wards or areas, have an appropriate flushing regime in place in accordance with SHTM guidelines (e.g. Clinical, Non-Clinical, Facilities, Domestics etc.)

A2.13 Authorised Person's (Water) AP(W)P (Capital or Minor Works)

The **AP(W)P**, has the key role and will be specifically qualified, trained and experienced to allow the efficient discharge of their responsibilities. **AP(W)P** will be recommended by the **AE(W)** for appointment by the **CRP(W)**. This role can be outsourced for projects if resource internally is unavailable, however must still be signed of to work on projects.

The **AP(W)P** will also be responsible for establishing and formally appointing a sufficient number of Competent Persons (Water), **CP(W)**, to carry out various modifications to the Water Systems.

The **AP(W)P** will ensure all **CP(W)** managed by the **AP(W)P** are suitably trained, and formally engaged competent contractor(s).

The responsibilities of the **AP(W)P** include:

- Ensuring that delegated projects comply with all NHS GG&C policy and procedures.
- Identifying and ensuring the efficient formal record of relative Water System risks and raising those considered appropriate to the **DRP(W)P** for projects or **CRP(W)** for Minor Works;
- Provide formal reports to the **DRP(W)P** for Capital or **CRP(W)** for Minor works assuring the **DP(W)** and **DDP(W)** that the Board's statutory responsibilities relating to Water Systems, in relative locations, are being safely and appropriately discharged for projects;
- Participate in a Compliance defined training programme for this role to maintain personal knowledge and a level of expertise allowing the efficient discharge of the **AP(W)P** responsibilities;
- Identify to the **DRP(W)P** for Capital or **CRP(W)** for Minor works a risk-based prioritisation of necessary resources required to effectively manage and control water system risks arising from the Water Systems within the scope of the project, to an acceptable level;
- Ensure during projects that risks are effective for the Water Systems in the relative locations of the NHSGGC Premises, to an acceptable level, as far as reasonably practicable during the project duration e.g. construction water safety plan;
- Ensuring during projects the implementation of all 'Statutory Instruments & Mandatory Guidance' related to Water Systems, (see examples in section, 'Guidance', in this Policy), and adherence to the NHSGGC Water Systems Safety Policy at all levels within the relative locations of the Directorate of Estates & Facilities;
- The **AP(W)P** will also be able to demonstrate:
 - o Successful completion of an appropriate professional course;
 - o A sufficient level of professional experience;
 - o Evidence of knowledge and skills relating to Water Systems;
- Participate in completion of :-
 - o **Form (025)** Design checklist for alterations to water systems ;
 - o **Form (029)** Record form for acceptance of work to be conducted and confirmation of work completed on a water system;

A2.14 Authorised Person's (Water) AP(W)

Including :-

Operational Estates – Estates Managers, Estates Supervisors etc.

The **AP(W)**, has the key operational role and will be specifically qualified, trained and experienced to allow the efficient discharge of their responsibilities. **AP(W)** will be recommended by the **AE(W)** for appointment by the **CRP(W)**.

Important elements of an **AP(W)** role are the comprehensive maintenance of formal records and the necessary quality of service and maintenance of systems to ensure their safety and integrity as detailed within the Written Scheme.

The **AP(W)** will also be responsible for establishing and formally appointing a sufficient number of Competent Persons (Water), **CP(W)**, to carry out maintenance and operational Procedures on Water Systems.

The **AP(W)** will ensure all **CP(W)** managed by the **AP(W)** are suitably trained, competent NHSGGC employees or formally engaged competent contractor(s).

Larger sites may require more than one **AP(W)**. Where more than one **AP(W)** is operating on a site, the **CRP(W)** will appoint one **AP(W)** to take a lead role **LAP(W)** ensuring effective, clear, unambiguous communications, with the purpose of safely discharging responsibilities and avoiding confusion and duplication.

The responsibilities of the **AP(W)** include:

- Identifying and ensuring the efficient formal record of relative Water System risks and raising those considered appropriate to the **RP(W)**;
- Provide formal reports to the **RP(W)** and **DRP(W)** assuring the **CRP(W)**, **DP(W)** and **DDP(W)** that the Board's statutory responsibilities relating to Water Systems, in relative locations, are being safely and appropriately discharged;
- Participate in a Compliance defined training programme for this role to maintain personal knowledge and a level of expertise allowing the efficient discharge of the **AP(W)** responsibilities;
- Identify to the **RP(W)**, **DRP(W)**, **CRP(W)**, **DP(W)** and **DDP(W)** a risk-based prioritisation of necessary resources required to effectively manage and control water system risks arising from the Water Systems to an acceptable level;
- Effectively manage and control identified risks arising from the Water Systems in the relative locations of the NHSGGC Premises, to an acceptable level, as far as reasonably practicable;
- Ensuring the implementation of all 'Statutory Instruments & Mandatory Guidance' related to Water Systems, (see examples in section, 'Guidance', in this Policy), and adherence to the NHSGGC Water Systems Safety Policy at all levels within the relative locations of the Directorate of Estates & Facilities;
 - Ensuring that estates staff, managed by the **AP(W)**, through the Directorate management structure, are fully aware and appropriately trained in the 'Statutory Instruments & Mandatory Guidance' and standards for the provision and maintenance of safe Water Systems;
- The **AP(W)** will also be able to demonstrate:
 - o Their application through familiarisation with the system(s) they are

- responsible for and the successful completion of an appropriate professional course;
 - o A sufficient level of professional experience;
 - o Evidence of knowledge and skills relating to Water Systems;
- Review and formally acceptance all installations, adoptions and modifications prior to implementation, engage with **RP(W)**, **RP(W)P** **DRP(W)P**, **DRP(W)** and/or **AE(W)** as required with respect to the scale, complexity and/or associated risks guidance.
- Participate in completion of :-
 - o **Form (025)** Design checklist for alterations to water systems ;
 - o **Form (029)** Record form for acceptance of work to be conducted and confirmation of work completed on a water system;

Appendix 3 – A3.0 Definitions and Acronyms

A3.1 Definitions

A3.1.1 Cleaning Compliance Checklist

A formal checklist of cleaning within the ward or department, signed off by the person in charge of the area confirming satisfaction of compliance with cleaning standards

A3.1.2 Control Measures

Considered, deliberate strategies, actions and activities employed, or stopped, which are designed to remove, reduce or mitigate risks that may diminish the ability to deliver safe and effective healthcare

A3.1.3 Domestic Cold Water

Cold potable water, either from water mains or storage systems, used by people for washing and drinking etc.

A3.1.4 Domestic Hot Water

Tempered Water for use by people for washing and bathing

A3.1.5 Engineering High Risk areas

The 'Engineering High Risk areas' are:

- In Water Systems treated with biocides, e.g. CLO2;
- Where water is stored;
- In water systems where the control levels of the treatment regime, e.g. temperature or disinfectant concentrations are not being consistently achieved or frequently vary from recommended levels;
- In water systems suspected or identified in a case or outbreak of Legionellosis where it is probable the Incident Control Team will require samples to be taken for analysis;
- In water systems suspected or identified in a case or outbreak linked to other potential water borne Pathogens where it is probable the Incident Control Team will require samples to be taken for analysis;
- In areas which have been identified within the current Water Safety Risk Assessment as being of a risk.

A3.1.6 Facilities Folder

A folder, held as documentary evidence and a formal record of procedures at ward / department level.

A3.1.7 Guidance / Mandatory Guidance

Guidance, policies, operational procedures/protocols and good industry practice etc. Guidance can be varied if the variation can be defended. Where Guidance is 'mandated' within general industry and in the NHS in Scotland, it becomes 'Mandatory Guidance' and may be referred to within Statutory Instruments as an 'Approved Code of Practice (ACOPs).

A3.1.8 High Risk Clinical Areas

- The ARHAI definition of High Risk (of infection) units are:
 - Haematology
 - Oncology
 - BMT

- Stem cell transplant units
- Neonatal Units
- Paediatric ICUs
- Adults ICUs
- Any other care areas where patients are severely immunocompromised through disease or treatments*(Renal, CF Units, ID).

A3.1.9 Infrequently Used Outlets

Water Systems' appliances that are used infrequently, as defined in 'Infrequently Used Outlets' definitions and Operating Procedure.

A3.1.10 NHSGGC Premises

All Hospitals, Health Centres, Clinics and other Properties, General Practice, Dental and other Surgeries, owned and or operated by NHSGGC where healthcare is delivered/provided to patients.

A3.1.11 Other Risk Systems

The following locations, systems and items of plant will have specific Control Measures applied to reduce the risk of infection.

- ultrasonic humidifiers/foggers
- spray humidifiers
- air washers, wet scrubbers, particle and trivial gas scrubbers
- water softeners
- emergency showers, eyebaths and face wash fountains
- sprinkler and hose reel systems
- spa pools
- whirlpool baths
- hydrotherapy pools
- birthing pool
- horticultural misting systems
- vehicle washers including automatic washers for cars, buses, lorries and railway rolling stock
- powered dental equipment
- fountains and decorative water features including those on display for sale
- non-disposable nebulisers used for respiratory therapy
- industrial effluent treatment plants
- irrigation systems
- fire, dust and odour suppression systems
- clinical wash-handbasins, drain outlets and connections
- wet drainage sump
- chilled beams
- cardiac heaters / coolers
- ECMO

A3.1.12 Incident Management Process SOP

The document [Incident Management Process Framework V1 - NHSGGC](#) provides a definition of an outbreak /incident and recommended actions. The actions include when to set up an incident meeting, who should be invited (including external expertise) and a sample agenda. It also provides guidance on communications within the HB, ARHAI and to the Scottish Government.

A3.1.13 Pathogens

Microorganisms that are, or may become, harmful to people.

A3.1.14 Risk Reduction Strategies

Risk Reduction strategies/procedures can include, but are not limited to:

- Policy awareness and implementation;
- Risk assessment both generic and specific;
- Training, e.g. WH001 Legionella Management HTM 04-01 and WH003 Legionella Control within Hot and Cold Water Systems used in NHSGGC for **APs(W)**, **DRP(W)**, **RP(W)** etc.;
- The development, approval and implementation of local procedures;
- Reporting and recording;
- Evaluating effectiveness of risk reduction strategies/procedures;
- Reviewing in the light of experience, e.g. looking at incident investigations and inspection reports. Do they show improvement?;
- Re-train Staff if required, reading available policies, strategies and procedures;
- Review clinical and workplace risk assessments after reports of any adverse events;
- Implementation of risk reduction strategies as defined by the findings of the risk assessment for the NHSGGC buildings;
- Implementation of a formal review and/or audit process of the risk reduction procedures;
- Implementation of contractor audit and review procedures;
- Review and update Written Scheme and water action plan every 2 years or following material system amendments/change of use.

A3.1.15 Sector

A designated area of NHSGGC that is a recognised Sector of NHSGGC Premises.

A3.1.16 Staff

People employed by NHSGGC on various contracts and will include locum, bank, volunteers etc.

A3.1.17 Statutory Instruments

Laws, regulations etc. that have legal standing and are applied by enforcing authorities.

A3.1.18 Water Systems

All domestic hot and cold water systems, water-dispensing equipment as well as defined, 'at risk' water-carrying systems across all NHSGGC premises.

A3.1.19 Water Dispensing Equipment

Equipment or machinery dispensing water, in all forms and states, for consumption and or use by people, e.g. Water coolers, Ice-making machines etc.

A3.1.20 Written Scheme & Operational Procedures

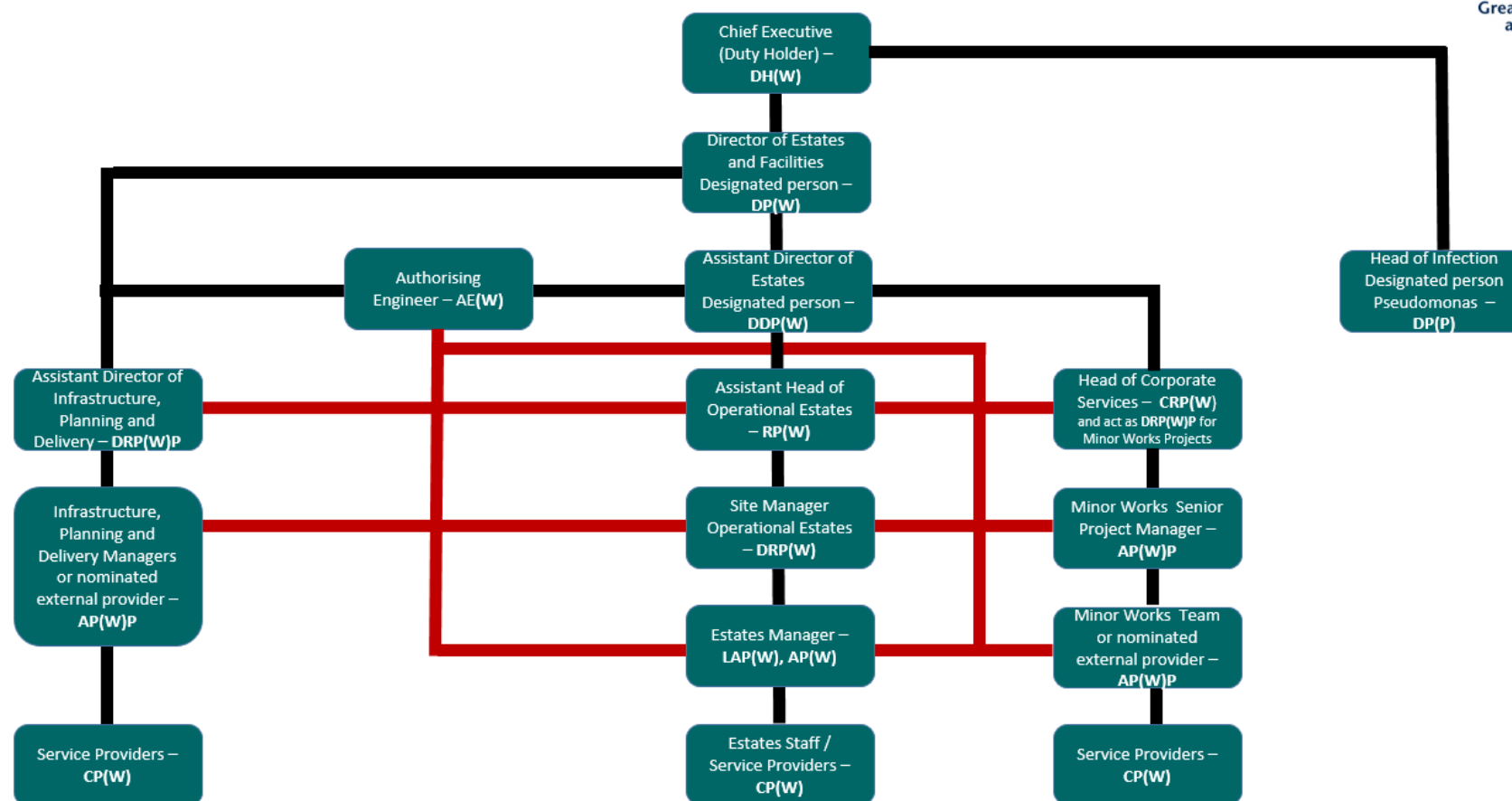
A document written to record and communicate, in detail, how responsibilities relating to the safe operation and management of Water Systems will be discharged and will describe who will have responsibilities for their safe and effective implementation

A3.2 Acronyms

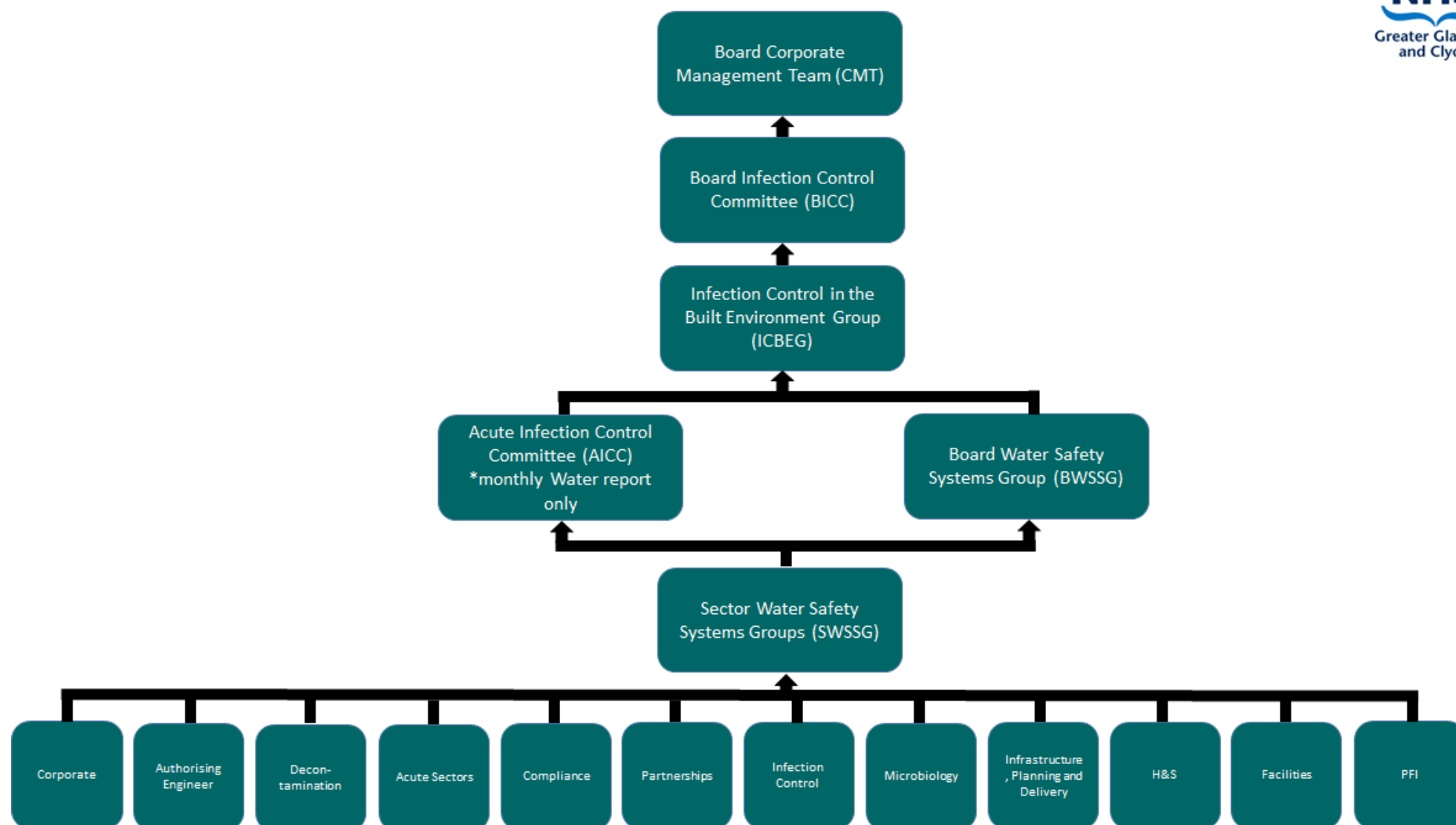
ACoP	Approved Code of Practice
AE(W)	Authorising engineer (Water)
AP(W)	Authorised Person (Water)
AP(W)P	Authorised Person (Water) Projects or Minor Works
ARHAI	Antimicrobial Resistance and Healthcare Associated Infection
BWSSG	NHSGGC Water Systems Safety Group
BICC	Board Infection Control Committee
BS	British Standards
CAFM	Computer Aided Facilities Management
CE	Chief Executive
CIBSE	Chartered Institute of Building Services Engineers
CHP	Community Health Partnership(s)
CMT	Corporate Management Team
COSHH	Control of Substances Hazardous to Health
CP(W)	Competent Person (Water)
CRP(W)	Corporate Responsible Person (Water)
DCW	Domestic Cold Water
DDP(W)	Deputy Designated Person (Water)
DE&F	Director of Estates & Facilities
DHW	Domestic Hot Water
DH(W)	Duty Holder (Water)
DIPC	Director Infection Prevention and Control
DP(P)	Designated Person (Pseudomonas)
DP(W)	Designated Person (Water)
DPP(W)	Designated Deputy Person (Water)
DRP(W)	Deputy Responsible Person (Water)
DRP(W)P	Deputy Responsible Person (Water) for Projects or Minor Works
E&F	Estates & Facilities
ECMO	Extracorporeal Membrane Oxygenation
FORM 025	SHTM Design checklist form
FORM 029	SHTM Acceptance form
HIIAT	Hospital Infection Incident Assessment Tool
HIORT	Hospital Infection Incident Reporting Template
ARHAI	Health Protection Scotland
HSE	The Health & Safety Executive
ICD	Infection Control Doctor
ICT	Infection Control Team
IMT	Incident Management Team
LAP(W)	Lead Authorised Person (Water)
LICD	Lead Infection Control Doctor
NIPCM	National Infection Prevention and Control Manual
NHS	National Health Service
NHSGGC	NHS Greater Glasgow & Clyde Health Board
P&CP	Property & Capital Planning
RP(W)	Responsible Person (Water)
RP(P)	Responsible Person (Pseudomonas)
SHTM	Scottish Health Technical Memoranda
SI	Statutory Instruments
SMT	Estates & Facilities Senior Management Team
SMOE	Site Manager Operational Estates
SWSSG	Sector Water Systems Safety Groups
TM	Technical Memorandum

Appendix 4 A4.0 – Governance Structure (by designation)

Governance Water Management – GG&C



Appendix 5 A5.0 – Governance Structure (by governance groups)





QEUH Campus Water Systems

WRITTEN SCHEME

Controlling the risks of exposure to Legionella and other harmful bacteria in
Water Systems

2023 Rev H

Reviewed by: E. Smith (RP)
K. Clarkson (DRP)
M. MacMillan (Lead AP)
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M. Feeney (Compliance Manager)

An electronic copy of this document is held on the QEUH Shared Drive at folder path:
S:\SCART Compliance\22 Water\Water Written Schemes\

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1.0 GENERAL OVERVIEW

Note 1: No work will be carried out on the water system without the knowledge and written consent of the Authorised Person (Water).

Note 2: This Written Scheme document is to be read in conjunction with the Operational Procedures for the Written Schemes document and should also be read in conjunction with the Control of Water Records document. For any alterations to the Water System this Written Scheme Document is to be read in conjunction with the Guidance for alterations to water systems document.

1.1 Introduction

This document contains six sections which have been derived from the Risk Assessment to aid the design, installation, maintenance and operational mode of all domestic and process water systems within the premises with respect to the likelihood of the proliferation of waterborne micro-organisms. The assessment also considered the risk of infection presented to building users and the general populous at large, and derived a series of risk ratings and appropriate Remedial Actions and Control Measures, which should be implemented to minimise the presented risks. This Risk Assessment was carried out in a manner consistent with the requirements of *BS8580:2010 Water Quality – Risk Assessments for Legionella Control – Code of Practice*, and is reviewed whenever system alterations or operational considerations may effect a change in the risk.

Section 1 contains an Executive Summary of the recommended control measures and corrective actions together with an overview of the QUEH Site layout and accommodation.

Section 2 contains a record of the logbook inspection, details on the location of records, defects, non-compliance issues, correspondence and archived information.

Section 3 provides information on the management structure associated with the control scheme for the water system and clear definitions of responsibilities held by those named, details of training undertaken and a summary of the designated tasks as detailed in section 4.

This section also provides information on the details of the risk assessment values associated with representative outlets, systems and plant items undertaken since 2013. A generic risk assessment for any positive legionella test results within designated Low Risk locations and a description of the installed plant and equipment with associated schematic layout plans for each of the installed water systems within the site is also contained within this section.

Section 4 of the document details the safe operation of the system and all appropriate Maintenance Procedures (Control Measures) which were derived from the Risk Assessment and recommendations within NHS Greater Glasgow and Clyde Water Systems Safety Policy.

This section of the document contains a task description with associated record (Log) sheet relating to these activities. It should be noted however, that in certain circumstances, specialist contractors are required to implement some Control Measures, and records pertaining to these activities may be held under separate cover. Such activities would typically include those associated with chemical water treatment regimes and drinks vending machines sanitising maintenance.

Refer to Section 2 for the location of records and archived information associated with the maintenance procedures and other control measures.

Section 5 contains supporting information relating to the Control Scheme, and should typically include the recording of system alterations or remedial actions together with utilised materials. Ad hoc maintenance activities should also be recorded in this section, such as system sterilisations which may be required from time to time. This section of the document also contains a glossary of supporting publications, where additional information relating to the risks associated with waterborne micro-organisms, and water quality generally, may be found.

1.2 Executive Summary

The purpose of this Written Scheme document is to assist in the correct and safe operation of the water systems within the QEUH Campus. The document outlines the specific roles, responsibilities, training requirements and regular maintenance procedures to be followed in order to ensure compliance with statutory and mandatory guidance.

Risk Assessments for the water services have been carried out on the instruction of the Board Water Safety Group. DMA Canyon Ltd are presently the appointed Water Systems Risk Assessor and have carried out Risk Assessments within all individual buildings on the campus.

Additionally there are two Hydrotherapy Pools in operation on the campus. These are situated within the New Childrens Hospital, and Spinal Injuries Unit. Separate Risk Assessments have been carried out for both of these facilities by a specialist Swimming Pool Risk Assessment provider.

Risk Assessments require to be reviewed and updated to reflect any changes in-use and / or functions that have taken place since the date of the original Risk Assessment or in the event of control measures becoming ineffective, changes in key personnel or in the event of a case of legionnaires disease / legionellosis associated with the water system. Guidance on the Risk Assessment review procedure is given in Appendix 3.

All documentation and log sheets used to record maintenance activities follow the format contained within guidance document SHTM 04-01 Part G: *Operational Procedures and Exemplar Written Scheme*.

1.3 Overview of Site Accommodation and Premises

The main new-build Adult Hospital building comprises of 12 stories, with the basement housing FM areas and the new-build Childrens Hospital comprising of 4 stories.

On the retained estate there are individual buildings comprising of Neurology, Neurosurgery, Spinal Injuries Unit, PDRU, Maternity, Neo-Natal, Podiatry and Westmarc stand alone with the Teaching and learning and office block new additions.

Full descriptions and information on the individual written schemes are available in the Log book/Risk Assessment folders for each building.

The building codes are as follows:

AC – Minor Injuries Unit
 AQ – Acute Medical Block (AMB)
 AS – Central Medical Block (CMB)
 BC – Neurosurgical Block (INS)
 BL – Maternity
 BW – Neurology
 DA – Spinal Injuries
 DB – Maternity Day Surgery
 DD – Podiatry
 DE – Physically Disabled Rehabilitation Unit (PDRU)
 DI – WestMARC
 EA – Neo Natal
 FA – Multi Storey Car Park 2
 FB – Multi Storey Car Park 1
 GA – Laboratory Medicine
 GB – Energy Centre
 HA – Adults Hospital
 HB – Childrens Hospital
 IA – Teaching & Learning Centre
 IB – Office Building
 IC – Imaging Centre of Excellence (ICE)

NOTE: ICE building is owned by University of Glasgow (UoG). Facilities management and maintenance is carried out under contract by NHS GG&C on behalf of UoG.

Langland Building is managed via PFI by Serco and MDU is managed via Vanguard.

See Site Map in Appendix 1

2.0 RECORDING

2.1 Written Scheme Inspection Records

Anyone inspecting this written scheme (either as part of the Management Control System or otherwise) is invited to make an entry in this inspection record. **Under no circumstances may this Written Scheme or any part of it be removed from site.**

Date/Time	Comments	Signature	Position
June 2018	Written scheme has been reviewed and re-formatted into this current form (Revision D) by Colin Purdon as part of the water systems review.		Site Manager Operational Estates
Feb 2019	Written scheme has been reviewed and re-formatted into this current form (Revision E) by Colin Purdon as part of the water systems review.		Interim Sector Estates Manager (Deputy Responsible Person)
May 2019 Rev B	Written scheme has been reviewed and re-formatted into this current form (2019 Rev A) by Colin Purdon as part of the water systems review.		Interim Sector Estates Manager (Deputy Responsible Person)
October 2020 Rev C	Written scheme has been reviewed to reflect changes to staff personnel and a review of procedures.		Site Manager Operational Estates
May 2021 Rev D	Written scheme has been reviewed to reflect changes to staff personnel and a review of procedures.		Site Manager Operational Estates
Aug 2022 Rev E	Written scheme has been reviewed to reflect changes to staff personnel and job titles. Additionally modified procedures for WS01 (Page 103)		Site Manager Operational Estates
Jan 2023 Rev F	Minor changes to words regarding daily flushing		Site Manager Operational Estates
May 2023 Rev G	Index section 2 missing now added back in		Site Manager Operational Estates
Oct 2023 Rev H	Inclusion of Vanguard who carry out maintenance of the MIU Unit and minor changes to wording. Also added fixed shower head disinfections. Changed Appendix 2 to reference WQS014		Site Manager Operational Estates

Additional entries should be completed on a separate sheet and inserted in Section 2.1 with this sheet.

Details of any correspondence, including Risk Assessments/Reviews and Ongoing Monitoring Reports, relating to water services should be entered on the sheet below, recording where held and by whom.

[illegible]

Version 2023 Rev H
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2.3 Non-Compliance Issues and Fault Detail Log

Record Form 004

All non-compliance and fault details in relation to the individual systems in each building must be recorded on Record Form 004 and brought to the attention of the Water Systems Lead AP as soon as possible. This process ensures that all non-compliance issues are documented, managed effectively and tracked through to completion and close –out of the issue. Copies of Record Form 004 are to be stored within the shared drive. SCART Compliance/22 Water/.

The process for sampling out of specification is documented in WQS – 017 Procedures in the event of out of specification sample for Legionella and other monitored bacteria, moulds etc.

2.4 Archived Information Record Sheet

All records associated with the management or maintenance procedures within this Written Scheme should be kept for a period of five years after they are no longer current. Records should be kept locally within the main Estates Office. The details of any archived information held separately in secure storage should be recorded in the table below.

Date	Procedure or Record Reference	Description	Held By/Location

Additional entries should be completed on a separate sheet and inserted in Section 2.4

2.5 Equipment Calibration Records

All equipment used for the measurement of temperatures should be calibrated at least annually to ensure the accuracy and consistency of the recording procedures.

Calibration certificates for handheld thermometers are held in hard copy within the QEUH Campus Log Book suite in the main estates office. Electronic copies are also held on the QEUH Shared Drive>Water Quality folder.

3.0 MANAGEMENT ARRANGEMENTS

3.1 Roles & Responsibilities

NHS Greater Glasgow & Clyde Chief Executive – (Duty Holder)	The Chief Executive has ultimate responsibility / accountability for water system safety within NHSGG&C. The responsibilities of the Chief Executive include: • Responsibility for implementation of the relevant mandatory and statutory elements contained within the Health & Safety Commissions Approved Code of Practice and Guidance “Legionnaires Disease. The control of Legionella bacteria in water systems” L8 (ACOP L8), SHTM04-01: The control of Legionella, hygiene safe” hot water, cold water and drinking water systems and CEL 08(2013) water sources and potential risk to patients in high risk units – revised guidance. The implementation of Guidance for neonatal units (NNU’s) (levels 1, 2 & 3) adult and paediatric intensive care units ICU’s in Scotland to minimise the risk of Pseudomonas aeruginosa infection from water. • Ensuring that adequate resources are provided to meet the Water Systems Safety requirements of NHSGG&C estate. Ensuring that the Water Systems Safety Policy is being implemented at all levels. • Reviewing and monitoring the operation of the Water Systems Safety Policy through the Board Corporate Management Team and ensuring that clear guidelines are provided for this tasked with compliance of legislative and statutory standards. • Appointing the Designated person (Pseudomonas) and Designated Person (Water) to assist in the execution of these responsibilities, who for NHSGG&C are the Infection Control Manager (Pseudomonas) and the Director of Facilities (Water).
NHS Greater Glasgow & Clyde Director of Estates and Facilities – (Duty Holder)	The Director of Estates and Facilities is the Designated Person (Water). They shall be responsible for: • Ensuring that Estates and Facilities staff, through the general management structure is fully aware of the current statutory and mandatory requirements and standards for the provision and maintenance of safe water systems. • Ensuring with the Responsible Person (Pseudomonas) that the Water System Safety Policy is regularly reviewed and updated. • Co-Chair the NHSGG&C Water Systems Safety Group. • Appointing in writing the Responsible Person (Water) at sector level and Deputy Responsible Person(s) (Water) at site level. This shall be the Sector Estates Manager (SEM) and the relevant Site Manager Operational Estates (SMOE)/Site Estates Manager within the Facilities Directorate management structure.

3.1 Roles and Responsibilities (cont)

NHS Greater Glasgow & Clyde Director of Estates and Facilities – (Assistant Duty Holder)	The Assistant Director of Estates and Facilities is the Assistant Designated Person (Water). They shall be responsible for assisting in : • Ensuring that Estates and Facilities staff, through the general management structure is fully aware of the current statutory and mandatory requirements and standards for the provision and maintenance of safe water systems. • Ensuring with the Responsible Person (Pseudomonas) that the Water System Safety Policy is regularly reviewed and updated. • Co-Chair the NHSGG&C Water Systems Safety Group. • Appointing in writing the Responsible Person (Water) at sector level and Deputy Responsible Person(s) (Water) at site level. This shall be the Sector Estates Manager (SEM) and the relevant Site Manager Operational Estates (SMOE)/Site Estates Manager within the Facilities Directorate management structure.
NHS Greater Glasgow and Clyde Infection Control Manager - Designated Person (Pseudomonas)	The Infection Control Manager supported by the Board Infection Control Doctor is the Responsible Person (Pseudomonas). They shall be responsible for: • Ensuring that Infection Control Teams are fully aware of current guidance on Legionella control matters and the minimisation of the risk of Pseudomonas aeruginosa infection from water. • The implementation of Guidance for neonatal units (NNU's) (levels 1, 2 & 3) adult and paediatric intensive care units ICU's in Scotland to minimise the risk of Pseudomonas aeruginosa infection from water. • Ensuring with the Designated Person (Water) that the Water System Safety Policy is regularly reviewed and updated. • Co-Chair the NHSGG&C Water Systems Safety Group. • Appointing in writing the Responsible Person(s) (Pseudomonas) at sector level. This shall be the relevant Infection Control Doctor.
Assistant Head of Estates - Responsible Person (Water)	The Assistant Head of Estates will be appointed as the Responsible Person (Water) at Sector level by the Director of Estates and Facilities in writing. The Sector Estates Manager is responsible for: • Ensuring the effective maintenance of engineering controls installed for the purposes of controlling water systems. • Ensuring that written schemes and risk assessments are in place and reviewed regularly. • Devising and maintaining procedures to ensure the quality of water on premises is maintained. • Ensuring operational procedures are carried out and documented. • Ensuring records are kept of all water systems and their purpose, giving locations recording and maintaining within the Boards estates management system. • Liaise closely with other professionals to ensure legislative and statutory compliance is maintained by the Board.

3.1 Roles and Responsibilities (cont)

3.1 Roles and Responsibilities (cont) Authorising Engineer (AE)	An Authorising Engineer acts as an independent professional advisor to the healthcare organisation, appointed by the organisation with a brief to provide services in accordance with Scottish Health Technical Memorandum (SHTM) guidance. He will be appointed in writing by the Director of Facilities/General manager (Estates). The Authorising Engineer acts as an assessor, making recommendations for the appointment of Authorised Persons, monitoring the performance of the service and providing an annual audit to the organisation's Designated Person.
Authorised Person (Water)	The Authorised Person (water) has the key operational responsibility for the service, qualified, sufficiently experienced and skilled for the purpose. They will be nominated by the Authorising Engineer and be able to demonstrate • They application through familiarization with the system and attendance at an appropriate professional course; • A level of experience; • Evidence of knowledge and skills. An important element of the Authorised Person (Water) role is the maintenance of records, quality of service and maintenance of system safety (integrity). The Authorised Person (Water) will also be responsible for establishing and maintaining the roles and validation of Competent Persons (Water) who shall be suitable trained employees of the organisation or appointed contractors. Larger sites may require more than one Authorised Person (Water) for a particular service. The Authorised Person (Water) will be appointed by the General Manager – Capital Planning.

3.1 Roles and Responsibilities (cont)

Head of Capital Planning (Water)	The Head of Capital Planning will be appointed as the Deputy Responsible Person (Water) at Board level by the Director of Estates and Facilities in writing. The General Manager for Capital Planning is responsible for: • Ensuring that any new works undertaken or refurbishment within existing premises shall comply with the requirements of this Policy and the Written Scheme and Operational Procedure for managing Water Safety including The control of <i>Legionella</i>, hygiene, 'safe' hot water, cold water and drinking Water systems and The implementation of Guidance for neonatal units (NNU's) (levels 1, 2 & 3) adult and paediatric intensive care units ICU's in Scotland to minimise the risk of <i>Pseudomonas aeruginosa</i> infection from water. • Ensuring that all potential interfaces between an operating system and new and refurbishment works shall meet the approval of the Responsible Person (Water) and Authorised Person (water) as to methodology for making that interface. • Ensuring that any work involving the installation of water services or equipment requiring a water supply shall follow the guidance in SHTM 04-01 and HSE document L8 and shall be certified by the design Engineer as to that compliance. • Ensuring that any works which will affect an operational water service will be discussed with the Estates Authorised Person (Water) prior to arranging that work.
Site Estates Manager Deputy Responsible Person (Water)	The Site Manager Operational Estates (SOME) shall be appointed in writing by the Director of Facilities/General Manager (Estates) in writing as the Deputy Responsible Person (Water) and will also act as the Designated Person Water in the absence of the Designated Person (Water). The Site Maintenance Manager/Site Estates Manager is responsible for: • Ensuring all staff conducting water system maintenance are competent to do so. • Ensuring water system maintenance records are maintained and kept up-to-date. • Regularly checking maintenance records. • Ensuring all work is completed in accordance with the NHS GG&C Estates Procedures.

3.1 Roles and Responsibilities (cont)

Acute Services Directors CH(C)P Directors and Corporate Division Directors	As Senior Managers, NHSGG&C Directors play an intrinsic role in ensuring that water safety is embedded within the culture of the organisation. The responsibilities of Directors include: - Supporting the designated person (Water) and (Pseudomonas) in the development of the Board's overall strategy in relation to water safety and for ensuring implementation within their areas of responsibility; - Ensuring that all staff are made aware of their requirement to attend Water Safety training at the appropriate frequency, as per the NHSGG&C Water Safety Policy and Operational Procedures which underpin this by facilitating staff release from duties to attend training; - Supporting action to address staff who put themselves and/or others at risk from a real or potential water safety incident.
Heads of Service, Departmental Managers, Clinical Managers, Senior Charge Nurse's	All managers who have a responsibility for the day to day management of facilities, staff or services, and/or premises, have water safety responsibilities that include: - Familiarise themselves with the NHSGG&C Water Safety Policy and local control measures including any water risk assessments for their area(s) of responsibility; - Ensuring that persons in the department, clinic or ward are fully aware of their responsibilities and duties in respect of Water Safety, in particular, the action required of them should the area be defined as High Risk by the local Water Safety Group - Ensure that persons in the department, clinic or ward are fully aware of the Infrequently Used Outlets definitions and Operating Procedure which underpins the NHSGG&C Water Safety Policy
Heads of Service, Departmental Managers, Clinical Managers, Senior Charge Nurse's (cont)	- Actively promoting Water Safety within the department or ward by maintaining good housekeeping within the department or ward at all times, ensuring that any flushing or documentation as described in the Water Safety Written Scheme and Operational Procedures documentation is completed on time - Responding appropriately to any water safety concerns that persons in the department, clinic or ward have; - Nominating a responsible person to complete the Monthly Infrequently Used Outlets Audit for each area, forwarding a copy to the Site Maintenance Manager, thereby assisting NHSGG&C to meet its statutory and mandatory requirements; - Ensuring that action is taken on a daily basis to address any access issues identified within the Cleaning Compliance Checklist Sign Off documentation retained in the Facilities Folder. - Liaising with the estates department as required

3.1 Roles and Responsibilities (cont)

Legionella Risk Assessor	The NHS Board appoints in writing a Legionella Risk Assessor with terms of reference to provide services in accordance with BS 8580, SHTM 04-01 and HSE guidance under this Policy. He/she will be appointed in writing by the Director of Facilities/General Manager (Estates)
Competent Person (Water)	The Competent Person (Water) provides skilled installation and/or maintenance of the specialist service. He/she will be appointed, or authorised to work (if a contractor) by the Authorised Person Water). He/she will demonstrate a sound trade background and specific skill in the specialist service, working under the direction of the Authorised Person (Water) in accordance with operating procedures, policies and standards of the service.
Maintenance Tradesperson	A Maintenance Tradesperson is someone who has sufficient technical knowledge and the experience necessary to carry out maintenance and routine testing of the water supply, storage and distribution system.
Installer	The Installer is the person or organisation responsible for the provision of the water storage and distribution system.
Contractor	A Contractor is the person or organisation designated by management to be responsible for the supply, installation, validation and verification of hot and cold water services, and for the conduct of the installation checks and tests in relation to the control of <i>Legionella</i>. The NHS Board will expect potential contractors to have suitable qualifications (for example companies/individuals who are members of the <i>Legionella</i> Control Association).

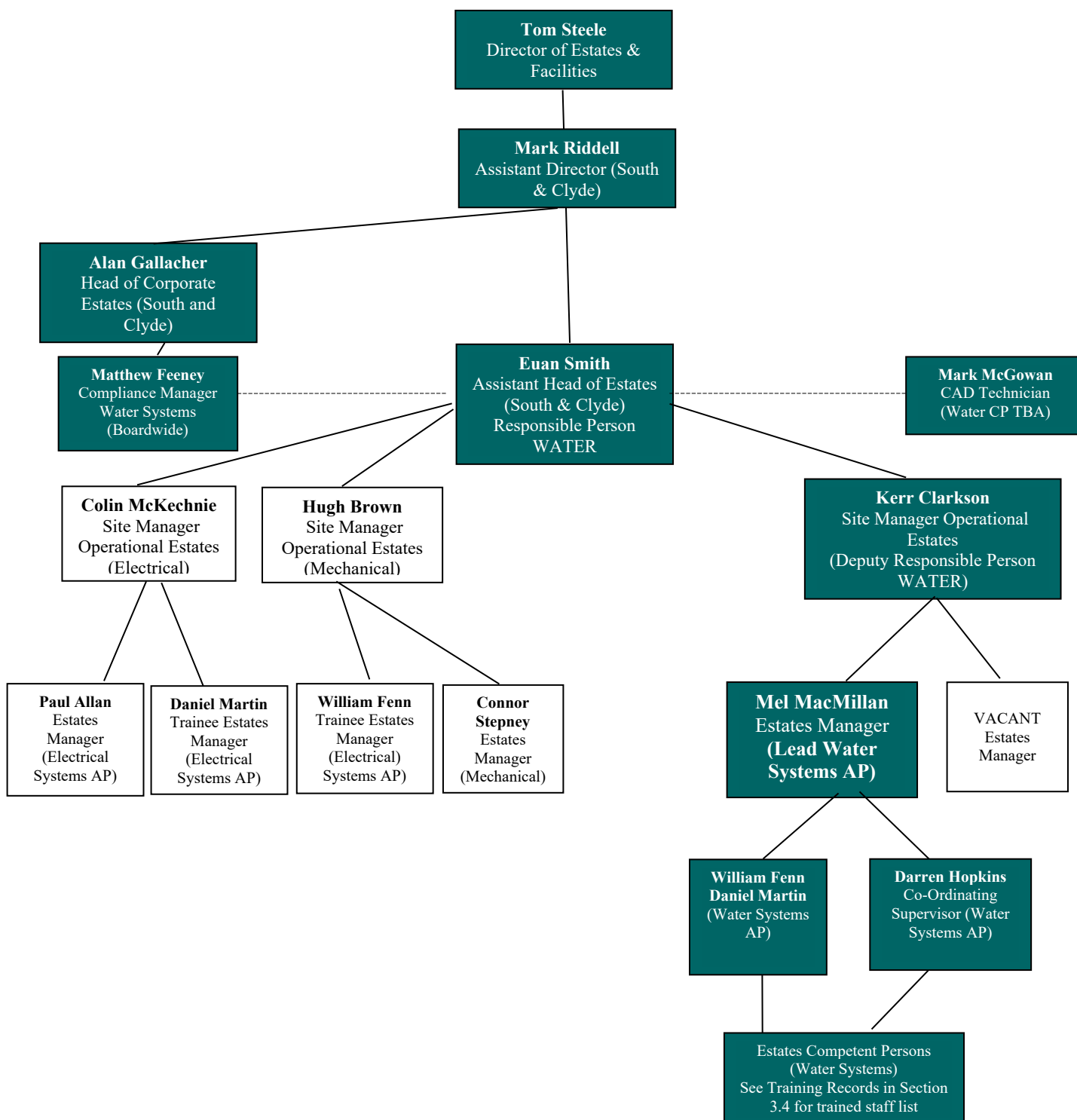
3.1 Roles and Responsibilities (cont)

NHS GG&C South Sector (QEUH) Hierarchy Appointment Table

Designation	Position	Name Tel Number
The Duty Holder	Chief Executive	Jane Grant
Designated Person (Water)	Director of Facilities/General Manager (Estates)	Tom Steele
	Assistant Director (Estates)	Mark Riddell.
Authorising Engineer (Water)	AE	Dennis Kelly [REDACTED]
Legionella Risk Assessor	DMA Water Services Ltd	David Watson Mike Kinghorn [REDACTED]
Responsible Person (Water)	Sector Estates Manger (South)	Euan Smith
Deputy Responsible Person (Water)	Site Manager Operational Estates (Building)	Kerr Clarkson
Deputy Responsible Person (Water)	Head of Capital Planning	James Huddleston
Lead Authorised Person	Estates Manager	Mel MacMillan
Authorised Persons	Estates Manager Co-ordinating Supervisor Co-ordinating Supervisor Co-ordinating Supervisor	Darren Hopkins Grant Bennet William Fenn Daniel Martin
Competent Persons	CAD Technician	Mark McGowan
Competent Persons	Plumbers/Engineers	See training records in Section 3.4
Others Involved		
Microbiology	Consultant Microbiologist	Alistair Leonard Linda Bagnade Aleksandra Marek
Infection Control	Director Lead Nurse Lead Nurse	Sandra Devine Gillian Bowskill Lynn Pritchard
Public Health		Dr Iain Kennedy
Laboratory Services		Sandra Higgins

3.2 QEUH Estates Staffing

Management organogram for QEUH Estates Dept as of Oct 2019



3.3 Required Maintenance Tasks

The maintenance and management of the water systems throughout the QEUH Campus is undertaken by a combination of both NHS Staff and external Contractors at the frequencies identified in the following tables.

QEUH Management staff manage and oversee the following tasks:

Procedure Reference	Operation(s)	Record Form Ref	Frequency
P1C1	BMS Temperature Monitoring (Carried out by NHS Estates)	Requires new number	Daily
P1CC1A	Manual Temperature Monitoring for calorifiers (different form used ONLY REQUIRED if no BMS Monitoring)	(005a)	Daily
N/A	Filtration Plant Checks (Carried out by NHS Estates)	028c	Twice Daily
WS01	Daily flushing of all outlets (Carried out by NHS Facilities)	-	Daily
WS01	Deluge shower/Eye wash flushing (1 off carried out by NHS Estates and 1 off by DMA)	(026)	Twice Weekly
WS01	Flushing of little used outlets * frequency based on risk (Carried out by NHS Clinical) see page 103	-	Daily or Twice weekly
P1C3	Pump operation/duty rotation (Carried out by NHS Estates)	(028a)	Weekly
P1C4	Temperature Recording of Sentinel Hot and Cold Water Outlets. (Carried out by NHS Estates)	(005c)	Monthly
P1C4	DHW Calorifier and Buffer Vessel Checks (Carried out by NHS Estates)	(005)	Monthly
P1C6	DWS Calorifier, Expansion Vessel Flushing (Carried out by NHS Estates)	(006) (023)	Monthly
P1C12	Showerhead/hose replacement/disinfection (<i>No longer carried out as shower head and hoses replaced quarterly</i>)	(005b)	Quarterly
WS01	Review of Rarely Used Water Outlets and Changes In-Use (As required by NHS Estates)		Quarterly
P1C9	DWS Calorifier / Expansion Vessel Inspection (Carried out by NHS Estates)	(006)	Annually
N/A	Water Services Pipework and Distribution System Checks (Carried out by NHS Estates during calorifier checks, Plant Room checks and by DMA during Tank Room checks)		Annually
N/A	Vibration coupling inspection (Carried out as part of checks on booster pumps) (Carried out by NHS Estates)		Annually
N/A	Carry out review of log books and Written Scheme		Annually (Sep)
N/A	Carry out review of drawings and schematics		Annually (Sep)

3.3 Required Maintenance Tasks (cont)

In addition to the tasks undertaken by NHS directly employed Competent Persons, there are also tasks undertaken by Contractors on a selection of buildings within the campus.

Appointed Service Providers presently undertake the following tasks:

Procedure Reference	Operation(s)	Record Form Ref	Frequency
WS01	Deluge shower/Eye wash flushing (Carried out by DMA)	DMA Records	Twice Weekly
WS01	Flushing Deadlegs and drain valves (Carried out by DMA)	DMA Records	Twice Weekly
WS01	Flushing Intermittently used outlets (Carried out by DMA)	DMA Records	Twice Weekly
	External Water Mains Valve Operation and Flushing Routines		Monthly
PIC4	Temperature and CL02 monitoring of outlets (Carried out by DMA)	DMA Records	Monthly
-	PPM Schedule Monthly Visually inspect chemical delivery system, Check chemical suction and delivery lines for correct operation Chemical level check and refill , Cross check measured ClO ₂ / Chlorite residual test against analyser & Palintest Kit, Check and Adjust controller settings as required (Carried out by ScotMas)	ScotMas Records	Monthly
	PAL Filters on taps outlets (Carried out by DMA)	DMA Records	
	'TMV' and Mixing Valve Sanitation and Maintenance Checks (Carried out by DMA)	Carried out 6 monthly	Quarterly
N/A	TMV/TMT & Thermostatic Shower Disinfection and Function Test (HIGH RISK) (Carried out 6 monthly)		Quarterly
	Shower Head and Flexible Hose Exchange (Carried out by DMA)	DMA Records	Quarterly
	Shower Head and Flexible Hose maintenance e.g. fixed shower heads, bath, eye wash heads etc (Carried out by WATER SERVICE PROVIDER)	DMA Records	Quarterly
WQS 001	HORNE Tap Flow Restrictor Exchange (Carried out by DMA)	DMA Records	Quarterly
	'TMV/TMT' Tap Outlet Sanitisation and Operational Checks (Carried out by DMA)	DMA Records	Six-Monthly
N/A	TMV/TMT & Thermostatic Shower Disinfection and Function Test (Non-HIGH RISK) (Carried out by DMA)	DMA Records	Six-Monthly
-	Maintenance of filtration units (Carried out by Veolia)	Veolia Records	Six-Monthly
-	6 Monthly Visit– All above, plus, Check ClO ₂ gas detector functionality and recording levels, Simulate fault circuitry and alarm on Sentinel Monitor, Change probe electrolyte and cross calibration test, Carry out manual Chlorate & Chlorite validation tests (12 representative outlets), Check water meter operation and report o Electrolyte top up, Probe calibrations (Carried out by Scotmas)	ScotMas Records	Six-Monthly
PIC7	CWST Inspection and Temperature Monitoring (Carried out by DMA)	DMA Records	Six-Monthly

3.3 Required Maintenance Tasks (cont)

	'TMV' Tap Outlet Sanitisation and Operational Checks (Carried out by Vanguard - MIU)	Vanguard Records	<i>Annual</i>
	CWST Inspection (Carried out by DMA)	DMA Records	<i>Annually</i>
	Hot and Cold Tap Outlet Sanitisation and Operational Checks (NOT CARRIED OUT UNLESS ISSUE IDENTIFIED THROUGH SAMPLING)	DMA Records	<i>Annually</i>
-	As per 6 monthly and ClO2 & Chlorite Probe membrane cap replacement, Dosing Pump diaphragm valve replacements, Replace ClO2 gas detector cartridge if required (Carried out by Scotmas)	ScotMas Records	<i>Annually</i>
P1C10	Representative Tap Temperature Monitoring Note all tap temperatures are checked through TMT/TMV maintenance (Carried out by DMA)	DMA Records	<i>Annually</i>
	BMS Sensors (Carried out by Schneider and MCE BMS Providers for respective BMS)	Schneider & MCE records	<i>Annually</i>

3.4 Training Records

The following NHS personnel are certified to have the required ability, experience, instruction, information and training to carry out the work associated with legionella precautions at QEUH Campus.

NAME	POSITION	NATURE OF TRAINING (QUALIFICATION, TRAINING COURSES ATTENDED)	DATE
Euan Smith	Sector Estates Manager RP	Responsible Person Course ENAP City & Guilds Authorised Person ENWS City & Guilds Managing Water Systems	
Kerr Clarkson	Site Manager Operational	WHH01 – Legionella Management for Water Systems SHTM-04 01 WH003 - Legionella Control Within Hot and Cold Water Systems	
Mel MacMillan	Estates Manager Lead AP	WHH01 – Legionella Management for Water Systems SHTM-04 01 WH003 - Legionella Control Within Hot and Cold Water Systems	
Daniel Martin William Fenn	Trainee Estates Managers AP	WHH01 – Legionella Management for Water Systems SHTM-04 01 WH003 - Legionella Control Within Hot and Cold Water Systems	
Grant Bennet Darren Hopkins	Co-Ordinating Supervisor AP	WHH01 – Legionella Management for Water Systems SHTM-04 01 WH003 - Legionella Control Within Hot and Cold Water Systems	

Copies of all relevant training records and appointment letters are held electronically on the QEUH Shared Drive within the folder path “Water Quality>Training and Appointments”.

The results achieved by each member of staff during their competency training are held on the central database managed by the Water Systems Compliance Manager.

NAME	POSITION	NATURE OF TRAINING (QUALIFICATION, TRAINING COURSES ATTENDED)	DATE
Martin Inglis	Tech Plumber	Competent Persons	
Andrew Hamilton	Tech Plumber	Competent Persons	
David Fickling	Tech Plumber	Competent Persons	
Mark McNally	Tech Plumber	Competent Persons	
Shawn O'Neill	Tech Plumber	Competent Persons	
Jason Weir	Tech Plumber	Competent Persons	
Adam Gardner	Tech Plumber	TBC	
Robert Grant	Tech Plumber	TBC	
Ryan Ogilvie	Tech Plumber	TBC	
Gavin Goodall	Apprentice	TBC	
Paul Kelly	Apprentice	TBC	
Mark McGowan	CAD Technician	TBC	

Copies of all relevant training records and appointment letters are held electronically on the QEUH Shared Drive within the folder path “Water Quality>Training and Appointments”.

The results achieved by each member of staff during their competency training are held on the central database managed by the Water Systems Compliance Manager.

3.5 Training Requirements

A programme of training and procedures to assist in assessing and ensuring the competence of ALL persons responsible for the operation, maintenance, repair and alteration to the water distribution system and associated plant and equipment requires to be progressed, developed and implemented.

QEUH Estates Staff - Interim Training Requirements:

Item	Training Requirement	Applicable to	Target Date for Completion	Date Completed
1	Toolbox talks on Written Scheme Section 4 for staff.	All plumbers		
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				

NOTE:- This table should be updated on a regular basis as part of the review process described in **Section 3.10.**

3.6 Water Systems Risk Assessment

The duly appointed *Legionella* Risk Assessor for *Legionella* and Water Systems Safety will update the *Legionella* risk assessment database as directed by the board.

Risk assessments for each building have been conducted by DMA Water Ltd and are filed in the main Estates Office at QEUEH. Each contains details of individual systems and a summary of the associated risks. The risk assessments each contain unique information in regard to the water distribution systems in the buildings and also guidance on the recommended maintenance procedures for mitigating risk.

Risk Assessment Review-Escalations

During the Risk Assessment, whenever an anomaly is discovered on either the hot or cold water systems, the Risk Assessors e-mail the AP (water) with their findings. These anomalies are actioned by creating a FM job for the onsite CP Plumbing Technician. The findings are held in the Estates office in the folder named (Pre Risk Assessment Jobs completed).

Risk Assessment Process for Removal of Identified Items

Points are actioned that have been identified in the Risk Assessment, all drawings are updated to reflect the changes and the Risk Assessment action point is closed.

Risk Assessment Review Schedule

A review of the Risk Assessments MUST be carried out after or during the following:

A change to the water system or its use

A change to the use of the building/ward/clinic/dept etc.

Changes in legislation or updates in control measures

Changes in immediate management or key personnel

Control measures becoming ineffective

Increased micro-bacterial levels found in the water system or a case of legionnaires disease/legionellosis associated with the water system.

Action plan details for each risk assessment are summarised on the Smartsheet tool.

Electronic copies of the Risk Assessments are also held on the QEUEH Shared Drive at the folder path

“Water Quality>Risk Assessments”

Further information on reviewing Risk Assessments is detailed in Appendix 3.

3.7 Plant Description and Schematics

Details of the plant in each building and schematic layouts are contained within the individual log books/risk assessments for each building. The log books/risk assessments are stored in the main Estates Office at QEUH.

These details are also held on the Shared Drive

All plant details and system schematics and as-fitted drawings for the Adult & Childrens Hospitals are contained in the ZUTEC cloud based document management system. All Estates Managers and Supervisors have access to these systems.

Additional access accounts can be set up at the request of the QEUH Site Manager Operational Estates.

[Brendan.egan](#) [REDACTED]

3.8 Water Systems Audits/Review Procedures

A duly appointed Authorising Engineer (Water) will audit the entire Water Safety procedures within *NHS Board* annually.

The appointed Authorising Engineer for Water Safety will produce an annual report for management review. *See Section 3.1 pg 18 for current appointments.*

AE Audit

The Lead Authorised Person (Water) must regularly gather and maintain all the relevant information and records, including relevant Water Safety Risk Assessments and Written Schemes.

Working with the Authorising Engineer (Water) and Responsible Person (Water), the relevant Authorised Person (Water) will review and analyse all records for compliance with *Legionella* and other water safety parameters.

The relevant Authorised Person (Water) will detail on these records any deviations from the *Legionella* and other water safety parameters giving a brief description as to the reason for this deviation.

The Audit Programme will consist of planned audits on the following elements, for example:

Risk Assessments;

All documentation associated with this Written Scheme

training review and records;

schematic drawings;

Water Safety Log Books/Maintenance records;

BMS trend log comparison.

A report will be produced summarising the audit for submission to the Sector Water Safety Group.

The Lead Authorised Person (Water) will file locally, all relevant information and maintain hard copy records in the Water Safety Log Books stored within the main Estates Office. All actions identified should be tracked to ensure completion and closure.

Summary of Internal/External Audit Procedures

Frequency	Task	By Whom
Annually	Carry out Authorising Engineers Audit and produce report for submission to Sector Water Safety Group (Section 3.8 WS)	Lead AP, AE,
Annually/May	Carry out annual review of written scheme and produce report for submission to Sector Water Safety Group (Section 3.9 WS)	RP/DRP, Lead AP, Compliance Mgr
6 monthly	Carry out management review (Section 3.10 WS)	RP/DRP, Lead AP, Compliance Mgr
Monthly	Carry out regular audit of SCART topic and update database (Section 3.11 WS)	Lead AP
Monthly	Conduct contractor meetings/audits to ensure compliance with legislation and training requirements.(Section 3.12 WS)	Lead AP

3.9 Written Scheme Audit Procedure

The Written Scheme will be audited at agreed intervals but should be at least annually.

An audit schedule will be prepared to ensure the entire procedure is audited. This should be done in conjunction with the Lead AP (Water Systems), Compliance manager, and Responsible Person (Water Systems). A report should be produced and submitted to the Sector Water Safety Group.

3.10 Management Review

The Responsible Person (Water) will hold regular review meetings to confirm current compliance with Water Safety System requirements, identification of any deficiencies and actions required to resolve staff training needs.

The management review will be based on following:

- Results of internal audits;
- Results of external audits;
- Staff suggestions;
- Training records;
- Operation of the system and procedures over a reasonable historic period (6 to 12 months)

3.11 Water Systems SCART Report

The Lead Authorised Person (Water) must regularly gather and maintain all the relevant information for import into the Campus SCART system.

All evidence confirming the SCART position and justification for risk rating adjustments should be uploaded to the SCART database in electronic format.

3.12 Contractor Management & Audit Report

Contractor Management Process

Regular review meetings should be set up with any contractors working on the water distribution system. Minutes of the meetings are held on the QEUH Estates Shared Drive at the path: SGH Estates>Water Quality>Contractor Meetings.

Discussions should include:

- Ongoing works;
- Future task programme;
- Recording procedures;
- RAMS;

Contractor Competency

Regular checks should be performed to ensure that any contractors working on the water distribution system are deemed competent and all operatives are suitably trained to conduct the delegated tasks. Copies of all Risk Assessments and Method Statements should be refreshed and all training records reviewed by the Water Systems AP. Copies are stored on the QEUH Campus Shared Drive in Water Quality.

Contractor Audit Report

A report should be produced at least annually to record the findings of the audit.

3.13 Permit to Work, Water Systems.

The Permit to Work Water Systems as per this written scheme is solely intended to be used when works on the hot and cold water systems and its ancillary equipment are to be completed within the QEUH and RHC campus. This includes break-ins to existing pipe work, removal of dead legs and any new installation works.

The Permit to Work may only be issued to Competent Persons (L8 approved) by the Authorised Person (AP) for water. This includes in house maintenance staff and approved contractors.

The Permit to Work form will include the following;

- Name of the organisation issuing the permit.
- Permit number.
- Name of Authorising Person (AP), including emergency contact details.
- Reasons for the works on the water system, (Plant Preventive Maintenance, Planned repairs or Emergency works).
- Exact location of the works
- Reference to any as built drawing numbers, (for update purposes).
- Name of Competent Person (CP) undertaking the works.
- Hazards and Risks, (copy of Risk assessment and Method Statements (RAMS) to be submitted for approval before start of works)
- Commissioning and Testing.

The above points on the Permit Work are broken into five categories, namely;

Part 1 Description of work and authorisation/permission to proceed.

Part 2 CP acceptance of work and conditions.

Part 3 Confirmation of work completion and engineering test results.

Part 4 Authorisation to use a system.

Part 5 Acceptance of system status by Nurse Manager.

Procedure to be followed for Permit to Work on water systems within the QEUH and RHC;

Sign into Estates office within the Laboratory building on the QEUH and RHC campus.

Receive induction from Authorised Person water.

Provide L8 Competent Person certification to Authorised Person water.

Provide applicable RAMS for the works to be completed.

3.14 Tool Box Talk, Hot and Cold Water Systems.

Estates Tool Box Talk on Hot and Cold water Systems is located on the shared drive / water quality / Estates Tool Talk. This is carried out in the form of a power point presentation.

4.0 MAINTENANCE PROCEDURES

Procedure Reference	Operation
4.1	SYSTEM INFORMATION
4.2	MAINTENANCE PROCEDURES SUMMARY
4.3	WEEKLY MAINTENANCE TASKS
4.4	MONTHLY MAINTENANCE TASKS
4.5	QUARTERLY MAINTENANCE TASKS
4.6	SIX MONTHLY MAINTENANCE TASKS
4.7	ANNUAL MAINTENANCE TASKS
4.9	BI-ANNUAL MAINTENANCE TASKS

NOTE:

Completed Log Sheet to be submitted to either the Authorised Person (Water Systems) or Site Manager Operational Estates for authorisation and copies filed as indicated in Section 2.2.

Due to the volume of information required for the recording of test results for each of the assets being maintained, the Log Sheets provided within this document are for indicative purposes only.

Detailed information on the assets and test records for same will be retained within the specific ‘Log Book’ for the location being maintained.

4.1 System Information

4.1.1 Correct and Safe Operation of the System

Measures should be in place to ensure that the water system is operated within the specific parameters as detailed in the following paragraphs:

4.1.2 Hot Water System

The storage of domestic hot water should be arranged to ensure that a water outflow temperature of at least 60°C is achieved. No two water systems are the same and through periodic monitoring operational system performance, the system outflow temperature should be set to over 60°C to ensure an outflow of 60°C is achieved under normal draw-off demand and achieve 55°C at the supply to the furthestmost draw-off point in the circulating system. It is important to maintain temperatures at above this figure (Legionellae organisms will survive for only a short period of time above this temperature - approximately two minutes).

Periodic performance monitoring and a system of continuous monitoring and recording of water temperatures via a building management system (BEMS) or data logger is essential to ensure compliant system performance.

The outflow water temperature, under prolonged maximum continuous demand (at least 20 minutes) from calorifiers should not be less than 60°C.

While it is accepted that occasionally under peak instantaneous or prolonged demand the water outflow temperature will fall, it is not acceptable if this occurs frequently (more than twice in any 24 hour period) and/or for long periods (exceeding 20 minutes).

Under no circumstances should the domestic hot water flow temperature fall below 55°C.

It is recommended that disinfection by pasteurisation is undertaken if the water temperature of the calorifier falls below 45°C. A minimum domestic hot water circulation (return) temperature of 55°C shall be maintained during the hours of occupancy.

4.1.3 Cold Water System

All domestic cold water storage cisterns and tanks shall comply with the requirements of the Scottish Water Byelaws.

Duplicate tanks often create a risk of water becoming stagnant in one of them, leading to risk of Legionella, Pseudomonas Spp or similar contamination. Consideration should be given to taking one of the tanks out of service. See guidance in “Guidance for Alterations to Water Systems”.

All cold water storage tanks are to be examined and the temperature tested on a regular summer / winter six monthly cycles and cleaned on an annual basis as required.

Temperatures in cold water storage tanks and the mains inlet to them should be checked during periods of high ambient temperatures (e.g. summer afternoons between June and August). Water temperatures should be less than 20°C.

At the same time, the furthest and nearest draw off points in the system should be checked to ensure that the water distribution temperatures are less than 20°C within 1 minute of running the water (at full flow). A similar temperature check regime should be undertaken during the winter months to identify the performance of cold water distribution systems and the impact of heat gain from heating systems.

4.1.4 Cold Water System Dump Valves

The cold water system installed in the Adult & Childrens Hospitals has a dump valve arrangement incorporated into the ground floor, 1st floor and 2nd floor layouts. The positions of the dump valves are shown on the Schneider BMS STRUXUREWARE system and connected via the KNX network.

Operating parameters for the dump valves are as follows:

Open at 23°C

Close at 20°C

4.1.5 End of Line Sensors (EOLs)

The hot and cold water system also incorporates End of Line (EOL) sensors which monitor the temperatures at specific sentinel points across all 11 floors of the Adult & Childrens installation. These can also be viewed via the Schneider BMS system.

4.1.6 Sampling

General microbiological and Legionella sampling in hot & cold water systems

Circumstances under which samples are taken:

- prior alterations to an existing water system;
- as part of commissioning process, prior to handover of a new building or introduction of a (altered, refurbished or new) water system into use;
- one week following handover of a new building or new water system;
- as part of the tank cleaning and disinfection process;
- as part of an assessment programme;
- in response to taste, odour or sustained discoloured water complaints.

When such samples are taken, a mains supply sample should be taken as a control to verify whether the supply could be the source of the identified problems. Scottish Water should also be contacted for distribution zone water quality data.

4.1.7 WS01 – Little Used Outlets

Control of Legionella in Water Systems, Intermittently used Water Outlets and Showers, Standard Operating Procedure WS01.

The Estates department is required to ensure that on a quarterly basis the list of ‘intermittent’ or ‘infrequently’ used water outlets or showers is reviewed to ensure it is accurate and up to date. Records of these reviews will be held within the system logbooks held locally.

If after investigation the taps or appliances identified within the reviewed list are deemed not necessary wherever possible the supply should be cut and the appliance removed from the water system. Where this is not possible then pipe work shall be cut back as close to the main circulating line as practicable to ensure that any dead-leg formed is minimised.

Nursing and other staff must be made aware of the issues surrounding legionella contamination and the link to low and underused water outlets and their assistance in formally identifying these possible outlets are sought.

Upon acknowledgement from the clinical staff of any intermittent or infrequently used outlets, the records are held on the Estates shared drive under Water Quality / WS01.

Any request from clinical staff regarding the removal of any intermittent or infrequently used outlets is assessed and surveyed by the AP (Water). If deemed appropriate a job is raised on FM for the Plumbing Technicians to remove, this is documented in the WS01 Records file in the Water Quality file on the shared drive. Subsequent hot and cold water pipe drawings are updated by the CAD Technician CP (water) where and when appropriate.

FILLING IN LOG SHEETS

Good water hygiene depends on maintaining high standards of cleanliness and freshness, together with careful temperature control. This section contains details of checks and recording sheets (marked “Log Sheets”) to be filled in when checks and measurements are made to show that the necessary standards are being kept up. Alternatively, where an electronic PPM system is used, Procedure references should be entered.

Follow the instructions within the boxes and make entries as each task is completed. The tasks are all listed at the front of each section e.g. weekly tasks at the front of the weekly section, monthly section, quarterly 6 monthly etc. The summary list of tasks in this section is to remind you of what is required. The Task and Log Sheets can be copied as required, completed Log Sheets will be filed where indicated in Section 2. **FM First ticket number MUST be included in all logsheets.**

PLANNING

The tasks and forms are organised into weekly, monthly, quarterly and annual sections. Always aim to carry out tasks early in the period when they are due to leave an opportunity to do them later if an emergency delays your plans.

ASK

If you have difficulties with the forms or do not understand the tasks, ask your Supervisor or line manager for clarification or guidance.

CHECKING

Incomplete or incorrect records are unacceptable in that they are misleading and do not do justice to the effort put in to achieve standards. Each log sheet includes a space for comment and tells you to check that all the boxes are complete: do make use of the comment space and double check the form, otherwise the record will have gaps and whoever is responsible for auditing will concentrate on what is missing and may not give you credit for the work that has been done.

LOG INSPECTION

Anyone inspecting this log (either as part of the Management Control System or not) is invited to make an entry in the inspection of Log Book record in front of Section One.

SURVEY

For survey purposes all surveys will be carried out starting left to right, where 2 off access doors are available the left access shall be taken first. Surveys shall be undertaken from top to bottom.

EQUIPMENT FITTINGS AND MATERIALS

Prior to carrying out alterations/ additions to distribution systems, the Water Fittings and Materials Directory published by the Water Regulations Advisory Scheme, should be consulted. This directory lists all materials and fittings approved for use to satisfy the requirements of current Water Byelaws.

Details of all new materials and fittings used in installations should be noted and recorded on the specific work document or project file for future reference.

SYSTEM ADDITIONS AND ALTERATIONS

Any additions, modifications or improvements to the water distribution system are to be noted and recorded and system record's amended to reflect such changes.

HYGIENE PRACTICES

Care should be taken to ensure high levels of personal hygiene, clean hands, clean clothing and PPE or gloves is maintained at all times when working on wholesome water operations. Tools, equipment, instrumentation and material's shall be free from contamination and appropriately disinfected before use.

Items such as pumps and hoses used in contact with water used for domestic purposes must be stored separately, clearly identified (ie colour coded or labelled) and **MUST NOT BE USED FOR ANY OTHER PURPOSE.**

Refer to Section 2.2 for location of maintenance records for the above.

4.2 Maintenance Procedures Summary

This section contains information in relation to the operational and maintenance checks managed by QEUH NHS Staff and appointed contractors to minimise the risk of exposure to *Legionella* and other waterborne micro-organisms within the domestic water systems, and to improve water quality. Procedures are as per the recommendations and exemplar models given in SHTM 04-01 Part G.

Procedure Reference	Operation(s)	Record Form Ref	Frequency
P1C1	BMS Temperature Monitoring (Carried out by NHS Estates)	Requires new number	Daily
P1CC1A	Manual Temperature Monitoring for calorifiers (different form used ONLY REQUIRED if no BMS Monitoring)	(005a)	Daily
N/A	Filtration Plant Checks (Carried out by NHS Estates)	028c	Twice Daily
WS01	Daily flushing of all outlets (Carried out by NHS Facilities)	-	Daily
WS01	Flushing of little used outlets * frequency based on risk (Carried out by NHS Clinical) see page 103	-	Daily or Twice weekly
WS01	Deluge shower/Eye wash flushing (1 off carried out by NHS Estates and 1 off by DMA)	(026)	Twice Weekly
P1C3	Pump operation/duty rotation (Carried out by NHS Estates)	(028a)	Weekly
P1C4	Temperature Recording of Sentinel Hot and Cold Water Outlets. (Carried out by NHS Estates)	(005c)	Monthly
P1C4	DHW Calorifier and Buffer Vessel Checks (Carried out by NHS Estates)	(005)	Monthly
P1C6	DWS Calorifier, Expansion Vessel Flushing (Carried out by NHS Estates)	(006) (023)	Monthly
P1C12	Showerhead/hose replacement/disinfection (No longer carried out as shower head and hoses replaced quarterly)	(005b)	Quarterly
WS01	Review of Rarely Used Water Outlets and Changes In-Use (Carried out by NHS Estates)		Quarterly
P1C9	DWS Calorifier / Expansion Vessel Inspection (Carried out by NHS Estates)	(006)	Annually
N/A	Water Services Pipework and Distribution System Checks (Carried out by NHS Estates)		Annually
N/A	Vibration coupling inspection (Carried out as part of checks on booster pumps) (Carried out by NHS Estates)		Annually
N/A	Carry out review of log books and Written Scheme		Annually (Sep)
N/A	Carry out review of drawings and schematics		Annually (Sep)

4.3 Required Maintenance Tasks (cont)

In addition to the tasks undertaken by NHS directly employed Competent Persons, there are also tasks undertaken by Contractors on a selection of buildings within the campus.

Procedure Reference	Operation(s)	Record Form Ref	Frequency
	CWST Inspection (Carried out by DMA)	DMA Records	Annually
	Hot and Cold Tap Outlet Sanitisation and Operational Checks (NOT CARRIED OUT UNLESS ISSUE IDENTIFIED THROUGH SAMPLING)	DMA Records	Annually
-	As per 6 monthly and ClO ₂ & Chlorite Probe membrane cap replacement, Dosing Pump diaphragm valve replacements, Replace ClO ₂ gas detector cartridge if required (Carried out by Scotmas)	ScotMas Records	Annually
P1C10	Representative Tap Temperature Monitoring Note: All tap temperatures are checked through TMT/TMV maintenance (Carried out by DMA)	DMA Records	Annually
P1C1 4.3.1	Daily BMS Temperature Monitoring (Carried out by Estates)	(021)	Daily
P1CC1A 4.3.2	Manual Temperature Monitoring (only required in absence of BMS) (Carried out by NHS Estates)	(005a)	Daily
4.3.3	Filtration Plant Checks (Carried out by NHS Estates)	(028c)	Twice Daily
-	Flushing all outlets (Carried out by NHS Facilities)	-	Daily
WS01	Flushing Intermittently used outlets (Carried out by DMA)	-	Twice Weekly
WS01	Flushing Deadlegs and drain valves (Carried out by DMA)	-	Twice Weekly
WS01	Deluge shower/Eye wash flushing (Carried out by DMA and NHS Estates)	(026)	Twice Weekly
P1C3	Pump operation/duty rotation (Carried out by NHS Estates)	(028a)	Weekly
P1C4	Temperature Recording of Sentinel Hot and Cold Water Outlets. (Carried out by NHS Estates)	(005c)	Monthly
-	Temperature Recording of Sentinel Hot and Cold Water Outlets for CL02 (Carried out by DMA)	-	Monthly
P1C4	DHW Calorifier and Plate Heat Exchanger Checks (Carried out by NHS Estates)	(005)	Monthly
-	PPM Schedule Monthly Visually inspect chemical delivery system, Check chemical suction and delivery lines for correct operation Chemical level check and refill, Cross check measured ClO ₂ / Chlorite residual test against analyser & Palintest Kit, Check and Adjust controller settings as required (Carried out by ScotMas)	-	Monthly
P1C6	DWS Calorifier, Expansion Vessel Flushing. (Carried out by NHS Estates)	(006) (023)	Monthly
	Replacement of PAL filters (Carried out by DMA)		31 Days or 62 Days

Procedure Reference	Operation(s)	Record Form Ref	Frequency
WQS 001	HORNE Tap Flow Restrictor Exchange (Carried out by DMA)		Quarterly
	TMV/TMT & Thermostatic Shower Disinfection and Function Test (HIGH RISK)		Quarterly
	'TMV' and Mixing Valve Sanitation and Maintenance Checks (Carried out by DMA)		Six-Monthly
	TMV/TMT & Thermostatic Shower Disinfection and Function Test (Non-HIGH RISK) (Carried out by DMA)		Six-Monthly
P1C7	CWST Inspection and Temperature Monitoring (Carried out by DMA) (Carried out by DMA)	(003)	Six-Monthly
	TMV' and Mixing Valve Sanitation and Maintenance Checks (Carried out by DMA)	DMA Records	Six-Monthly
N/A	TMV/TMT & Thermostatic Shower Disinfection and Function Test (Non-HIGH RISK) (Carried out by DMA)	DMA Records	Six-Monthly
-	Maintenance of filtration units (Carried out by Veolia)	Veolia Records	Six-Monthly
-	6 Monthly Visit– As per monthly, plus, Check ClO2 gas detector functionality and recording levels, Simulate fault circuitry and alarm on Sentinel Monitor, Change probe electrolyte and cross calibration test, Carry out manual Chlorate & Chlorite validation tests (12 representative outlets), Check water meter operation and report o Electrolyte top up, Probe calibrations (Carried out by Scotmas)	ScotMas Records	Six-Monthly
P1C7	CWST Inspection and Temperature Monitoring (Carried out by DMA)	DMA Records	Six-Monthly
N/A	TMV/TMT & Thermostatic Shower Disinfection and Function Test (Non-HIGH RISK) (Carried out by Vanguard for MIU only)	Vanguard Records	Annually
	CWST Inspection (Carried out by DMA)	-	Annually
	Hot and Cold Tap Outlet Sanitisation and Operational Checks (NOT CARRIED OUT UNLESS ISSUE IDENTIFIED THROUGH SAMPLING)	-	Annually
-	As per 6 monthly and ClO2 & Chlorite Probe membrane cap replacement, Dosing Pump diaphragm valve replacements, Replace ClO2 gas detector cartridge if required (Carried out by Scotmas)	-	Annually
P1C10	Representative Tap Temperature Monitoring Note all tap temperatures are checked through TMT/TMV maintenance (Carried out by DMA)	-	Annually
P1C9	DWS Calorifier / Expansion Vessel Inspection (Carried out by NHS Estates)	(006)	Annually
	Water Services Pipework and Distribution System Checks (Carried out by NHS Estates)		Annually
P1C10	Representative Tap Temperature Monitoring (Carried out by DMA as part of TMV checks)	(005)	Annually
	Vibration coupling inspection Carried out monthly as part of checks of Booster sets (Carried out by NHS Estates)		Annually
	BMS Sensors (Carried out by Schneider and MCE BMS Providers for respective BMS)		Annually

4.3 Daily Maintenance Tasks

Reference	Operation
4.31	BMS Temperature Monitoring
4.32	Manual Temperature Monitoring
4.33	Filtration Plant Checks

NOTE:

Completed Log Sheet to be submitted to either the Authorised Person (Water Systems) or Site Manager Operational Estates for authorisation and copies filed as indicated in Section 2.2.

Due to the volume of information required for the recording of test results for each of the assets being maintained, the Log Sheets provided within this document are for indicative purposes only.

Detailed information on the assets and test records for same will be retained within the specific ‘Log Book’ for the location being maintained.

4.31 – BMS TEMPERATURE MONITORING

DAILY

FM First Template No 826

IN ACCORDANCE WITH SHTM 04-01 Part G (*V1 July 2015*) Page 26 para 3.11

RECORD FORM - (021)

PROCEDURE REF - P1C1

SCHEDULE REF – BMS 01

HAISCRIBE/Risk Assessment Ref – N/A See Appendix 4

The following actions must be undertaken **DAILY** as a minimum:

Description of Works

- Refer to the BMS Temperature Monitoring Schedule BMS 01.
- Log onto both STRUXUREWARE BMS and DISTECH BMS front ends and check all temperatures from listed locations.
- Complete Schedule BMS 01 to confirm all temperatures have been checked.
- Any temperatures found outside the defined parameters stated on the BMS Temperature Monitoring Schedule should be investigated and resolved immediately. Details must be entered on Record Form (021) and escalated to the Water Systems AP.

CHECK

1. Record all details of any fault or discrepancy on the FAULT LOG and complete Incident Form (04) and report to Manager.
2. Complete Schedule BMS 01 and Incident form **04** if required, ensuring that you date, sign it and enter FM First ticket number.
3. Return forms to the Water Systems AP.

NOTE: Both Struxureware and Distech BMS systems are capable of generating temperature trend logs. These logs will be checked on a regular basis by the Water Systems AP to confirm accuracy of information.

4.32 – MANUAL TEMPERATURE MONITORING **(in absence of BMS)**

DAILY

FM First Template No 830

IN ACCORDANCE WITH SHTM 04-01 Part G (*VI July 2015*) Page 26 para 3.15

RECORD FORM – (005a) (021a)

PROCEDURE REF - P1CC1A

SCHEDULE REF – MTM 01

HAISCRIBE/Risk Assessment Ref – N/A See Appendix 4

The following actions must be undertaken **DAILY** as a minimum:

Description of Works

- Refer to the Manual Temperature Monitoring Schedule MTM 01.
- MANUALLY visit each location and obtain and record temperatures from all plant as listed on Schedule MTM 01.
- Any temperatures found outside the defined parameters stated on the MTM 01 Temperature Monitoring Schedule should be investigated and resolved immediately. Details must be entered on Incident Form (004a) and escalated to the Water Systems AP.

CHECK

1. Record all details of any fault or discrepancy on the FAULT LOG and complete Incident Form (04) and report to Manager.
2. Complete Record Forms (005a) and (004) if required, ensuring that you date, sign it and enter FM First ticket number.
3. Return form to the Water Systems AP.

4.33 – FILTRATION PLANT CHECKS**TWICE DAILY**

FM First Template No 836

IN ACCORDANCE WITH BOARD POLICY

RECORD FORM – (028c)**PROCEDURE REF – N/A****HAISCRIBE/Risk Assessment Ref – N/A** See Appendix 4The following actions must be undertaken **TWICE DAILY** as a minimum AM and PM:**Description of Works**

- Refer to the Filtration Plant Daily Checks Log sheet (028c).
- Complete all listed checks and ensure plant is running if selected as DUTY, or available to run if selected as STAND-BY.
- Details must be entered on Record Form (028c) and any issues escalated to the Water Systems AP immediately.

CHECK

1. Record all details of any fault or discrepancy on the FAULT LOG and complete Incident Form (04) and report to Manager.
2. Complete Record Forms (028c) if required, ensuring that you date, sign it and enter FM First ticket number.
3. Return form to the Water Systems AP.

4.4 Weekly Maintenance Checks

Reference	Operation
4.41	Flushing of Rarely Used Water Outlets (Twice Weekly)
4.42	Flushing of Deadlegs & Drain Valves (Twice Weekly)
4.43	Rotation of Water Services Duty/Stand-By Pumps
4.44	Operation and Checks to Emergency Deluge Shower/Eye Wash (Twice Weekly)

NOTE:

Completed Log Sheet to be submitted to either the Authorised Person (Water Systems) or Site Manager Operational Estates for authorisation and copies filed as indicated in Section 2.2.

Due to the volume of information required for the recording of test results for each of the assets being maintained, the Log Sheets provided within this document are for indicative purposes only.

Detailed information on the assets and test records for same will be retained within the specific 'Log Book' for the location being maintained.

4.41 – FLUSHING OF INTERMITTENTLY USED WATER OUTLETS

FM First Template No 824

TWICE WEEKLY

IN ACCORDANCE WITH SHTM 04-01 Part G (*V1 July 2015*) Page 101 para 6.36

RECORD FORM - (DMA)

PROCEDURE REF - WS01

HAISCRIBE/Risk Assessment Ref – N/A See Appendix 4

The following actions must be undertaken **TWICE WEEKLY** as a minimum:

Description of Works

- Refer to the locations listed by DMA.
- Estates to arrange for the Schedule to be updated to record on a regular basis.
- Flush water from ALL outlets identified at a minimum frequency of Twice Weekly for a minimum period of 3 minutes per tap outlet taking care not to cause splashing or exposure to water aerosols / droplets.

CHECK

1. Record all details of any fault or discrepancy on the FAULT LOG and complete Incident Form (04) and report to Manager.
2. Complete Record Form ensuring that you date, sign it.
3. DMA to send flushing records to Water Systems AP.

NOTES:

In circumstances where there has been a lapse in the flushing regime, the stagnant and potentially contaminated water from within the shower or tap and associated dead leg should be purged to drain without discharge of aerosols before the appliance is used.

NHSGG&C consider the cleaning of wash hand basins, toilets and showers etc by Domestic Services staff to fulfil the criteria of having been used /flushed.

As part of the ward/departments standard cleaning schedule Domestic Services staff will clean all wash hand basins, showers, baths, WC's and bidets. For the purposes of Legionella and Pseudomonas control the Board deems this to be considered adequate to fulfil guidance on the use of water outlets.

Facilities Management send on flushing records of all taps to Water Systems AP monthly.

Refer to Facilities Procedure - Wash Hand Basin Cleaning (including point of use filter).

4.42 – FLUSHING OF DEADLEGS & DRAIN VALVES

FM First Template No 827

TWICE WEEKLY

IN ACCORDANCE WITH SHTM 04-01 Part G (*V1 July 2015*) Page 101 para 6.36

RECORD FORM - DMA

PROCEDURE REF – WS01

HAISCRIBE/Risk Assessment Ref – N/A See Appendix 4

The following actions must be undertaken **TWICE WEEKLY** as a minimum:

Description of Works

- Refer to the locations listed on Record Form (DMA).
- Estates to arrange for the Schedule to be updated to record on a regular basis.
- Flush water from ALL outlets identified on Record Form on a Weekly basis for a minimum period of 3 minutes per tap outlet taking care not to cause splashing or exposure to water aerosols / droplets. Drain Valves to be purged to ensure the removal of any built up residue in the line.

CHECK

1. Record all details of any fault or discrepancy on the FAULT LOG and complete Incident Form (04) and report to Manager.
2. Complete Record ensuring that you date, sign it and Complete FM work request.
3. Return form to the Water Systems AP.

4.43 – ROTATION OF WATER SERVICES DUTY/STAND-BY PUMPS

FM First Template No 820

WEEKLYIN ACCORDANCE WITH SHTM 04-01 Part G (*V1 July 2015*) Page 27 para. 3.24**RECORD FORM - (028a)****PROCEDURE REF - P1C3****HAISCRIBE/Risk Assessment Ref – N/A** See Appendix 4The following actions must be undertaken **WEEKLY**:**Description of Works**

- Inspect and confirm operation of all listed duty/stand-by pumps by interrogating the programmer to check hours run for each pump motor.
- Check pump rig and associated valves for correct operation, signs of damage, leakage or corrosion.
- Record all details on Record Form (028a)

CHECK

1. Record all details of any fault or discrepancy on the FAULT LOG and complete Incident Form (04) and report to Manager.
2. Complete Record Form (028a) ensuring that you date, sign it and enter FM First ticket number.
3. Return form to the Water Systems AP.

4.44 – OPERATION AND CHECKS TO EMERGENCY DELUGE SHOWERS/EYE WASH

FM First Template No 825

TWICE WEEKLYIN ACCORDANCE WITH SHTM 04-01 Part G (*V1 July 2015*) Page 57**RECORD FORM - (026c) and DMA record for separate shower.****PRECEDURE REF – WS01****HAISCRIBE/Risk Assessment Ref – N/A** See Appendix 4**RISK CONTROL NOTICE - RCN 11/04**The following actions must be undertaken **TWICE WEEKLY**:**Description of Works**

- Refer to the locations listed on Record Form (026c) NHS only (DMA complete flushing records).
- Operate shower for a minimum period of 3 minutes taking care not to cause splashing or exposure to water aerosols / droplets. Measure and record temperatures until discharge water drops to the same temperature as the incoming mains water.

NOTE: For thermostatic showers and taps, the outlet should be flushed on the full cold setting for 2 minutes, then again on the full hot setting for a further 2 minutes, using override setting where available. Cold water should be less than 20°C, Hot water should be between 55°C and 60°C, and Mixed water in the range 41-43°C.

CHECK

1. Record all details of any fault or discrepancy on the FAULT LOG and complete Incident Form (04) and report to Manager.
2. Complete Record Form (026c) ensuring that you date, sign it and enter FM First ticket number.
3. Return form to the Water Systems AP.

4.5 Monthly Maintenance Checks

Reference	Operation
4.51	Sentinel Outlet Temperature Recording
4.52	DWS Calorifier – Temperature Checks & Blowdown
4.53	CL02 checks

NOTE:

Completed Log Sheet to be submitted to Site Estates Manager / Authorised Person (Water) for authorisation and copies filed as indicated in Section 2.20.

Due to the volume of information required for the recording of test results for each of the assets being maintained, the Log Sheets provided within this document are for indicative purposes only.

Detailed information on the assets and test records for same will be retained within the specific ‘Log Book’ for the location being maintained.

4.51 – SENTINEL OUTLET TEMPERATURE RECORDING

FM First Template No 828

MONTHLY

IN ACCORDANCE WITH SHTM 04-01 Part G (*V1 July 2015*) Page 28 para 3.27

RECORD FORM - (005c)

PROCEDURE REF - P1C4

HAISCRIBE/Risk Assessment Ref – N/A See Appendix 4

The following actions must be undertaken **MONTHLY**:

Description of Work

- Check the temperatures at the sentinel taps as defined in the local plan of the system being checked. NOTE: Where the sentinel is a TMV or TMT the temperature readings should be taken from the pipework or directly from the hot and cold supply.
- Using a calibrated temperature probe, check the temperature of water from the cold water tap does not rise above 20°C after running the tap for 2 minutes.
- Using a calibrated temperature probe, check the temperature of water from the hot water tap does not drop below 55°C whilst running the tap for 1 minute.
- Record all temperatures on Record Form (005c).

CHECK

1. Record all details of any fault or discrepancy on the FAULT LOG and complete Incident Form (04) and report to Manager.
2. Complete Record Form **(005c)** ensuring that you date, sign it and enter FM First ticket number. Complete FM Work Request.
3. Return form to the Water Systems AP.

4.52 - DWS CALORIFIER – TEMPERATURE CHECKS & BLOWDOWN

FM First Template No 821

MONTHLYIN ACCORDANCE WITH SHTM 04-01 Part G (*V1 July 2015*) Page 28 para 3.30**RECORD FORM - (005)****PROCEDURE REF - P1C4****HAISCRIBE/Risk Assessment Ref – N/A** See Appendix 4The following actions must be undertaken **MONTHLY**:**Description of Work**

- MANUALLY CHECK and record the flow and return temperatures on the domestic hot water system as defined on Record Form (005), using the temperature gauges fitted or a suitable surface temperature probe.
- MANUALLY CHECK and record the calorifier storage temperature at top and bottom gauges if fitted.
- The flow temperature to be at least 60°C and the return temperature shall be no less than 55°C
- MANUALLY CHECK and record the cold water feed temperature using the temperature gauges fitted or a suitable surface temperature probe.
- Blowdown drain valves (if fitted) on all calorifiers and expansion vessels by opening the drain valve 3 times, each time for a 3 minute period. Where required, the hose from the drain valve connection should be discharged to the nearest drain/gulley. If there is no drain valve make note on Record Form 005.
- Check all local pipework to and from calorifier is in good order and all insulation is intact.
- Operate all isolation valves through their full range of motion.
- Check, confirm and record operation of de-stratification pump.
- Record all information on the Record Form (005).

CHECK

1. Record all details of any fault or discrepancy on the FAULT LOG and complete Incident Form (04) and report to Manager.
2. Complete Record Form **(005)** ensuring that you date, sign it and enter FM First ticket number.
3. Return form to the Water Systems AP.

4.53 – CL02 PLANT CHECKS

FM First Template N/A

MONTHLY

IN ACCORDANCE WITH SHTM 04-01

RECORD FORM – N/A**PROCEDURE REF – N/A****HAISCRIBE/Risk Assessment Ref – N/A** See Appendix 4The following actions must be undertaken **MONTHLY**:**Description of Work**

- PPM Schedule Monthly Visually inspect chemical delivery system.
- Check chemical suction and delivery lines for correct operation Chemical level check and refill.
- Cross check measured ClO₂ / Chlorite residual test against analyser & Palintest kit.
- Check and Adjust controller settings as required.

CHECK

1. Record all details of any fault or discrepancies and report to Water Lead AP who will complete Incident Form (04).

4.6 Quarterly & Other Maintenance Checks

Reference	Operation
4.61	Shower Head and Flexible Hoses Disinfection/Replacement
4.62	DHWS Calorifier and Expansion Vessel - Flush
4.63	HORNE Tap Flow Restrictor Exchange
4.64	Review of Rarely Used Water Outlets and Changes In-Use
4.65	TMV/TMT & Thermostatic Shower Disinfection and Function Test (HIGH RISK)
4.66	PAL filter replacement

NOTE:

Completed Log Sheet to be submitted to either the Authorised Person (Water Systems) or Site Manager Operational Estates for authorisation and copies filed as indicated in Section 2.2.

Due to the volume of information required for the recording of test results for each of the assets being maintained, the Log Sheets provided within this document are for indicative purposes only.

Detailed information on the assets and test records for same will be retained within the specific 'Log Book' for the location being maintained.

4.61 SHOWER HEAD AND HOSE REPLACEMENT/DISINFECTION

FM First Template No 869
Schedules: 1997 to 2724

QUARTERLY

IN ACCORDANCE WITH SHTM 04-01 Part G (*VI July 2015*) Page 32 para 3.51

RECORD FORM -See DMA records

PROCEDURE REF - P1C12 CURRENTLY CONTRACTED TO DMA CANYON WATER

HAISCRIBE/Risk Assessment Ref – N/A See Appendix 4

The following actions must be undertaken every **THREE MONTHS**:

NOTE: If PALL filter is fitted it must be left in place and recorded as such on DMA records)

Description of Work

- Exchange shower head and hose assembly inc sealing washers with new disposable unit. Place old shower head and hose assembly into re-sealable plastic bag.
- Check that the new head and hose package is intact;
- Open replacement new shower head and hose assembly sealed packaging, remove and fit following the manufacturer's instructions;
- Run water and flush for 3 minutes in accordance with Legionella Risk Assessment in such a way as to avoid the creation of aerosols;
- Check final temperature for compliance and working order and return shower appliance to use.
- Return redundant sealed bag with shower head and hose assembly to collection point for recycling in accordance with Waste Procedures;
- Record all actions on the Record Form (005b).

CHECK

1. Record all details of any fault or discrepancy on the FAULT LOG and complete Incident Form (04) and report to Manager.
2. Complete Record Form (005b) ensuring that you date, sign it and enter FM First ticket number.
3. Return form to the Water Systems AP.

NOTE: This procedure replaces the previous Clean & Disinfect method from 1st April 2019 for majority of showers. Where fixed showers exist, eye wash stations, baths etc DMA will carry out clean disinfection of these.

Fixed Shower Head / Bath shower, eye wash shower heads**Description of Work**

- Exchange shower head and hose assembly inc sealing washers with previously cleaned and sanitised unit. Place old shower head and hose assembly into re-sealable plastic bag.
- Check that the new clean disinfected head and hose package is intact;
- Open replacement new clean disinfected shower head and hose assembly sealed packaging, remove and fit following the manufacturer's instructions;
- Run water and flush for 3 minutes in accordance with Legionella Risk Assessment in such a way as to avoid the creation of aerosols;
- Check final temperature for compliance and working order and return shower appliance to use;
- Return redundant sealed bag with shower head and hose assembly to workshop for disposal in accordance with Waste Procedures;
- Record all actions on the Record Form (005b).

CHECK

4. Record all details of any fault or discrepancy on the FAULT LOG and report to Manager.
5. Complete Record Form (005b) ensuring that you date, sign it and enter FM First ticket number.
6. Return form to the Water Systems AP.

4.62 - DWS CALORIFIER AND EXPANSION VESSEL - FLUSH

FM First Template No 821

QUARTERLY

IN ACCORDANCE WITH SHTM 04-01 Part G (*V1 July 2015*) Page 29 para 3.34

RECORD FORM - (006) and (023)

PROCEDURE REF - P1C6

HAISCRIBE/Risk Assessment Ref – N/A See Appendix 4

The following actions must be undertaken every **THREE MONTHS**:

Description of Work

- Flush each Domestic Hot Water Calorifier and Buffer Vessel through its drain valve by opening the drain valve 3 times, each time for a 3 minute period. Where required, the hose from the drain valve connection should be discharged to the nearest drain/gulley.
- Record all actions on the top section of Record Form (006).
- Where the domestic hot water system has a stratification pump(s) fitted to circulate the hot water from the top to the base of the calorifier or the storage/buffer vessel, and the history data shows no sludge deposits during flushing, then this procedure should be risk assessed to determine if the maintenance frequency can be changed. This assessment should be recorded on Record Form (023).

NOTE: this flushing process can air lock the hot water system, so only carry it out when there is no hot water demand and the calorifier is valved off from the system.

CHECK

1. Record all details of any fault or discrepancy on the FAULT LOG and complete Incident Form (04) and report to Manager.
2. Complete Record Forms (006) and/or (023) ensuring that you date, sign them and enter FM First ticket number.
3. Return form to the Water Systems AP.

4.63 – HORNE TAP FLOW RESTRICTOR EXCHANGE

FM First Template No N/A

QUARTERLY

IN ACCORDANCE WITH IC GUIDANCE

RECORD FORM – (See DMA Records)

PROCEDURE REF – WQS 001

HAISCRIBE/Risk Assessment Ref – N/A See Appendix 4

The following actions must be undertaken every **THREE MONTHS**:

Description of Work

PPE:- Surgical gloves should be worn when carrying out this task. Cross contamination of the replacement flow restrictor should be considered and avoided at all times.

Restrictor should only be replaced at outlets without PALL filters. If PALL filter is fitted it should be left in place and noted on Record Form.

- Assemble all tools and materials required to complete task.
- Check with ward staff to ensure access can be granted to each area without Infection Control restriction.
- Remove existing restrictor using the appropriate tool and dispose of the restrictor in general waste.
- Use disinfectant wipes to sanitise tap outlet and tools used before re-fitting new restrictor.
- Change gloves to avoid cross contamination of new components and tools.
- Unpack new restrictor components and insert into tap as per the manufacturer's instructions.
- Test on completion and fill out log sheet to record all relevant information.

CHECK

1. Record all details of any fault or discrepancy on the FAULT LOG and complete Incident Form (04) and report to Manager.
2. Complete Record Form (DMA WATER) ensuring that you date, sign them and enter FM First ticket number.
3. Return form to the Water Systems AP.

4.64 - REVIEW OF INTERMITTENTLY USED WATER OUTLETS/CHANGE IN-USE

IN ACCORDANCE WITH BOARD POLICY

QUARTERLY**RECORD FORM – (001) (026)****PROCEDURE REF – WS01****HAISCRIBE/Risk Assessment Ref – N/A** See Appendix 4The following actions must be undertaken every **THREE MONTHS**:**Description of Work**

- Liaise with Site Facilities Manager and Heads of Department to review existing accommodation occupancy and usage on a 3 monthly basis.
- Issue Quarterly circular email to all HoDs requesting to identify little used outlets and to confirm that they have a flushing regime implemented.
- Identify any water services outlets that are not used OR changes to the occupancy.
- Schedule to be updated to record all areas which change in-use, become unoccupied or otherwise out of use.

CHECK

1. Record all details of any dept closures or little used outlets on Record Form (001) and add outlets to flushing register.
2. Ensure outlets are brought to the attention of the maintenance person carrying out the flushing activity and details added to Record Form (026) or arrange with DMA to add to flushing requirements if required. Wards should be carrying out flushing as per requirements and provide evidence on WS01 form.
3. All completed Record Forms to be stored in the building specific Log Book.

4.65 – TMV/TMT & THERMOSTATIC SHOWER DISINFECTION AND FUNCTION TEST (HIGH RISK)

QUARTERLY

FM First Template No

IN ACCORDANCE BOARD POLICY

RECORD FORM - **REQUIRES CONFIRMATION IF THIS SHOULD BE CARRIED OUT**
THREE MONTHLY

PROCEDURE REF -

HAISCRIBE/Risk Assessment Ref – N/A See Appendix 4

The following actions must be undertaken every **THREE MONTHS**:

Description of Work

- Examine all thermostatic taps for scale build-up or other deposits. De-scale any which are not clean.
- Check and remove any installed plastic flow straighteners from tap outlet
- Inspect and Clean and Disinfect filters / strainers by removing and immersing in a solution of 1000ppm free residual chlorine (50cc CLO2 in 5 litres of water) in water for 5 minutes.
- All HORNE Optitherm taps **MUST** have the flow straightener replaced during three monthly service tasks.
- Pasteurise outlets by over-riding thermostatic controls drawing water through each thermostatic tap until a temperature of 60°C is achieved. Run the tap at this temperature for five minutes. If this is not possible disassemble tap assembly and spray all accessible components with 'Shower Head plus' mixed to a 1:3 solution, (one part chemical, 3 parts water) or equal and approved and let stand for 5 minutes.
- Reassemble and verify fail safe operation by isolating hot and cold water supplies separately.
- Ensure thermostatic controls are re-adjusted to permit blending.
- Should controls not be able to be over-ridden, verify the temperatures at the inlet connections to the thermostatic valve utilising a contact type probe and electronic thermometer.
- Run and test tap and record hot and cold water inlet temperatures and mixed water outlet temperature.
- Log all actions.

4.66 – PAL FILTER REPLACEMENT

FM First Template No

31& 62 Day

IN ACCORDANCE WITH AGREED FILTER LOCATIONS

RECORD FORM - DMA RECORDS

PROCEDURE REF -

HAISCRIBE/Risk Assessment Ref – N/A See Appendix 4

The following actions must be undertaken every **31 Days or 62 Days based on filter types and locations**:

Description of Work

- Replace filters prior to end date on tap and shower filters as per programme.
- Process for replacement as per DMA Procedures.
- Log all replacements as per DMA Procedures and record in DMA Records.
- Any issues should be reported to Water Lead AP.

4.7 Six Monthly Checks

Reference	Operation
4.71	TMV/TMT & Thermostatic Shower Disinfection and Function Test (Non-HIGH RISK)
4.72	CWST Inspection and Temperature Monitoring
4.73	Maintenance of filtration units
4.74	CL02 checks

NOTE:

Completed Log Sheet to be submitted to either the Authorised Person (Water Systems) or Site Manager Operational Estates for authorisation and copies filed as indicated in Section 2.2.

Due to the volume of information required for the recording of test results for each of the assets being maintained, the Log Sheets provided within this document are for indicative purposes only.

Detailed information on the assets and test records for same will be retained within the specific 'Log Book' for the location being maintained.

4.71 – TMV/TMT & THERMOSTATIC SHOWER DISINFECTION AND FUNCTION TEST (NON HIGH RISK)

IN ACCORDANCE WITH BOARD POLICY

SIX MONTHLY

RECORD FORM -

ANNUAL FOR MIU

PROCEDURE REF -

HAISCRIBE/Risk Assessment Ref – N/A See Appendix 4

The following actions must be undertaken every **SIX MONTHS**:

Description of Work

- Examine all thermostatic taps for scale build-up or other deposits. De-scale any which are not clean.
- Check and remove any installed plastic flow straighteners from tap outlet
- Inspect and Clean and Disinfect filters / strainers by removing and immersing in a solution of 1000ppm free residual chlorine (50cc CLO2 in 5 litres of water) in water for 5 minutes.
- All HORNE Optitherm taps MUST have the flow straightener replaced during three monthly service tasks.
- Pasteurise outlets by over-riding thermostatic controls drawing water through each thermostatic tap until a temperature of 60°C is achieved. Run the tap at this temperature for five minutes. If this is not possible disassemble tap assembly and spray all accessible components with 'Shower Head plus' mixed to a 1:3 solution, (one part chemical, 3 parts water) or equal and approved and let stand for 5 minutes.
- Reassemble and verify fail safe operation by isolating hot and cold water supplies separately.
- Ensure thermostatic controls are re-adjusted to permit blending.
- Should controls not be able to be over-ridden, verify the temperatures at the inlet connections to the thermostatic valve utilising a contact type probe and electronic thermometer.
- Run and test tap and record hot and cold water inlet temperatures and mixed water outlet temperature.
- Log all actions.

4.72 – CWST INSPECTION AND TEMPERATURE MONITORING:

FM First Template No 819

SIX MONTHLYIN ACCORDANCE WITH SHTM 04-01 Part G (*V1 July 2015*) Page 29 para 3.37**RECORD FORM – Carried out by DMA – refer to records****PROCEDURE REF – P1C7****HAISCRIBE/Risk Assessment Ref – N/A See Appendix 4**The following actions must be undertaken every **SIX MONTHS** seasonally during Summer and Winter:**Description of Work**

- Inspect the tank and associated pipework including insulation, valves etc for damage or corrosion and sediment.
- Operate all isolation valves through their full range of motion.
- Check the operation of the ball-valve by pressing down on it and lifting the float to confirm that water flows and stops.
- Inspect the tank overflows if visible. Confirm that there is no blockage or other foreign material and that the mesh screen is not damaged.
- Measure and record the temperature of the water in the tanks, by dipping the thermometer into the top as far from the ball-valve as possible.
- Check and record ambient outside air temp and tank room temp.
- Check the flow and record the temperature of water feeding the tanks. There should be a steady rapid flow when the ball float is down.

CHECK

1. Record all details of any fault or discrepancy on the FAULT LOG and complete Incident Form (04) and report to Manager.
2. Complete Records and send information to Water Systems AP.

4.73 – MAINTENANCE OF WATER FILTRATION UNITS:

FM First Template N/A

SIX MONTHLY

N/A

RECORD FORM – Carried out by Veolia– refer to records**PROCEDURE REF – N/A****HAISCRIBE/Risk Assessment Ref – N/A**The following actions must be undertaken every **SIX MONTHS**:**Description of Work**

- Check on feedwater quality
- Check on treated water quality & flows
- The condition of valves & diaphragms
- Operational cycle simulation
- General plant condition & safety
- The condition of system pumps
- The condition of the pre-filters
- Level control function

CHECK

1. Record all details of any fault or discrepancy and pass to Water Lead AP to record on the FAULT LOG and complete Incident Form (04).

4.74 – MAINTENANCE OF CL02 PLANT:

FM First Template N/A

SIX MONTHLY

N/A

RECORD FORM – Carried out by Scotmas– refer to records**PROCEDURE REF – N/A****HAISCRIBE/Risk Assessment Ref – N/A**The following actions must be undertaken every **SIX MONTHS**:**Description of Work**

- As per monthly plus :-
- Check ClO₂ gas detector functionality and recording levels.
- Simulate fault circuitry and alarm on Sentinel Monitor.
- Change probe electrolyte and cross calibration test.
- Carry out manual Chlorate & Chlorite validation tests (12 representative outlets).
- Check water meter operation and report on Electrolyte top up, Probe calibrations

CHECK

1. Record all details of any fault or discrepancy and pass to Water Lead AP to record on the FAULT LOG and complete Incident Form (04).

4.8 Annual Maintenance Checks

Reference	Operation
4.81	DWS Calorifier / Expansion Vessel Inspection
4.82	Water Services Pipework and Distribution System Checks
4.83	Representative Tap Temperature Monitoring
4.84	Vibration coupling inspection
4.85	BMS Temperature Sensor Test and Calibration
4.86	TMT Maintenance of MIU

NOTE:

Completed Log Sheet to be submitted to either the Authorised Person (Water Systems) or Site Manager Operational Estates for authorisation and copies filed as indicated in Section 2.2.

Due to the volume of information required for the recording of test results for each of the assets being maintained, the Log Sheets provided within this document are for indicative purposes only.

Detailed information on the assets and test records for same will be retained within the specific 'Log Book' for the location being maintained.

4.81 - DWS CALORIFIER/EXPANSION VESSEL INSPECTION

FM First Template No 821

ANNUAL

IN ACCORDANCE WITH SHTM 04-01 Part G (*V1 July 2015*) Page 31 para 3.44

RECORD FORM - (006)

PROCEDURE REF - P1C9

HAISCRIBE/Risk Assessment Ref – N/A See Appendix 4

The following actions must be undertaken **ANNUALLY**

Description of Work

Follow the manufacturers' maintenance instructions from O&M manuals. Record all actions where applicable on Record Form (006) for each system.

- Isolate domestic hot water calorifier or hot, cold or chilled water storage/buffer vessel service valves;
- Heat any domestic hot water calorifier or hot water storage/buffer vessel up until the contents has reached 60°C and hold at this temperature for a period of at least 1 hour;
- Drain domestic hot water calorifier and expansion vessel and remove inspection hatch;
- Hose out the domestic hot water calorifier or hot and expansion vessel to remove any debris, scale or other deposit. Care should be taken to keep aerosols to a minimum.
- If the domestic hot water calorifier or expansion vessel does not have an inspection hatch, the pipework at the top of the vessel should be disconnected to allow the insertion of a water hose to allow debris to be washed down off internal surfaces;
- Examine the internal and external condition of the domestic hot water calorifier and expansion vessel and pipework, any defects should be reported in writing to the relevant Authorised Person (Water). The safety valve should be checked, overhauled and reset as necessary. The temperature and pressure gauges to be checked for operation.
- On completion of examination and any repairs, the domestic hot water calorifier and expansion vessel should be re-assembled and the following sequence must be undertaken:
 - Refill with cold water;
 - Drain the domestic hot water calorifier and expansion vessel;
 - Refill with cold water, leave cold feed valve open;
 - Run domestic hot water calorifier or hot water storage/buffer vessel at a temperature of 60°C for at least 1 hour. Test the operation of high limit cut-out system if fitted. Check the temperature of the calorifier/vessel top and bottom with a surface thermometer;

- Adjust any controls as necessary.
- Take bacteriological samples from the base of the calorifier and submit to GRI Water Lab for analysis. (THIS TASK TO BE CARRIED OUT BY DMA CANYON WATER)

NOTE: this flushing process can air lock the hot water system, so only carry it out when there is no hot water demand and the calorifier is valved off from the system.

CHECK

1. Record all details of any fault or discrepancy on the FAULT LOG and complete Incident Form (04) and report to Manager.
2. Complete Record Forms (006) ensuring that you date, sign them and enter FM First ticket number.
3. Return form to the Water Systems AP.

4.82 - PIPEWORK AND DISTRIBUTION SYSTEM CHECKS

FM First Template No 829

ANNUAL

IN ACCORDANCE WITH SHTM 04-01 Part G (*V1 July 2015*) Page 31 para 3.

RECORD FORM - (0)

PROCEDURE REF -

HAISCRIBE/Risk Assessment Ref – N/A See Appendix 4

The following actions must be undertaken **ANNUALLY**:

Estates Manager or Water Systems AP will define areas to be checked in each building.

Description of Work

- Check all accessible pipework for damage, or corrosion.
- Check for missing or damaged pipework insulation
- This is carried within the Tank Room by DMA during sampling and tank inspections monthly.
- This is carried out by NHS Estates within Plantrooms during plantroom inspections monthly
- This is carried out as per above procedures and noted on FM First PPM's..

CHECK

1. Record all details of any fault or discrepancy on the FAULT LOG and complete Incident Form (04) and report to Manager.
2. Complete Record Forms as per above procedures ensuring that you date, sign them and enter FM First ticket number.
3. Return form to the Water Systems AP.

4.83 – REPRESENTATIVE TAP TEMPERATURE MONITORING

FM First Template No 917

ANNUAL

IN ACCORDANCE WITH SHTM 04-01 Part G (*V1 July 2015*) Page 32 para 3.39

RECORD FORM - (005d)

PROCEDURE REF – P1C10

HAISCRIBE/Risk Assessment Ref – N/A See Appendix 4

The following actions must be undertaken at regular intervals throughout the year to ensure 20% of the requirement is completed **ANNUALLY**:

Description of Work

- **OBJECTIVE:** Carry out water temperature monitoring to ensure consistency and performance of the system as per design. 20% of all outlets to be assessed annually to ensure entire system is completed within a 5 year period (*ref: SCART2 Question 54*)
- Check the temperatures at a representative number of hot and cold outlets on a rotational basis as defined in the local plan of the system being checked. Lead AP (Water) to define areas to be checked each month.
- Using a temperature probe check the temperature of the cold water tap does not go above 20°C after running the tap for 2 minutes;
- Using a temperature probe check the temperature of the hot water tap does not go below 55°C within running the tap for 1 minute;
- If the outlet being tested is protected by a TMV/TMT then temperatures should be taken directly from the supply pipework or by bypassing the thermostatic device by use of an appropriate purging kit.
- Record all temperatures and locations tested on the Record Form (005d) or if carried out by DMA to reflect in records.

CHECK

1. Record all details of any fault or discrepancy on the FAULT LOG and complete Incident Form (04) and report to Manager.
2. Complete Record Forms (005d) ensuring that you date, sign them and enter FM First ticket number.
3. Return form to the Water Systems AP.

4.84 - VIBRATION COUPLING INSPECTION

FM First Template No 831

ANNUAL

IN ACCORDANCE WITH HSG 274 Part 2 (2014) Page 19 para 2.35

RECORD FORM - (008)**PROCEDURE REF – WQMS 001****HAISCRIBE/Risk Assessment Ref – N/A See Appendix 4**The following actions must be undertaken **ANNUALLY**:**Description of Work**

- Refer to list of vibration coupling locations to be assessed.
- Visually check the condition of the coupling for any signs of leakage, deterioration or corrosion.
- Ensure flexible portion of coupling is intact and free from damage or deterioration.
- Carried out on Cold Water Booster sets as part of the inspection.

CHECK

1. Record all details of any fault or discrepancy on the FAULT LOG and complete Incident Form (04) and report to Manager.
2. Complete Record Forms ensuring that you date, sign them and enter FM First ticket number.
3. Return form to the Water Systems AP.

4.85 – BMS TEMPERATURE SENSOR CALIBRATION**ANNUAL**

FM First Template No

IN ACCORDANCE WITH

RECORD FORM -**PROCEDURE REF –****HAISCRIBE/Risk Assessment Ref – N/A See Appendix 4**The following actions must be undertaken **ANNUALLY**:**Description of Work**

- This task should be included in the BMS Service Contract Specification.
- All temperature sensors related to domestic hot and cold water services to be checked and calibrated annually.
- All calorifiers, storage tanks, flow and return monitoring devices.
- Include all End of Line (EOL) sensors and cold water flushing devices.
- Records should be kept and made available to the estates dept on request.

4.86 – MAINTENANCE OF WATER FILTRATION UNITS:

FM First Template N/A

ANNUAL

N/A

RECORD FORM – Carried out by Veolia– refer to records**PROCEDURE REF – N/A****HAISCRIBE/Risk Assessment Ref – N/A**The following actions must be undertaken **ANNUALLY**:**Description of Work**

- As per 6 monthly and ClO₂ & Chlorite Probe membrane cap replacement.
- Dosing Pump diaphragm valve replacements.
- Replace ClO₂ gas detector cartridge if required

CHECK

1. Record all details of any fault or discrepancy and pass to Water Lead AP to record on the FAULT LOG and complete Incident Form (04).

4.87 – TMV/TMT & THERMOSTATIC SHOWER DISINFECTION AND FUNCTION TEST (NON HIGH RISK)

IN ACCORDANCE WITH BOARD POLICY

RECORD FORM -

ANNUAL FOR MIU

PROCEDURE REF -

HAISCRIBE/Risk Assessment Ref – N/A See Appendix 4

The following actions must be undertaken **ANNUALLY** :

Description of Work

- Examine all thermostatic taps for scale build-up or other deposits. De-scale any which are not clean.
- Check and remove any installed plastic flow straighteners from tap outlet
- Inspect and Clean and Disinfect filters / strainers by removing and immersing in a solution of 1000ppm free residual chlorine (50cc CLO2 in 5 litres of water) in water for 5 minutes.
- Pasteurise outlets by over-riding thermostatic controls drawing water through each thermostatic tap until a temperature of 60°C is achieved. Run the tap at this temperature for five minutes. If this is not possible disassemble tap assembly and spray all accessible components with 'Shower Head plus' mixed to a 1:3 solution, (one part chemical, 3 parts water) or equal and approved and let stand for 5 minutes.
- Reassemble and verify fail safe operation by isolating hot and cold water supplies separately.
- Ensure thermostatic controls are re-adjusted to permit blending.
- Should controls not be able to be over-ridden, verify the temperatures at the inlet connections to the thermostatic valve utilising a contact type probe and electronic thermometer.
- Run and test tap and record hot and cold water inlet temperatures and mixed water outlet temperature.
- Log all actions.

4.9 Bi-Annual Maintenance Checks

Reference	Operation
4.91	Flexible Hose/Connection Inspection and Exchange
4.92	CWST Drop Test

NOTE:

Completed Log Sheet to be submitted to either the Authorised Person (Water Systems) or Site Manager Operational Estates for authorisation and copies filed as indicated in Section 2.2.

Due to the volume of information required for the recording of test results for each of the assets being maintained, the Log Sheets provided within this document are for indicative purposes only.

Detailed information on the assets and test records for same will be retained within the specific 'Log Book' for the location being maintained.

4.91 – FLEXIBLE HOSE/CONNECTION INSPECTION AND EXCHANGE

FM First Template No

BI-ANNUAL

IN ACCORDANCE WITH QEUH RISK ASSESSMENT RECOMMENDATIONS 2017

RECORD FORM - (009)**PROCEDURE REF – WQMS 002****HAISCRIBE/Risk Assessment Ref – N/A See Appendix 4**The following actions must be undertaken **ANNUALLY**:**Description of Work**

- Refer to list of flexible connection locations to be assessed as per WQMS 002.
- Visually check the condition of the coupling for any signs of leakage, deterioration or corrosion.
- Safely isolate the water services and exchange the flexible connection with a BRAND NEW UNUSED replacement.
- Apply tag/label to indicate the intended date of future replacement (todays date + 24 months)
- Record all details on the Record Form (009).

CHECK

1. Record all details of any fault or discrepancy on the FAULT LOG and complete Incident Form (04) and report to Manager.
2. Complete Record Forms (009) ensuring that you date, sign them and enter FM First ticket number.
3. Return form to the Water Systems AP.

4.92 – CWST DROP TESTS

FM First Template No 819

BI-ANNUAL

IN ACCORDANCE WITH

RECORD FORM -

PROCEDURE REF -

HAISCRIBE/Risk Assessment Ref – N/A See Appendix 4

The following actions must be undertaken **ANNUALLY**:

Description of Work

- Shut off mains cold water supply to tank.
- Record the start time and allow tank to drain naturally through usage. DO NOT OPEN THE DRAIN.
- Periodically monitor the tank until usage has reduced tank to exactly half of its starting capacity.
- Record the stop time and estimate the number of hours of storage of water in the tank.
- Record all inspection details on the Record Form (010).

CHECK

1. Record all details of any fault or discrepancy on the FAULT LOG and complete Incident Form (04) and report to Manager.
2. Complete Record Forms (010) ensuring that you date, sign them and enter FM First ticket number.
3. Return form to the Water Systems AP.

5.0 INCIDENT AND EMERGENCY PROCEDURES

Procedure Reference	Operation
5.10	FAILURE OF CONTROL MEASURES
5.20	HIGH COLD WATER SUPPLY TEMPERATURE TO OUTLET
5.30	LOW HOT WATER SUPPLY TEMPERATURE TO OUTLET
5.40	CALORIFIER OR HEAT EXCHANGER TEMPERATURE FAULT
5.50	POSITIVE LEGIONELLA TEST RESULT
5.60	IDENTIFICATION OF LITTLE USED WATER OUTLET
5.70	EMERGENCY REPAIRS
5.80	DISINFECTION OF WATER SYSTEM
5.90	PSEUDOMONAS

NOTE:

Completed Log Sheet to be submitted to either the Authorised Person (Water Systems) or Site Manager Operational Estates for authorisation and copies filed as indicated in Section 2.2.

Due to the volume of information required for the recording of test results for each of the assets being maintained, the Log Sheets provided within this document are for indicative purposes only.

Detailed information on the assets and test records for same will be retained within the specific 'Log Book' for the location being maintained.

THE FOLLOWING PAGES DESCRIBE REMEDIAL ACTIONS TO BE TAKEN IN THE EVENT OF AN INCIDENT, EMERGENCY, OUT-OF-SPECIFICATION TEST RESULT AND / OR WHERE *LEGIONELLA* HAS BEEN IDENTIFIED AND/OR BACTERIA COUNTS BEING IN EXCESS OF THE RECOMMENDED LIMITS IN THE WATER SYSTEM ARE IDENTIFIED.

The Health and Safety at Work Act places a duty on employers to ensure, so far as is reasonably practicable, the maintenance of safe working conditions without risks to health, not only to employees, but also to the general public.

The risk to personnel associated with the presence of *Legionella* depends on a number of variables and may be quite low. However, since the actions to eradicate it are straightforward and reasonably practicable, it would be wise to put them in hand without delay if *Legionella* has been identified.

When analysis confirms that the levels of bacteriological contamination are in excess of acceptable limits, and/or the presence of Coliforms or *E.coli* is identified, the procedures recommended in this section should be applied.

5.1 Failure of Control Measures:

Where any reported test result, non-compliance issue or defect is made known which affects the integrity of the water system and indicates the failure of Control Measures and / or increased risk of Legionella the following procedures shall be followed and duly recorded within Section 2.3 of this document and brought to the attention of the relevant Infection Control Team and Water Management Group.

IN ALL CASES THE INCIDENT RECORD FORM (004) SHOULD BE COMPLETED AND INSERTED IN THE BUILDING SPECIFIC WATER SAFETY LOG BOOK.

5.2 High Cold Water Supply Temperature

Incident Plan

In the event of plant failure suppliers and installers guidance should be consulted. The location of all relevant literature should be recorded in the site logbook (e.g. Mercury fault finding guidance).

Mains and Stored Water

Currently there is no legal maximum water supply temperature from the Licensed Provider. In practice the water supply temperature to boundary point will be subject to seasonal variation. In winter this would normally be expected to be in the 5°C – 10°C range and in summer up to 20°C.

The following staged risk assessment escalation procedure should be employed where the water temperature in Cold Water Storage Tanks is 20°C or higher.

Stage 1 - Verification

- Where tepid cold water occurrence (i.e. $\geq 20^{\circ}\text{C}$) is reported from any numbers of cold water outlets, from maintenance/ppm, flushing procedures, from BEMS monitoring, or from the manual monitoring of storage tanks, the person identifying, or making a report must notify the relevant Authorised Person (Water) as soon as the problem is identified and confirm this in writing within 24 hours;
- The Authorised Person (Water) should liaise with the person identifying the problem and verify the problem by independently re-checking by means of taking the water temperature of the appropriate cold water storage tank, the temperature of each incoming mains supplies at the site boundary point (and building entry points of other buildings within the QEUH campus served by the same mains lines) and the outflow distribution temperature;
- If the cold water storage temperature is confirmed as being 20°C or higher at any of the above noted points, then the Authorised Person (Water) should record this in writing as well as conducting continuous monitoring of the incoming cold water mains, the cold water storage and the outflow temperatures to establish the temperature profiles and in more detail over at least a one week period to determine the level of risk;
- If only one of the incoming mains lines is $\geq 20^{\circ}\text{C}$ the consideration should be given to switching to the other mains supply until such times as “out-of-specification” mains line has returned to compliant parameters. Ensure if either mains line is non-operational it is included in a daily flushing regime and treated as per escalation procedures to follow.
- The Authorised Person (Water) should also review the Water Safety Log Book and take into account the recent water system history specifically to include:
 - the primary water treatment levels (for mains cold water supplied with Chlorine or Chloramination treatment);
 - any water sampling results;
 - system monitoring data including temperature monitoring and water quality chlorine or chloramination checks;
 - recent maintenance history; recent alterations, changes or additions to the water system;
 - any other changes made by Duty Holders or users of the water system; On reviewing continuous monitoring temperature profiles action as Stage 2, 3 or 4 as appropriate of this escalation procedure should be undertaken. The Authorised Person (Water) will ensure that the Responsible Person (Water) is notified immediately in writing at each stage and also recorded in the Water Safety log book.

Stage 2 - Initial Action – High Incoming Mains Cold Water Temperature

- Where the incoming mains cold water is 18°C or higher for more than a 48 hour period the Responsible Person (Water) should contact Business Stream (the Licensed Provider) who will work with Scottish Water to establish the reasons and determine a resolution. Continuous monitoring should continue and recorded in the risk assessment

Stage 3 - Water temperatures fluctuating above and below 20°C (but not higher than 25°C)

- Where water temperatures are fluctuating above and below 20°C in a regular cyclical manner over 72 hour periods in response to regular user water demand (but not higher than 25°C) and are more than 2°C higher than the incoming cold water mains supply temperature at the building entry point, then continuous monitoring should be continued by the Authorised Person (Water). The reason(s) for failure(s) should be identified and rectified as soon as possible. This should be recorded by updated risk assessment (specifically in relation to the patient risk rating – where there may be increased risk and appropriate actions may be required to mitigate exposure. An up to date register of all areas and their subsequent patient risk ratings should be maintained).
- considerations for failures include:
 - accuracy of temperature sensors (requiring recalibration);
 - temperature sensors being located in water (requiring reposition where tank storage levels been reduced and sensor no longer sensing stored water);
 - inappropriate standby tank configuration;
 - temperature sensor in standby system;
 - temperature sensor measuring stagnation (requires reposition);
 - inappropriate siting (not in a cool location);
 - heat gain to the tank and pipework (due to lack of appropriate insulation or located close to heat gain from other heat sources);
 - storage capacity not minimised to match daily use (12 hours storage is recommended);
 - ingress of hot water through cross connection or mixing valve failure (i.e. from DHW system or MTHW systems);

Stage 4 - water temperatures fluctuating above and below 25°C (and rarely below 20°C)

- In this situation continuous monitoring should be continued by the Authorised Person (Water), the reason(s) for failure(s) (as Stage 3) identified and rectified on an urgent basis. This should be recorded by updated risk assessment (specifically in relation to the patient risk rating – where there will be an increased risk and appropriate actions will be required to mitigate exposure. An up to date register of all areas and their subsequent patient risk ratings should be maintained);
- In this situation a permanent solution, such as ventilation for the plant room, or changing the water storage arrangements, or forming a circulating distribution system (with or without chilling depending on the circumstances) would require to be implemented;
- The Authorised Person (Water) should, unless instructed in writing to the contrary by Responsible Person (Water) implement the following:
 - o arrange to drain the tank contents and clean if necessary (*and/or carry out local disinfections where appropriate*);
 - o inform the users of the failed system that they must not draw off any water from the affected system until further notice;
 - o suitable disinfection of the tank and/or distribution system shall be carried out.

Please Note: *Due to the system design and installation complete disinfection of all downservices fed from the Raw and Bulk water storage tanks may not be practical as “high risk” system such as renal dialysis is fed from these tanks. Alternative protocols/method statements for local disinfections should be prepared and maintained;*

- o thereafter the tank/local area being disinfected shall be brought back into service;
- o finally the users shall be informed that the system is back in operation.

The Authorised Person (Water) shall complete an Incident Report Record Form. An entry should also be made in the Water Safety Log Book and the Responsible Person (Water) should be notified in writing as soon as possible.

5.3 Low Hot Water Supply Temperature

Incident Plan

In the event of plant failure suppliers and installers guidance should be consulted. The location of all relevant literature should be recorded in the site logbook (e.g. Mercury fault finding guidance).

Mains and Stored Water

Currently there is no legal maximum water supply temperature from the Licensed Provider. In practice the water supply temperature to boundary point will be subject to seasonal variation. In winter this would normally be expected to be in the 5°C – 10°C range and in summer up to 20°C.

The following staged risk assessment escalation procedure should be employed where the water temperature in Cold Water Storage Tanks is 20°C or higher.

Stage 1 - Verification

- Where tepid cold water occurrence (i.e. $\geq 20^{\circ}\text{C}$) is reported from any numbers of cold water outlets, from maintenance/ppm, flushing procedures, from BEMS monitoring, or from the manual monitoring of storage tanks, the person identifying, or making a report must notify the relevant Authorised Person (Water) as soon as the problem is identified and confirm this in writing within 24 hours;
- The Authorised Person (Water) should liaise with the person identifying the problem and verify the problem by independently re-checking by means of taking the water temperature of the appropriate cold water storage tank, the temperature of each incoming mains supplies at the site boundary point (and building entry points of other buildings within the Southern General Hospital served by the same mains lines⁸) and the outflow distribution temperature;
- If the cold water storage temperature is confirmed as being 20°C or higher at any of the above noted points, then the Authorised Person (Water) should record this in writing as well as conducting continuous monitoring of the incoming cold water mains, the cold water storage and the outflow temperatures to establish the temperature profiles and in more detail over at least a one week period to determine the level of risk;
- If only one of the incoming mains lines is $\geq 20^{\circ}\text{C}$ the consideration should be given to switching to the other mains supply until such times as “out-of-specification” mains line has returned to compliant parameters. Ensure if either mains line is non-operational it is included in a daily flushing regime and treated as per escalation procedures to follow.
- The Authorised Person (Water) should also review the Water Safety Log Book and take into account the recent water system history specifically to include:
 - the primary water treatment levels (for mains cold water supplied with Chlorine or Chloramination treatment);

- any water sampling results;
- system monitoring data including temperature monitoring and water quality chlorine or chloramination checks;
- recent maintenance history; recent alterations, changes or additions to the water system;
- any other changes made by Duty Holders or users of the water system;

On reviewing continuous monitoring temperature profiles action as Stage 2, 3 or 4 as appropriate of this escalation procedure should be undertaken. The Authorised Person (Water) will ensure that the Responsible Person (Water) is notified immediately in writing at each stage and also recorded in the Logbook via Incident form (04).

Stage 2 - Initial Action – High Incoming Mains Cold Water Temperature

- Where the incoming mains cold water is 18°C or higher for more than a 48 hour period the Responsible Person (Water) should contact Business Stream (the Licensed Provider) who will work with Scottish Water to establish the reasons and determine a resolution. Continuous monitoring should continue and recorded in the risk assessment.
-

Stage 3 - water temperatures fluctuating above and below 20°C (but not higher than 25°C)

- Where water temperatures are fluctuating above and below 20°C in a regular cyclical manner over 72 hour periods in response to regular user water demand (but not higher than 25°C) and are more than 2°C higher than the incoming cold water mains supply temperature at the building entry point, then continuous monitoring should be continued by the Authorised Person (Water). The reason(s) for failure(s) should be identified and rectified as soon as possible. This should be recorded by updated risk assessment (specifically in relation to the patient risk rating – where there may be increased risk and appropriate actions may be required to mitigate exposure. An up to date register of all areas and their subsequent patient risk ratings should be maintained).
- considerations for failures include:
 - accuracy of temperature sensors (requiring recalibration);
 - temperature sensors being located in water (requiring reposition where tank storage levels been reduced and sensor no longer sensing stored water);
 - inappropriate standby tank configuration;
 - temperature sensor in standby system;
 - temperature sensor measuring stagnation (requires reposition);
 - inappropriate siting (not in a cool location);
 - heat gain to the tank and pipework (due to lack of appropriate insulation or located close to heat gain from other heat sources);
 - storage capacity not minimised to match daily use (12 hours storage is recommended);
 - ingress of hot water through cross connection or mixing valve failure (i.e. from DHW system or MTHW systems);

Stage 4 - water temperatures fluctuating above and below 25°C (and rarely below 20°C)

- In this situation continuous monitoring should be continued by the Authorised Person (Water), the reason(s) for failure(s) (as Stage 3) identified and rectified on an urgent basis. This should be recorded by updated risk assessment (specifically in relation to the patient risk rating – where there will be an increased risk and appropriate actions will be required to mitigate exposure. An up to date register of all areas and their subsequent patient risk ratings should be maintained);
- In this situation a permanent solution, such as ventilation for the plant room, or changing the water storage arrangements, or forming a circulating distribution system (with or without chilling depending on the circumstances) would require to be implemented;
- The Authorised Person (Water) should, unless instructed in writing to the contrary by Responsible Person (Water) implement the following:
 - o arrange to drain the tank contents and clean if necessary (*and/or carry out local disinfections where appropriate*);
 - o inform the users of the failed system that they must not draw off any water from the affected system until further notice;
 - o suitable disinfection of the tank and/or distribution system shall be carried out.

Please Note: *Due to the system design and installation complete disinfection of all downservices fed from the Raw and Bulk water storage tanks may not be practical as “high risk” system such as renal dialysis is fed from these tanks. Alternative protocols/method statements for local disinfections should be prepared and maintained;*

- thereafter the tank/local area being disinfected shall be brought back into service;
- finally the users shall be informed that the system is back in operation.

The Authorised Person (Water) shall complete an Incident Report Record Form. An entry should also be made in the Water Safety Log Book and the Responsible Person (Water) should be notified in writing as soon as possible. Record on Incident form (04).

Hot Water Services

When hot water storage or distribution temperatures fall below those required (60°C storage, 55°C at outlets and returning to calorifier) these will almost inevitably be caused a mechanical fault. Appropriate maintenance procedures, including the Mercury Fault Finding guidance documents, should be created and referenced to assist in timely rectification.

This escalation procedure (taken from SHTM 04-01 Part G (Draft)) should be employed if the Calorifier/Plate Heat Exchangers outflow temperature falls below 45°C.

The table below should be used to decide on the actions necessary in the event of a plant breakdown such as power failure or gas supply failure.

Breakdown leading to temperature <45°C, lasting for:	Risk Category	Action
<12 hrs	High	Verify
	Significant	Verify
	Moderate	Verify
>12 hrs	High	Thermally pasteurise
	Significant	Verify
	Moderate	Verify
>24 hrs	High	Thermally pasteurise
	Significant	Thermally pasteurise
	Moderate	Verify
>72 hrs	High	Thermally pasteurise
	Significant	Thermally pasteurise
	Moderate	Thermally pasteurise

In the event of a reduction in domestic hot water temperature the **Authorised Person (Water)** should be notified in writing as soon as possible. The reason for failure must be identified and rectified as soon as possible.

The **Authorised Person (Water)** shall notify the **Duty Holder** and users on the failed system that they must not draw off any hot water from the affected services until further notice.

The relevant **Duty Holder** shall ensure that their staff are aware of the situation, and that they in turn shall prevent patients from using affected services.

Where thermal pasteurisation is to be carried out, the temperature of the calorifier or plate heat exchanger shall be raised to 70°C, and the water shall be circulated throughout the affected distribution system for at least one 1 hour. Each tap or appliance should be run in sequence until full temperature is achieved (this should be measured). To be effective the temperature in the calorifier or plate heat exchanger should be high enough to ensure that all distribution outlets receive water at a temperature of greater than 60°C. Ensure the return flow to the calorifier or plate heat exchanger is no less than 55°C.

The **Authorised Person (Water)** shall inform users that the system is back in operation. Bacteriological samples should be taken in consultation with the Infection Prevention and Control team. The **Authorised Person (Water)** shall complete an Incident Report Record and ensure the **Responsible Person (Water)** is notified in writing as soon as possible. Maintain hard copy records in the Water Safety Log.

5.4 Positive Legionella Test Result

Microbiological Sampling (Legionella)

Sampling requirements and frequency are to be formulated by NHS GG&C and written scheme should be updated as appropriate.

Legionella testing may be required:

- In systems where the temperature control regimes are not consistently achieved, frequent testing e.g. weekly should be carried out to provide early warning of loss of control. Once the system is brought back under control as demonstrated by monitoring, the frequency of testing should be reviewed
- Weekly checks are recommended until the system is brought under control;
- When an outbreak is suspected or has been identified;
- In wards with at-risk patients – for example those who are immuno-compromised (“high risk patient” areas still to be confirmed to DMA).

As a minimum, samples should be taken as follows:

- From the cold water storage and the furthestmost outlet from the tank, on every loop;
- From the calorifier flow, or the closest tap to the calorifier, and the furthestmost tap on the hot water service circulating system (these should be identified on sentinel outlet register);
- Additional samples should be taken from the base of the calorifier via drain valves;
- From areas where the target control parameters are not met (i.e. where temperatures are below 55°C for hot water systems or $\geq 20^{\circ}\text{C}$ for cold water systems);
- From areas subject to low usage, stagnation, excess storage capacity, dead legs, excessive heat loss, crossflow from the water system or other anomaly.
- High Risk Patient Areas
- Additional random samples may also be considered appropriate where systems are known to be susceptible to colonisation.

The temperature control regime is the preferred strategy for reducing the risk from *Legionella* and other waterborne organisms in water systems. This will require monitoring on a regular basis. The recommended test frequencies for various outlets are set out in Table 2 in Section 7.

HSG 274 Part 2 Table 2.3 Actions to be taken following legionella sampling in hot and cold water systems in healthcare premises with susceptible patients

Legionella bacteria (cfu/Litre)	Action required
More than 100 but less than 1,000	Low risk area Estates action only If only one or two samples are positive, system should be re-sampled. If a similar count is found again, a review should be carried out to identify any remedial actions a) If the majority of samples are positive, the system may be colonised, albeit at low level, with Legionella. Disinfection of the system should be considered but an immediate review of control measures and risk assessment should be carried out to identify any other remedial actions required. If remedial action is ineffective further measures will be discussed and approved by the Board Water Safety Group
More than 100 but less than 1,000	High Risk areas Impact on patient care Discuss results with ICD and agree actions and any closure of area.
More than 1,000	Low Risk Estates action only The system should be re-sampled and an immediate review of the control measures and risk assessment carried out to identify any remedial actions, including possible disinfection of the system. If remedial action is ineffective further measures will be discussed and approved by the Board Water Safety Group
More than 1,000	High Risk areas Discuss results with ICD and agree actions and any closure of area.

Communication pathway for Legionella results from water samples:

Water samples are sent to; UKASS-accredited laboratories which provide this service for NHS and other organisations that manage buildings. Reports will come back initially to the estates department.

Negative water samples are recorded as part of the documentation of Legionella control. If they are related to investigation of an “incident” such as a clinical case or a previous positive sample then these results are communicated to those managing that incident.

The information on the report which needs to be communicated is:

- Date of sampling
- Location and type of water outlet
- Identification of the organism, (Legionella pneumophila with serogroup, or Legionella species other than L pneumophila.)
- Count of organisms per Litre.

Estates will

- Inspect the system and take further action in accordance with HSE guidance and locally agreed procedures
- Inform Charge Nurse and or Clinical Nurse Manager of the Clinical Area concerned if appropriate of any control measures being taken/required
- Inform GM for the Sector if appropriate.

The results of this initial risk assessment must be communicated to all those noted above and also to the Facilities General Manager for the site involved.

The Infection Control Manager for Infection Prevention and Control will inform NHS GG&C

If there is impact on patient care then an Incident Management Team (IMT) may be convened to assess the risk and further actions.

Refer to WQS – 017 for out of spec procedure

See table in Appendix 2

5.5 Intermittent or Infrequently Used Water Outlets

If after investigation the taps or appliances identified within the reviewed list, to be updated on a quarterly basis, is deemed not necessary wherever possible the supply pipe work shall be cut back as close to the main circulating line as practicable to ensure that any dead leg formed is minimised and the appliance is removed from the water system.

In circumstances where there has been a lapse in the flushing regime, the stagnant and potentially contaminated water from within the shower or tap and associated dead leg should be purged to drain without discharge of aerosols before the appliance is used.

Where a ward or department is closed or taken out-of-use for an extended period of time e.g.: pending refurbishment, change in-use or other reason, arrangements shall be put in place to ensure the regular flushing and recording of water outlets within such areas. If such closures are considered to be long term or permanent consideration should be given to the disconnection of all water services to the affected areas.

5.6 Emergency Repairs

Emergency repairs may be required at any time and should be undertaken by trained and competent personnel. Such repairs can vary from a simple repair to a section of pipework, replacement of a component or major burst or loss of service. In all such cases the integrity and safety of the water distribution system must be maintained at all times.

5.7 Disinfection of Water System and Components

There are a number of different chemical and thermal disinfection methods available ALL of which shall be undertaken by trained and competent personnel in strict accordance with all Statutory Requirements, Safety Precautions and Manufacturers Instructions.

Disinfection – is the process of destroying or inactivating Pathogenic organisms and is generally applied to the water supply.

Sterilisation – is the process of destroying or inactivating all Organic Life Forms and is generally applied to all systems of transmission and storage materials.

In ALL instances no matter what disinfection method is employed, due regard shall be taken of patient groups, specialist equipment and processes which may be sensitive to the disinfection process being used – eg Renal Dialysis patients **must not** be exposed to Silver Hydrogen Peroxide chemicals as such the RO Water Treatment Plant and Dialysis Machines must be disconnected from the water system until the disinfection process is completed.

Silver Hydrogen Peroxide should NOT be used for a period of 90 days or longer, as required by the Drinking Water Inspectorate.

The disinfection process may be required for the following situations:

REPAIRS -	Repair fittings and exposed pipe ends should be clean and disinfected before use. Such items should be sprayed with a suitable disinfection solution such as a Sodium Hypochlorite @ a strength of 1000 mg/l (1000ppm) with a minimum contact time of 5 minutes or equal and approved.
MINOR ALTERATIONS -	Pipework should be cleaned internally by spraying with a suitable disinfection solution such as a Sodium Hypochlorite @ a strength of 1000 mg/l (1000ppm) or where pipes are long and internal surfaces cannot be reached with sprays then a swab soaked in a solution of 50mg/l (50ppm) with a contact time of one hour or equal and approved.
NEW SUPPLY PIPEWORK -	Pipes are filled with a solution such as a Sodium Hypochlorite @ a strength of 20 mg/l (20ppm) with a contact time of 24 hours. Or Sodium Hypochlorite and water at a strength of 50mg/l (50ppm) for a contact period of one hour. Minimum free chlorine after one hour – 30mg/l (30ppm) or equal and approved
SYSTEM DISINFECTION -	This will include water storage tanks and possibly the water distribution system. The advice and use of Legionella Control Association (LCA) approved contractors will be used for this purpose

NOTE:

Appropriate Method Statements and Risk Assessments will be compiled and obtained prior to any disinfection process commencing. Water Disinfection Risk Based Assessment Form (024) should be completed prior to any disinfection process being carried out. (SHTM 04-01 Part G (V1 July 2015) Page 38 para 5.9)

An alternative to chemical disinfection is to pasteurise the system. This involves increasing the temperature to greater than 60°C by increasing the thermostat setting at the calorifier or boiler and recirculation as necessary to maintain this temperature throughout for at least one hour. This should effectively sterilise the calorifier, and kill any *Legionella* organisms present.

The water should be flushed through the system more than once. It is important that all taps are run for at least 5 minutes (preferably longer) at full temperature to ensure that the complete system is pasteurised and that the hot water has reached all parts of the system.

5.8 Pseudomonas SOP

Standard Operating Procedure for minimising the risk of Pseudomonas

This SOP provides direction and guidance for ward based staff to meet their responsibilities as stated in *HPS(2013) Guidance for neonatal units (NNUs) (levels 1,2&3), adult and paediatric intensive care units (ICUs) in Scotland to minimise the risk of Pseudomonas aeruginosa infection from water*. This document refers to critical control points 2 – 4 (inclusive) only. (Critical points 1, 5 and 6 are considered in the NHSGGC Water Safety Policy 2013.

*High Dependency Units (HDUs) which are adjoining/ integrated with an ICU should be included in this guidance.

Responsibilities:

Senior Charge Nurses (SCNs) must:

- Follow this SOP.
- Ensure that they are aware of access issues to wash hand basins. Where access is an issue they must arrange for flushing to occur and document this.
- Keep records of daily flushing for at least one month within the Facilities Folder.
- Inform a member of the local Estates Team if this SOP cannot be followed in relation to flushing water outlets.
- Inform a member of the local Estates Team of infrequently used outlets which could be removed.
- Allow members of the local Estates Team access to complete maintenance as appropriate.

Estates must:

- Undertake actions deemed the responsibility of the local Estates Department as per the Water Safety Policy.
- Keep a record of outlets reported that are deemed to be infrequently used and actions taken by them to remove this risk.
- Provide a report of maintenance actions and issues/ anomalies to the Sector Water Safety Group.
- Support staff locally to undertake their responsibilities in terms of reducing risk associated with pseudomonas.

Domestic Services must:

- Ensure that water outlets are flushed at full flow for 1 minute (not causing splashing) as part of the cleaning process and to ensure for Mixer taps that this ensures an equal mix of cold and hot. If full flow cannot be achieved taps should be flushed for a longer period following assessment.
- Ensure this is the first task completed of the day.
- Record this in the Domestic services Compliance Checklist “Water Outlets”
- Ensure the Checklist is retained within the facilities Folder at ward level for one month.
- Send a copy of flushing records to Water AP and to ensure any rooms/areas which were not flushed are identified.
- Domestic Services Supervisors and Managers must also notify Estates LAP, if they identify any unused areas or outlets as per SHTM04-01 Part G Section 8.3.

Managers must:

- Make this SOP available to their staff.
- Support SCNs in following this SOP.

Water Systems Group must:

- Keep this SOP up-to-date.
- Audit compliance with this SOP.
- Provide guidance via the Water Systems Policy.

5.9 Flushing Water Outlets

Flushing of water outlets is necessary to control the build-up of biofilm in water systems to reduce the risk of transmission of pathogens via the environment and equipment to patients.

The Senior Charge Nurse (SCN) in each unit has responsibility (under current guidance) to ensure that the following recommendations are complied with in their area. The SCN should ensure that:

All little used outlets outlets that are not used at least twice weekly in general areas and daily on high risk area identified on WS01a form. These must be flushed at full flow (but not so that splashing goes beyond the basin. However if taps cannot be flushed on full flow they should be flushed for longer based on specific assessment. The manager responsible for the ward or department must put systems in place for the outlet to be flushed to waste for 3 minutes as per SHTM04-01 Part G Page 111.

Where the outlet may be used by high-risk patients, more frequent flushing may be needed and the frequency should be determined following a risk assessment.

Additionally high high-risk environments (adult, paediatric and Neonatal ICUs and associated HDU's), flushed daily, first thing in am for 1 minute at full flow (but not so that splashing goes beyond the basin). However if taps cannot be flushed on full flow they should be flushed for longer based on specific assessment.

Additionally Facilities (Domestic Services) to ensure that all water outlets are flushed daily where access is available and all outlets flushed for 1 minute at full flow (but not so that splashing goes beyond the basin). However if taps cannot be flushed on full flow they should be flushed for longer based on specific assessment. Records must reflect where access is not available or outlets not able to flush e.g. rooms/areas under Estates, Minor Works, Capital or no access at the weekend.

Domestic Services Supervisors and Managers will also notify Estates if they identify any unused areas or outlets or outlets not able to flush as per requirements of *SHTM04-01 Part G Section 8.3*.

These should be reflected on the department flushing records.

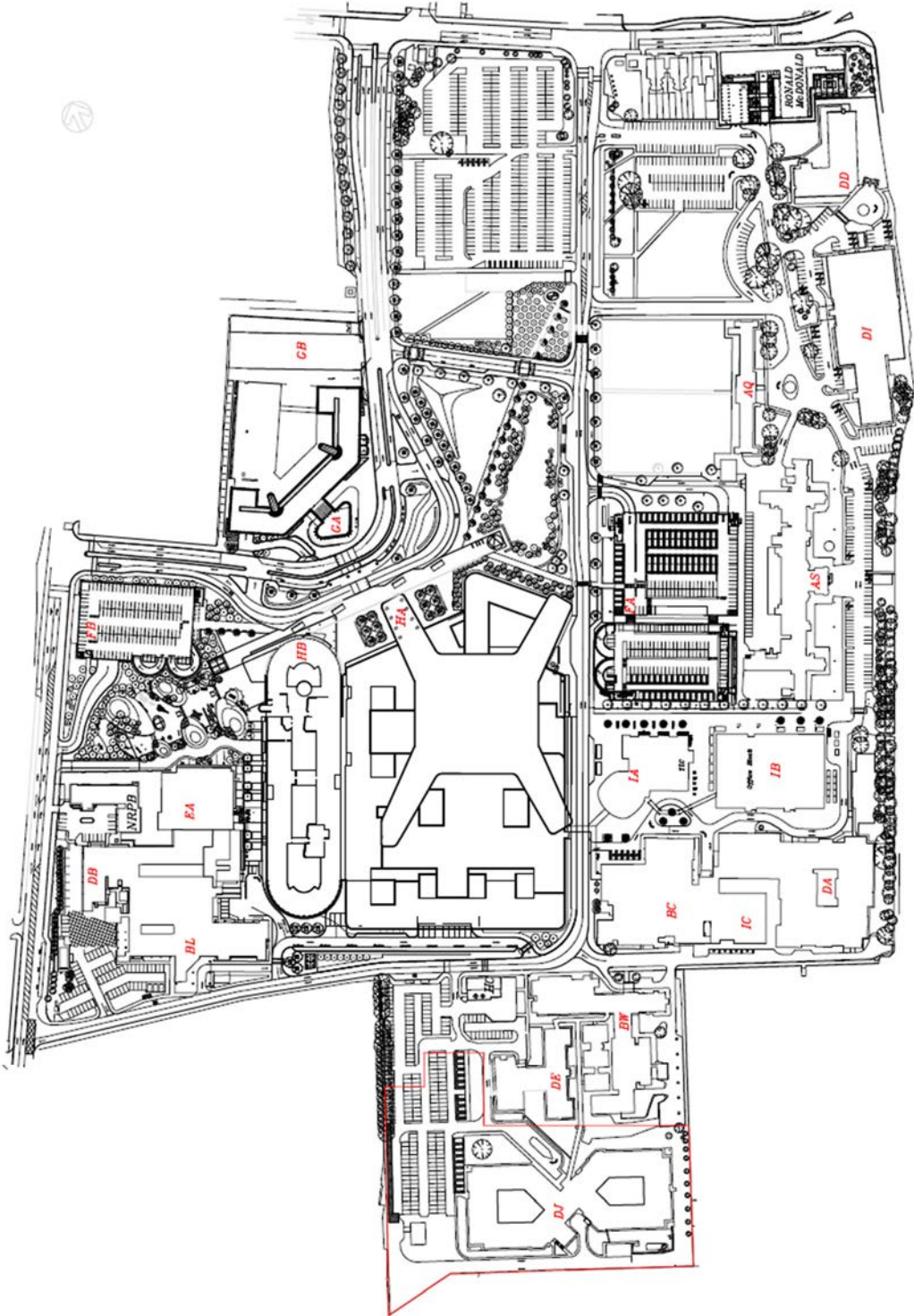
These must be reviewed on a daily basis by the SCN and appropriate action taken when this is identified as not having been completed.

Any problems or concerns relating to the safety, maintenance, reduced usage, any changes in use and cleanliness of all water outlets are identified and reported to the ICT, Facilities and Estates Department as relevant.

For more information refer to NHS Greater Glasgow and Clyde
'Water Systems Safety Policy Written Scheme and Operational Procedures'

Appendix 1

Site Plan with
Block Codes



Queen Elizabeth University Hospital

Appendix 2

Procedures in the event of out of specification sample for Legionella, Pseudomonas and other monitored bacteria, fungi, moulds, yeasts etc.

Document **WQS014** details.

- Sampling frequencies and details what is sampled and where.
- Out of specification process
 - o Resampling.
 - o Out of specification on point of use filter.
- Sampling standards.
- Waste sampling out of specification definition.
- Designated High Risk Areas.

Appendix 3

Risk Assessment Review Guidance

Summary of L8 Management Tasks Required for L8 and SHTM 04-01 Compliance	Guidance Documents	Allocated to
Regular check to ensure that legislation and guidance has not changed	L8 HSG 274 Pt 2 SHTM 04-01	
Regular review of all policies relating to legionella control (e.g. Maintenance, Water Treatment, Water Management, Energy) to ensure still valid and correct	L8 HSG 274 Pt 2 SHTM 04-01	
Regular review of L8 Management Structure to ensure up-to-date and accurate	L8 HSG 274 Pt 2 SHTM 04-01	
Regular review of communication lines to ensure still accurate and correct	L8 HSG 274 Pt 2 SHTM 04-01	
Regular review of escalation & emergency procedures to ensure still valid and correct	L8 HSG 274 Pt 2 SHTM 04-01	
Regular review of duties allocated to site staff and ensure accurate and recorded	L8 HSG 274 Pt 2 SHTM 04-01	
Regular review of duties of sub-contractors and ensure accurate and recorded and contractors are suitably qualified/competent for tasks assigned to them (e.g. Water Hygiene contractors should be LCA Approved, Plumbing contractors should be SNIPEF and Water Safe Registered)	L8 HSG 274 Pt 2 SHTM 04-01	
Regular review of staff training requirements and update training matrix	L8 HSG 274 Pt 2 SHTM 04-01	
Regular review of method statements and risk assessments to ensure still valid and correct	L8 HSG 274 Pt 2 SHTM 04-01	
Regular review of site documentation to ensure all records up to date and present	L8 HSG 274 Pt 2 SHTM 04-01	
Regular update of "Patient Risk Rating" register for all areas of hospital.	SHTM 04-01 Part B	
Regular review of sentinel outlet locations register.	SHTM 04-01 Part B	
Regular review of primary, sub-ordinate and tertiary hot flow and return loops to reflect any system alterations.	HSG 274 Pt 2	
Regular review of plant and equipment maintenance schedules.	Manufacturer's Instructions	
Regular review of BEMS temperature sensor locations to reflect any system alterations	HSG 274 Pt 2	
Regular review of schematic/as-fitted drawings to ensure up-to-date and accurate	L8 HSG 274 Pt 2 SHTM 04-01	
Regular review of L8 risk assessment with a maximum period of two years between updates. (e.g. if change of use or changes in legislation or any other factor which could affect validity of current assessment)	L8 SHTM 04-01	

Appendix 4

HAISCRIBE Risk Assessments

All relevant HAISCRIBE risk assessments produced and approved for Water Systems related tasks are stored on the QEUH Shared Drive within the folder path “

HAI SCRIBE



Water Systems Safety Policy

**(To be read in conjunction with NHSGG&C Water
Safety Written Scheme and Operational Procedures)**

Lead Manager	Associate Director Facilities & Infection Control Manager
Responsible Director	Director of Property, Procurement and Facilities Management
Approved By	Board Infection Control Committee (BICC) & SCART Steering Group
Date Approved	May 2017
Review date	May 2018

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1.0 Introduction

NHS GG&C has a duty to protect all patients, employees, contractors, voluntary workers, visitors as well as members of the public from the risk of being infected by bacteria or pathogens which occur naturally in water supply systems and water dispensing equipment

Those that should be considered at risk and vulnerable include:

- Vulnerable patients with suppressed immune systems as defined and agreed by Sector Water Safety Groups and the Board Water Safety Group in all locations.

2.0 Scope

NHSGG&C has established a system of control for the management of water systems that shall ensure the safety of those within its premises by putting in place, both physical and procedural controls.

These controls shall be systematically examined and monitored by the Facilities Directorate, Infection Control, Health and Safety Department and the Board Water Safety Group which is a sub group of the Board Infection Control Committee.

This policy shall apply to all NHSGG&C managed and controlled premises.

3.0 Roles and Responsibilities

3.1 Chief Executive – Duty Holder

The Chief Executive (CE) has ultimate responsibility / accountability for water system safety within NHSGG&C.

The responsibilities of the Chief Executive (CE) include:

- Responsibility for implementation of the relevant mandatory and statutory elements contained in the following documents;
 - Health & Safety Commissions Approved Code of Practice and Guidance L8 (ACOP L8) - “Legionnaires Disease, The control of legionella bacteria in water systems”;
 - HSG 274 Part 2 – “Legionnaires Disease, The control of legionella bacteria in hot and cold water systems”;
 - HSG 274 Part 3 – “Legionnaires Disease, Technical guidance, The control of legionella bacteria in other risk systems”;
 - SHTM 04-01: The control of Legionella, hygiene, safe, hot water, cold water and drinking water systems;
 - CEL 08(2013) water sources and potential risk to patients in high risk units – revised guidance.
 - The implementation of Guidance for neonatal units (NNU’s) (levels 1, 2 & 3) adult and paediatric intensive units ICU’s in Scotland to minimise the risk of Pseudomonas aeruginosa infection from water.

- Ensuring that adequate resources are provided to meet the Water Systems Safety requirements of NHS GG&C estate;
- Ensuring that the Water Systems Safety Policy is being implemented at all levels;
- Reviewing and monitoring the operation of the Water Systems Safety Policy through the Board Corporate Management Team and ensuring that clear guidelines are provided for this tasked with compliance of legislative and statutory standards;
- Appointing the Designated person (Pseudomonas) and Designated person (Water) to assist in the execution of these responsibilities, who for NHS GG&C are the Infection Control Manager (Pseudomonas) and the Director of Facilities (Water).

3.2 Director of Property, Procurement & Facilities Management – Designated Person (Water)

The Director of Property, Procurement & Facilities Management is the Designated Person (Water). He shall be responsible for the following and if required delegate appropriately:

- Ensuring that Facilities staff, through the general management structure, are fully aware of the current statutory and mandatory requirements and standards for the provision and maintenance of safe water systems;
- Ensuring with the Responsible Person (Pseudomonas) that the Water System Safety Policy is regularly reviewed and updated;
- Co-Chair the NHS GG&C Water Systems Safety Group;
- Appointing in writing the Responsible Person (Water) at sector level (Sector Estates Manager), Deputy Responsible Person(s) (Water) at site level (Site Maintenance/Estates Manager) and the Authorised Person (AP) (Water) at site level within the Facilities Directorate Management structure.

3.3 Infection Control Manager – Designated Person (Pseudomonas)

The Infection Control Manager (ICM) supported by the Board Infection Control Doctor is the Responsible Person (Pseudomonas). They shall be responsible for:

- Ensuring that Infection Control Teams are fully aware of current guidance on Legionella control matters and the minimisation of the risk of Pseudomonas aeruginosa infection from water;
- The implementation of Guidance for neonatal units (NNU's) (levels 1, 2 & 3) adult and paediatric intensive care units ICU's in Scotland to minimise the risk of Pseudomonas aeruginosa infection from water;
- Ensuring with the Designated Person (Water) that the Water System Safety Policy is regularly reviewed and updated;
- Co-Chair the NHS GG&C Water Systems Safety Group;
- Appointing in writing the Responsible Person(s) (Pseudomonas) at sector level. This shall be the relevant Infection Control Doctor.

3.4 Sector Estates Manager – Responsible Person (Water)

The Sector Estates Manager (SEM) will be appointed as the Responsible Person (Water) at Sector level by the Director of Property, Procurement & Facilities Management in writing. The Sector Estates Manager is responsible for:

- Ensuring the effective maintenance of engineering controls installed for the purposes of controlling water systems;
- Ensuring that written schemes and risk assessments are in place and reviewed regularly;
- Devising and maintaining procedures to ensure the quality of water on premises is maintained;
- Ensuring operational procedures are carried out and documented;
- Ensuring records are kept of all water systems and their purpose, giving locations recording and maintaining within the Boards estates management system;
- Liaise closely with other professionals to ensure legislative and statutory compliance is maintained by the Board.

3.5 Authorising Engineer (AE)

The Authorising Engineer (AE) is appointed in writing (or as delegated by) the Director of Property, Procurement & Facilities Management and is employed independently of NHS Boards and acts as an independent professional advisor to the healthcare organisation, appointed by the organisation with a brief to provide services in accordance with Scottish Health Technical Memorandum (SHTM) 04-01 guidance.

The AE will have specialist knowledge of large scale domestic and commercial hot and cold water services installations including incoming supplies, fire fighting services, wet risers, etc., and in particular, these installations for which an Authorised person (AP) (Water) will assume responsibility for an appointment.

The AE (Water) is free to comment on the organisational risk basis and give guidance on the numbers of AP (Water) being proposed by NHSGG&C across sites.

The Authorising Engineer will carry out the following main duties:

- act as an assessor, making recommendations for the appointment of Authorised Persons (AP) (Water) in terms of skills, training and site familiarity;
- monitor the performance of the service against ACoP L8, HSG274 and SHTM 04-01 guidance;
- provide an annual audit to the organisation's Designated Person.

3.6 Authorised Person (Water)

The Authorised Person (Water) has the key operational responsibility for the service, qualified, sufficiently experienced and skilled for the purpose. He/she will be nominated by the Authorising Engineer (AE) and be able to demonstrate

- His/her application through familiarisation with the system and attendance at an appropriate professional course;
- A sufficient level of experience;
- Evidence of knowledge and skills.

An important element of the Authorised Person (Water) role is the maintenance of records, quality of service and maintenance of system safety (integrity).

The Authorised Person (Water) will also be responsible for establishing and maintaining the roles and validation of Competent Persons (Water) who shall be suitable trained employees of the organisation or appointed contractors.

Larger sites may require more than one Authorised Person (Water) for a particular service.

3.7 Senior General Manager – Property & Capital Planning – Deputy Responsible Person (Water)

The Senior General Manager – Property & Capital Planning will be appointed as a Deputy Responsible Person (Water) at Board level by the Director of Property, Procurement & Facilities Management or his delegated Manager in writing. The Head of Capital Planning is responsible for:

- Ensuring that any new works undertaken or refurbishment within existing premises shall comply with the requirements of this Policy and the Written Scheme and Operational Procedure for managing Water Safety including The control of legionella, hygiene, 'safe' hot water, cold water and drinking Water systems;
- Ensuring all works are handed over to estates in compliance with the handover protocol for water as identified in the written scheme;
- Ensuring that all potential interfaces between an operating system are new and refurbishment works shall meet the approval of the Responsible Person (Water) and Authorised Person (Water) as to methodology for making that interface;
- Ensuring that any work involving the installation of water services or equipment requiring a water supply shall follow the guidance in SHTM 04-01, HSG274 Parts 2 & 3 and HSE document L8 and shall be certified by the design engineer at to that compliance;
- Ensuring that any works which will affect an operational water service will be discussed with the estates Authorised Person (Water) prior to arranging that work.
-

3.8 Site Maintenance Manager/Site Estates Manager – Deputy Responsible Person (Water)

The Site Maintenance Manager/Site Estates Manager shall be appointed in writing by the Director of Property, Procurement & Facilities Management in writing as the Deputy Responsible Person (Water) and will also act as the Designated Person Water in the absence of the Designated Person (Water). The Site Maintenance Manager/Site Estates Manager is responsible for:

- Ensuring building water systems are operated in accordance with the current guidance, and with the assessed risk of the individual systems under their control;
- Ensuring all staff conducting water system maintenance are competent to do so;
- Ensuring water system maintenance records are maintained and kept up-to-date;
- Regularly checking maintenance records;
- Ensuring all work is completed in accordance with the NHS GG&C Estates Procedures.

3.9 Acute Services Directors, CH(C)P Directors and Corporate Division Directors

As Senior Managers, NHS GG&C Directors play an intrinsic role in ensuring that water safety is embedded within the culture of the organisation.

The responsibilities of Directors include:

- Supporting the Designated Persons (Water) and (Pseudomonas) in the development of the Board's overall strategy in relation to water safety and for ensuring implementation within their areas of responsibility;
- Ensuring that all staff are made aware of their requirement to attend Water Safety training at the appropriate frequency, as per the NHS GG&C Water Safety Policy and Operational Procedures which underpin this by facilitating staff release from duties to attend training;
- Support action to address staff who put themselves and/or others at risk from a real or potential water safety incident;

3.10 Heads of Service, Departmental Managers, Clinical Managers, Senior Charge Nurse's

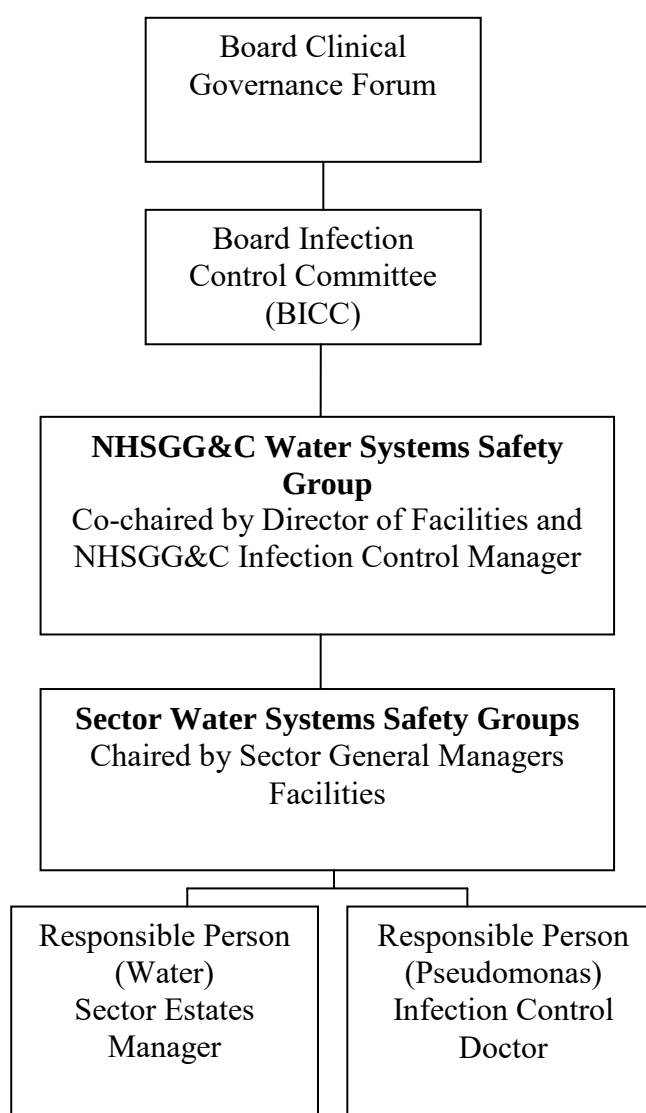
All managers who have a responsibility for the day to day management of facilities, staff or services, and/or premises, have water safety responsibilities that include:

- Familiarise themselves with the NHS GG&C Water Safety Policy and local control measures including any water risk assessments for their area(s) of responsibility;
- Ensuring that persons in the department, clinic or ward are fully aware of their responsibilities and duties in respect of Water Safety, in particular, the

action required of them should the area be defined as High Risk by the local Water Safety Group

- Ensure that persons in the department, clinic or ward are fully aware of the 'Infrequently Used Outlets' definitions and Operating Procedure which underpins the NHSGG&C Water Safety Policy
- Actively promoting Water Safety within the department or ward by maintaining good housekeeping within the department or ward at all times, ensuring that any flushing or documentation as described in the Water Safety Written Scheme and Operational Procedures documentation is completed on time
- Responding appropriately to any water safety concerns that persons in the department, clinic or ward have;
- Nominating a responsible person to complete the Monthly 'Infrequently Used Outlets' Audit for each area, forwarding a copy to the Site Maintenance/Estates Manager, thereby assisting NHSGG&C to meet its statutory and mandatory requirements;
- Ensuring that action is taken on a daily basis to address any access issues identified within the Cleaning Compliance Checklist Sign Off documentation retained in the Facilities Folder.
- Liaising with the estates department as required

4.0 Governance Structure



The governance arrangements described above shall be put in place within NHSGG&C.

The responsibilities of the **Corporate Management Team** include:

- Implementing the Boards overall Water Systems Safety Policy including legislative compliance.
- Liaising with the Infection Control Manager (Designated Person (Pseudomonas)) and the Director of Property, Procurement and Facilities Management (Designated Person (Water)) to ensure the Boards Water Systems Policy is understood and applied across all areas of the Board.
- Formulating with the Infection Control Manager and Director of Property, Procurement and Facilities Management a Water Systems safety compliance programme for both passive and active measures in both existing building and new projects.

- Performing governance responsibility for reviewing operational arrangements effectiveness. The Corporate Management Team will be advised on this by the Boards Infection Control Committee (BICC) with contributions from the Infection Control Manager (Designated Person (Pseudomonas)) and the Director of Property, Procurement and Facilities Management (Designated Person (Water)) via the Board Water Systems Safety Group

5.0 Risk Reduction Strategy / Procedures

Following any assessment of the risk, risk reduction strategies and procedures must be implemented where possible to reduce the likelihood and/or severity of incidents from infection

Risk Reduction strategies/procedures include:

- Policy awareness and implementation;
- Risk assessment both generic and specific;
- Training;
- Local procedure development;
- Reporting and recording;
- Evaluating effectiveness of risk reduction strategies/procedures;
- Reviewing in the light of experience; look at incident investigation and inspection reports. Do they show improvement?
- Re-train staff if required, reading available policies, strategies and procedures;
- Review clinical and workplace risk assessments after reports of any adverse events;
- Implementation of risk reduction strategies as defined by the findings of the risk assessment for the NHSGGC buildings;
- Implementation of a formal review/audit process of the risk reduction procedures;
- Implementation of contractor audit and review procedures.

Sector Water Safety Groups are responsible for ensuring that a multi disciplinary approach is taken to Risk Reduction within the Board at local level.

6.0 Operational Arrangements

Water systems throughout NHSGG&C are subject to a routine planned maintenance system. NHSGG&C shall have in place a site specific Written Scheme and Operational Procedure for Water System Safety

The written scheme and Operational procedure for Water System safety shall be followed for the management of water systems for the prevention of infection

7.0 Testing for Legionella

In keeping with the current HSE guidance, testing for legionella will be carried out within NHSGG&C as follows:-

Clinical Risk Areas;

- It has been agreed with the NHS GG&C Lead Infection Control Doctor that the following area is a 'high-risk clinical area' where immune-compromised patients are present;
 - Transplant units.

The 'clinical high risk areas' will be specifically identified within the site specific 'written scheme';

Engineering Risk Areas;

Due to the 'age' of the current building stock within NHS GG&C it is recognised that there are areas where a 'high-risk' is present due to current water distribution configuration and as such testing will be required. The 'engineering risk areas' are as follows:

- In water systems treated with biocides where water is stored or distribution temperatures are reduced;
- In water systems where the control levels of the treatment regime, eg temperature or disinfectant concentrations, are not being consistently achieved;
- In water systems suspected or identified in a case or outbreak of legionellosis where it is probable the Incident Control Team will require samples to be taken for analysis;
- In areas which have been identified within the current Water Safety Risk Assessment as being of a risk.

The 'engineering high risk areas' will be specifically identified within the site specific 'written scheme'.

8.0 Pseudomonas

NHS GG&C complies with the HFS, HPS and *Pseudomonas aeruginosa* and Water (Scotland) Group guidance document titled '*Guidance for neonatal units (NNUs) (levels 1, 2 & 3), adult and paediatric intensive care units (ICUs) in Scotland to minimise the risk of Pseudomonas aeruginosa infection from water*' version 2 dated July 2014.

9.0 Reporting and Monitoring

If, following a legionella water sample, a reading of legionella bacteria is shown to be present and, following the criteria that the usual control measures to eliminate this legionella bacteria have been undertaken, that should the follow-up reading still record that legionella bacteria is present, then a record of this incident will be made on NHS GG&C's Datix reporting and recording system in line with the NHS GG&C's

Incident Management Policy and Procedure. The Facilities Directorate must be copied into all Datix reported incidents.

Line managers must ensure that a review and investigation of an infection incident which can be demonstrated as originating in a water system is carried out and recorded.

They should be reviewed as a significant adverse event as per the Incident Management Policy and Procedure.

In order to ensure the implementation and effectiveness of this policy all incident reports relating to water management should be reviewed regularly by the responsible manager via the Sector Water Safety Group.

10.0 Audit

The application and effectiveness of this policy throughout the organisation shall be monitored by the Health and Safety Department reporting via the Board Water Safety Group and the Estates Senior Management Team (SMT).

The policy will be reviewed and revised on a regular basis or as a result of changes in legislation and national guidance.

11.0 Guidance

The following references form a compendium of literature available at the present time to which reference should be made –

- Health & Safety at Work, etc. Act 1974
- The Management of Health and Safety at Work Regulations 1999 & (Amendment) Regulations 2006
- The Control of Substances Hazardous to Health Regulations (COSHH) 2002 7 (Amendment) Regulations 2004
- Approved Code of Practice & Guidance, 'Legionnaires' disease: The control of Legionella bacteria in water systems', L8
- Public Health (Infectious Diseases) Regulations 1988
- NHS Estates - Scottish Health Technical Memorandum 04-01 (SHTM 04-01)
- The Chartered Institute of Building Services Engineers (CIBSE) - Technical Memorandum (TM13), Minimising the Risk of 'Legionnaires' Disease'
- Water Regulations Advisory Scheme - Water Supply (Water Fittings) Regulations 1999
- Water Regulations Advisory Scheme - Water Fittings and Materials Directory

- The Water Byelaws 2004 (Scotland).
- Water Supply (Water Quality) (Scotland) Regulations 2001
- Food Safety Act 1990
- BS 8580:2010 Water quality. Risk assessments for Legionella control. Code of practice
- BS 6700; 2006, 'Design, Installation, Testing & Maintenance of services supplying water for domestic use within buildings & their cartilages - Specification',
- BS EN 806; (2010) 'Specification for installations inside buildings conveying water for human consumption'.
- BS 1710; 1984 Specification for Identification of Pipelines and Services
- Thermostatic Mixing Valve Manufacturers Association - Recommended Code of Practice for Safe Water Temperatures
- Guidance for neonatal units (NNU's) (levels 1, 2 & 3) adult and paediatric intensive care units ICU's in Scotland to minimise the risk of Pseudomonas aeruginosa infection from water.
- HSG 274 Part 2 – "Legionnaires Disease, The control of legionella bacteria in hot and cold water systems;
- HSG 274 Part 3 – "Legionnaires Disease, Technical guidance, The control of legionella bacteria in other risk systems;

This policy is not intended to replace or usurp the above documents, which should be consulted for more comprehensive information and guidance.



QEUH Campus Water Systems

WRITTEN SCHEME

Controlling the risks of exposure to Legionella and other harmful bacteria in
Water Systems

2019 Rev B

Reviewed by: C. Purdon (DRP)
M. MacMillan (Lead AP)
P. Urquhart (Compliance Manager)

An electronic copy of this document is held on the QEUH Shared Drive at folder path:
SGH Estates Shared>Water Quality>Written Schemes

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1.0 GENERAL OVERVIEW

Note 1: No work will be carried out on the water system without the knowledge and written consent of the Authorised Person (Water).

Note 2: This Written Scheme document is to be read in conjunction with the Operational Procedures for the Written Schemes document and should also be read in conjunction with the Control of Water Records document. For any alterations to the Water System this Written Scheme Document is to be read in conjunction with the Guidance for alterations to water systems document.

1.1 Introduction

This document contains six sections which have been derived from the Risk Assessment to aid the design, installation, maintenance and operational mode of all domestic and process water systems within the premises with respect to the likelihood of the proliferation of waterborne micro-organisms. The assessment also considered the risk of infection presented to building users and the general populous at large, and derived a series of risk ratings and appropriate Remedial Actions and Control Measures, which should be implemented to minimise the presented risks. This Risk Assessment was carried out in a manner consistent with the requirements of *BS8580:2010 Water Quality – Risk Assessments for Legionella Control – Code of Practice*, and is reviewed whenever system alterations or operational considerations may effect a change in the risk.

Section 1 contains an Executive Summary of the recommended control measures and corrective actions together with an overview of the QUEH Site layout and accommodation.

Section 2 contains a record of the logbook inspection, details on the location of records, defects, non-compliance issues, correspondence and archived information.

Section 3 provides information on the management structure associated with the control scheme for the water system and clear definitions of responsibilities held by those named, details of training undertaken and a summary of the designated tasks as detailed in section 4.

This section also provides information on the details of the risk assessment values associated with representative outlets, systems and plant items undertaken since 2013. A generic risk assessment for any positive legionella test results within designated Low Risk locations and a description of the installed plant and equipment with associated schematic layout plans for each of the installed water systems within the site is also contained within this section.

Section 4 of the document details the safe operation of the system and all appropriate Maintenance Procedures (Control Measures) which were derived from the Risk Assessment and recommendations within NHS Greater Glasgow and Clyde Water Systems Safety Policy.

This section of the document contains a task description with associated record (Log) sheet relating to these activities. It should be noted however, that in certain circumstances, specialist contractors are required to implement some Control Measures, and records pertaining to these activities may be held under separate cover. Such activities would typically include those associated with chemical water treatment regimes and drinks vending machines sanitising maintenance.

Refer to Section 2 for the location of records and archived information associated with the maintenance procedures and other control measures.

Section 5 contains supporting information relating to the Control Scheme, and should typically include the recording of system alterations or remedial actions together with utilised materials. Ad hoc maintenance activities should also be recorded in this section, such as system sterilisations which may be required from time to time. This section of the document also contains a glossary of supporting publications, where additional information relating to the risks associated with waterborne micro-organisms, and water quality generally, may be found.

1.2 Executive Summary

The purpose of this Written Scheme document is to assist in the correct and safe operation of the water systems within the QEUH Campus. The document outlines the specific roles, responsibilities, training requirements and regular maintenance procedures to be followed in order to ensure compliance with statutory and mandatory guidance.

Risk Assessments for the water services have been carried out on the instruction of the Board Water Safety Group. DMA Canyon Ltd are presently the appointed Water Systems Risk Assessor and have carried out Risk Assessments within all individual buildings on the campus.

Additionally there are two Hydrotherapy Pools in operation on the campus. These are situated within the New Childrens Hospital, and Spinal Injuries Unit. Separate Risk Assessments have been carried out for both of these facilities by a specialist Swimming Pool Risk Assessment provider.

Risk Assessments require to be reviewed and updated to reflect any changes in-use and / or functions that have taken place since the date of the original Risk Assessment or in the event of control measures becoming ineffective, changes in key personnel or in the event of a case of legionnaires disease / legionellosis associated with the water system. Guidance on the Risk Assessment review procedure is given in Appendix 3.

All documentation and log sheets used to record maintenance activities follow the format contained within guidance document SHTM 04-01 Part G: *Operational Procedures and Exemplar Written Scheme*.

1.3 Overview of Site Accommodation and Premises

The main new-build Adult Hospital building comprises of 12 stories, with the basement housing FM areas and the new-build Childrens Hospital comprising of 4 stories.

On the retained estate there are individual buildings comprising of Neurology, Neurosurgery, Spinal Injuries Unit, PDRU, Maternity, Neo-Natal, Podiatry and Westmarc stand alone with the Teaching and learning and office block new additions.

Full descriptions and information on the individual written schemes are available in the Log book/Risk Assessment folders for each building.

The building codes are as follows:

AQ – Acute Medical Block (AMB)
AS – Central Medical Block (CMB)
BC – Neurosurgical Block (INS)
BL – Maternity
BW – Neurology
DA – Spinal Injuries
DB – Maternity Day Surgery
DD – Podiatry
DE – Physically Disabled Rehabilitation Unit (PDRU)
DI – WestMARC
EA – Neo Natal
FA – Multi Storey Car Park 2
FB – Multi Storey Car Park 1
GA – Laboratory Medicine
GB – Energy Centre
HA – Adults Hospital
HB – Childrens Hospital
IA – Teaching & Learning Centre
IB – Office Building
IC – Imaging Centre of Excellence (ICE)

NOTE: ICE building is owned by University of Glasgow. Facilities management and maintenance is carried out under contract by NHS GG&C on behalf of UoG.

See Site Map in Appendix 1

2.0 RECORDING

2.1 Written Scheme Inspection Records

Anyone inspecting this written scheme (either as part of the Management Control System or otherwise) is invited to make an entry in this inspection record. **Under no circumstances may this Written Scheme or any part of it be removed from site.**

Date/Time	Comments	Signature	Position
June 2018	Written scheme has been reviewed and re-formatted into this current form (Revision D) by Colin Purdon as part of the water systems review.		Site Manager Operational Estates
Feb 2019	Written scheme has been reviewed and re-formatted into this current form (Revision E) by Colin Purdon as part of the water systems review.		Interim Sector Estates Manager (Deputy Responsible Person)
May 2019	Written scheme has been reviewed and re-formatted into this current form (2019 Rev A) by Colin Purdon as part of the water systems review.		Interim Sector Estates Manager (Deputy Responsible Person)

Additional entries should be completed on a separate sheet and inserted in Section 2.1 with this sheet.

2.2 Location of Records and Correspondence

Details of any correspondence, including Risk Assessments/Reviews and Ongoing Monitoring Reports, relating to water services should be entered on the sheet below, recording where held and by whom.

Date	Procedure or Record ref	Description	Held by/location
16/07/18	Flushing Outlets 026	Email correspondence in relation to Flushing DCFP kitchen dishwasher and outlets with John Heron and Adam Wright	Colin Purdon email archive. Hard copy in correspondence logbook

Additional entries should be completed on a separate sheet and inserted in Section 2.2 with this sheet.

2.3 Non-Compliance Issues and Fault Detail Log

Record Form 004

All non-compliance and fault details in relation to the individual systems in each building must be recorded on Record Form 004 and brought to the attention of the Water Systems Lead AP as soon as possible. This process ensures that all non-compliance issues are documented, managed effectively and tracked through to completion and close –out of the issue. Copies of the all Record Form 004 are to be stored locally within the Estates Management office.

2.4 Archived Information Record Sheet

All records associated with the management or maintenance procedures within this Written Scheme should be kept for a period of five years after they are no longer current. Records should be kept locally within the main Estates Office. The details of any archived information held separately in secure storage should be recorded in the table below.

Date	Procedure or Record Reference	Description	Held By/Location

Additional entries should be completed on a separate sheet and inserted in Section 2.4

2.5 Equipment Calibration Records

All equipment used for the measurement of temperatures should be calibrated at least annually to ensure the accuracy and consistency of the recording procedures.

Calibration certificates for handheld thermometers are held in hard copy within the QEUEH Campus Log Book suite in the main estates office. Electronic copies are also held on the QEUEH Shared Drive>Water Quality folder.

3.0 MANAGEMENT ARRANGEMENTS

3.1 Roles & Responsibilities

NHS Greater Glasgow & Clyde Chief Executive – (Duty Holder)	The Chief Executive has ultimate responsibility / accountability for water system safety within NHSGG&C. The responsibilities of the Chief Executive include: • Responsibility for implementation of the relevant mandatory and statutory elements contained within the Health & Safety Commissions Approved Code of Practice and Guidance “Legionnaires Disease. The control of Legionella bacteria in water systems” L8 (ACOP L8), SHTM04-01: The control of Legionella, hygiene safe” hot water, cold water and drinking water systems and CEL 08(2013) water sources and potential risk to patients in high risk units – revised guidance. The implementation of Guidance for neonatal units (NNU’s) (levels 1, 2 & 3) adult and paediatric intensive care units ICU’s in Scotland to minimise the risk of Pseudomonas aeruginosa infection from water. • Ensuring that adequate resources are provided to meet the Water Systems Safety requirements of NHSGG&C estate. Ensuring that the Water Systems Safety Policy is being implemented at all levels. • Reviewing and monitoring the operation of the Water Systems Safety Policy through the Board Corporate Management Team and ensuring that clear guidelines are provided for this tasked with compliance of legislative and statutory standards. • Appointing the Designated person (Pseudomonas) and Designated Person (Water) to assist in the execution of these responsibilities, who for NHSGG&C are the Infection Control Manager (Pseudomonas) and the Director of Facilities (Water).
NHS Greater Glasgow and Clyde Director of Facilities- (Designated Person)	The Director of Facilities/General Manager (Estates) is the Designated Person (Water). They shall be responsible for: • Ensuring that Facilities staff, through the general management structure is fully aware of the current statutory and mandatory requirements and standards for the provision and maintenance of safe water systems. • Ensuring with the Responsible Person (Pseudomonas) that the Water System Safety Policy is regularly reviewed and updated. • Co-Chair the NHSGG&C Water Systems Safety Group. • Appointing in writing the Responsible Person (Water) at sector level and Deputy Responsible Person(s) (Water) at site level. This shall be the Sector Estates Manager (SEM) and the relevant Site Manager Operational Estates (SMOE)/Site Estates Manager within the Facilities Directorate management structure.

3.1 Roles and Responsibilities (cont)

NHS Greater Glasgow and Clyde Infection Control Manager - Designated Person (Pseudomonas)	The Infection Control Manager supported by the Board Infection Control Doctor is the Responsible Person (Pseudomonas). They shall be responsible for: • Ensuring that Infection Control Teams are fully aware of current guidance on Legionella control matters and the minimisation of the risk of Pseudomonas aeruginosa infection from water. • The implementation of Guidance for neonatal units (NNU's) (levels 1, 2 & 3) adult and paediatric intensive care units ICU's in Scotland to minimise the risk of Pseudomonas aeruginosa infection from water. • Ensuring with the Designated Person (Water) that the Water System Safety Policy is regularly reviewed and updated. • Co-Chair the NHSGG&C Water Systems Safety Group. • Appointing in writing the Responsible Person(s) (Pseudomonas) at sector level. This shall be the relevant Infection Control Doctor.
Sector Estates Manager – Responsible Person (Water)	The Sector Estates Manager will be appointed as the Responsible Person (Water) at Sector level by the Director of Facilities/General manager (Estates) in writing. The Sector Estates Manager is responsible for: • Ensuring the effective maintenance of engineering controls installed for the purposes of controlling water systems. • Ensuring that written schemes and risk assessments are in place and reviewed regularly. • Devising and maintaining procedures to ensure the quality of water on premises is maintained. • Ensuring operational procedures are carried out and documented. • Ensuring records are kept of all water systems and their purpose, giving locations recording and maintaining within the Boards estates management system. • Liaise closely with other professionals to ensure legislative and statutory compliance is maintained by the Board.
Authorising Engineer (AE)	An Authorising Engineer acts as an independent professional advisor to the healthcare organisation, appointed by the organisation with a brief to provide services in accordance with Scottish Health Technical Memorandum (SHTM) guidance. He will be appointed in writing by the Director of Facilities/General manager (Estates). The Authorising Engineer acts as an assessor, making recommendations for the appointment of Authorised Persons, monitoring the performance of the service and providing an annual audit to the organisation's Designated Person.

3.1 Roles and Responsibilities (cont)

Authorised Person (Water)	The Authorised Person (water) has the key operational responsibility for the service, qualified, sufficiently experienced and skilled for the purpose. He/she will be nominated by the Authorising Engineer and be able to demonstrate • His/her application through familiarization with the system and attendance at an appropriate professional course; • A level of experience; • Evidence of knowledge and skills. An important element of the Authorised Person (Water) role is the maintenance of records, quality of service and maintenance of system safety (integrity). The Authorised Person (Water) will also be responsible for establishing and maintaining the roles and validation of Competent Persons (Water) who shall be suitable trained employees of the organisation or appointed contractors. Larger sites may require more than one Authorised Person (Water) for a particular service. The Authorised Person (Water) will be appointed by the Director of facilities/General Manager (Estates).
Head of Capital Planning – Deputy Responsible Person (Water)	The Head of Capital Planning will be appointed as the Deputy Responsible Person (Water) at Board level by the Director of Facilities/General Manager (Estates) in writing. The Head of Capital Planning is responsible for: • Ensuring that any new works undertaken or refurbishment within existing premises shall comply with the requirements of this Policy and the Written Scheme and Operational Procedure for managing Water Safety including The control of <i>Legionella</i>, hygiene, ‘safe’ hot water, cold water and drinking Water systems and The implementation of Guidance for neonatal units (NNU’s) (levels 1, 2 & 3) adult and paediatric intensive care units ICU’s in Scotland to minimise the risk of <i>Pseudomonas aeruginosa</i> infection from water. • Ensuring that all potential interfaces between an operating system and new and refurbishment works shall meet the approval of the Responsible Person (Water) and Authorised Person (water) as to methodology for making that interface. • Ensuring that any work involving the installation of water services or equipment requiring a water supply shall follow the guidance in SHTM 04-01 and HSE document L8 and shall be certified by the design Engineer as to that compliance. • Ensuring that any works which will affect an operational water service will be discussed with the Estates Authorised Person (Water) prior to arranging that work.

3.1 Roles and Responsibilities (cont)

Site Estates Manager Deputy Responsible Person (Water)	The Site Manager Operational Estates (SMOE)/Site Estates Manager shall be appointed in writing by the Director of Facilities/General Manager (Estates) in writing as the Deputy Responsible Person (Water) and will also act as the Designated Person Water in the absence of the Designated Person (Water). The Site Maintenance Manager/Site Estates Manager is responsible for: • Ensuring all staff conducting water system maintenance are competent to do so. • Ensuring water system maintenance records are maintained and kept up-to-date. • Regularly checking maintenance records. • Ensuring all work is completed in accordance with the NHS GG&C Estates Procedures.
Acute Services Directors CH(C)P Directors and Corporate Division Directors	As Senior Managers, NHSGG&C Directors play an intrinsic role in ensuring that water safety is embedded within the culture of the organisation. The responsibilities of Directors include: • Supporting the designated person (Water) and (Pseudomonas) in the development of the Board's overall strategy in relation to water safety and for ensuring implementation within their areas of responsibility; • Ensuring that all staff are made aware of their requirement to attend Water Safety training at the appropriate frequency, as per the NHSGG&C Water Safety Policy and Operational Procedures which underpin this by facilitating staff release from duties to attend training; • Supporting action to address staff who put themselves and/or others at risk from a real or potential water safety incident.
Heads of Service, Departmental Managers, Clinical Managers, Senior Charge Nurse's	All managers who have a responsibility for the day to day management of facilities, staff or services, and/or premises, have water safety responsibilities that include: • Familiarise themselves with the NHSGG&C Water Safety Policy and local control measures including any water risk assessments for their area(s) of responsibility; • Ensuring that persons in the department, clinic or ward are fully aware of their responsibilities and duties in respect of Water Safety, in particular, the action required of them should the area be defined as High Risk by the local Water Safety Group • Ensure that persons in the department, clinic or ward are fully aware of the Infrequently Used Outlets definitions and Operating Procedure which underpins the NHSGG&C Water Safety Policy

3.1 Roles and Responsibilities (cont)

Heads of Service, Departmental Managers, Clinical Managers, Senior Charge Nurse's (cont)	• Actively promoting Water Safety within the department or ward by maintaining good housekeeping within the department or ward at all times, ensuring that any flushing or documentation as described in the Water Safety Written Scheme and Operational Procedures documentation is completed on time • Responding appropriately to any water safety concerns that persons in the department, clinic or ward have; • Nominating a responsible person to complete the Monthly Infrequently Used Outlets Audit for each area, forwarding a copy to the Site Maintenance Manager, thereby assisting NHSGG&C to meet its statutory and mandatory requirements; • Ensuring that action is taken on a daily basis to address any access issues identified within the Cleaning Compliance Checklist Sign Off documentation retained in the Facilities Folder. • Liaising with the estates department as required
Legionella Risk Assessor	The NHS Board appoints in writing a Legionella Risk Assessor with terms of reference to provide services in accordance with BS 8580, SHTM 04-01 and HSE guidance under this Policy. He/she will be appointed in writing by the Director of Facilities/General Manager (Estates)
Competent Person (Water)	The Competent Person (Water) provides skilled installation and/or maintenance of the specialist service. He/she will be appointed, or authorised to work (if a contractor) by the Authorised Person Water). He/she will demonstrate a sound trade background and specific skill in the specialist service, working under the direction of the Authorised Person (Water) in accordance with operating procedures, policies and standards of the service.
Maintenance Tradesperson	A Maintenance Tradesperson is someone who has sufficient technical knowledge and the experience necessary to carry out maintenance and routine testing of the water supply, storage and distribution system.
Installer	The Installer is the person or organisation responsible for the provision of the water storage and distribution system.
Contractor	A Contractor is the person or organisation designated by management to be responsible for the supply, installation, validation and verification of hot and cold water services, and for the conduct of the installation checks and tests in relation to the control of <i>Legionella</i>. The NHS Board will expect potential contractors to have suitable qualifications (for example companies/individuals who are members of the <i>Legionella</i> Control Association).

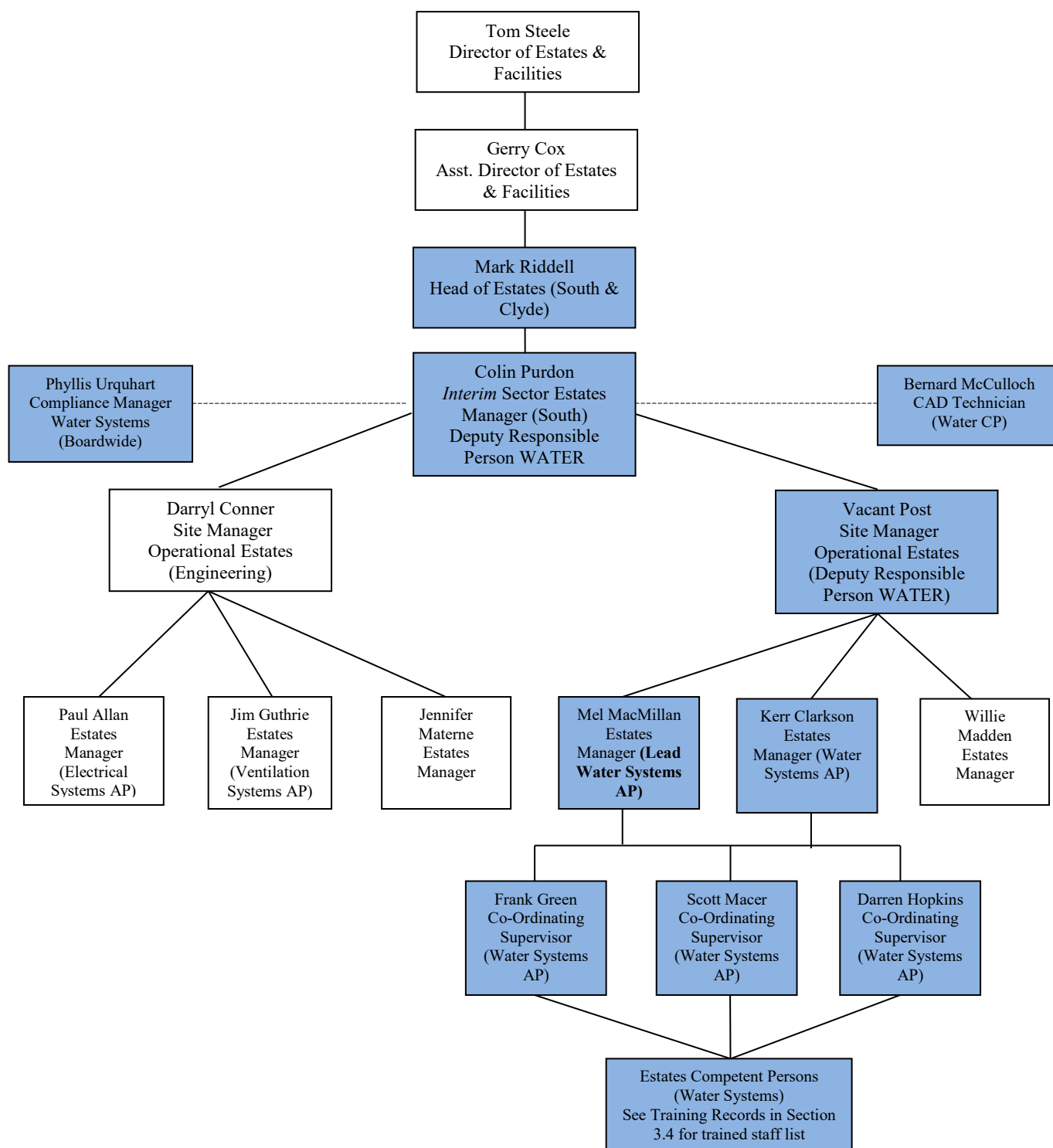
3.1 Roles and Responsibilities (cont)

NHS GG&C South Sector (QEUH) Hierarchy Appointment Table

Designation	Position	Name Tel Number
The Duty Holder	Chief Executive	Jane Grant
Designated Person (Water)	Director of Facilities/General Manager (Estates)	Alan Gallacher Mary-Anne Kane
Authorising Engineer (Water)	Legionella Control International Ltd	Dennis Kelly [REDACTED]
Legionella Risk Assessor	DMA Water Services Ltd	David Watson Mike Kinghorn Allan McRobbie [REDACTED]
Responsible Person (Water)	Sector Estates Manger (South)	Colin Purdon (Interim) TBC in writing
Deputy Responsible Person (Water)	Site Manager Operational Estates (Building)	VACANT
Deputy Responsible Person (Water)	General Manager Capital Planning	Hazel McIntyre [REDACTED]
Lead Authorised Person	Estates Manager	Mel MacMillan
Authorised Persons	Estates Manager Co-ordinating Supervisor Co-ordinating Supervisor Co-ordinating Supervisor	Kerr Clarkson Scott Macer Darren Hopkins Frank Green
Competent Persons	CAD Technician	Bernard McCulloch
Competent Persons	Plumbers/Engineers	See training records in Section 3.4
Others Involved		
Infection Control	Lead Microbiologist	Dr Teresa Inkster
Public Health		Dr Iain Kennedy
Laboratory Services		Janet Young

3.2 QEUH Estates Staffing

Management organogram for QEUH Estates Dept as of Oct 2019



3.3 Required Maintenance Tasks

The maintenance and management of the water systems throughout the QEUH Campus is undertaken by a combination of both NHS Staff and external Contractors at the frequencies identified in the following tables.

QEUH Management staff manage and oversee the following tasks:

Procedure Reference	Operation(s)	Record Form Ref	Frequency
P1C1	BMS Temperature Monitoring	(004)	Daily
P1CC1A	Manual Temperature Monitoring	(005a)	Daily
N/A	Filtration Plant Checks		Twice Daily
WS01	Flushing Intermittently used outlets	(026)	Twice Weekly
WS01	Flushing Deadlegs and drain cocks	(026)	Twice Weekly
WS01	Deluge shower/Eye wash flushing	(026)	Twice Weekly
P1C3	Pump operation/duty rotation	(028)	Weekly
P1C4	Temperature Recording of Sentinel Hot and Cold Water Outlets.	(005)	Monthly
P1C4	DHW Calorifier and Buffer Vessel Checks	(005)	Monthly
P1C12	Showerhead/hose replacement/disinfection	(005b)	Quarterly
P1C6	DWS Calorifier, Expansion Vessel Flushing	(006) (023)	Quarterly
WQS 001	HORNE Tap Flow Restrictor Exchange		Quarterly
WS01	Review of Rarely Used Water Outlets and Changes In-Use		Quarterly
N/A	TMV/TMT & Thermostatic Shower Disinfection and Function Test (HIGH RISK)		Quarterly
N/A	TMV/TMT & Thermostatic Shower Disinfection and Function Test (Non-HIGH RISK)		Six-Monthly
P1C7	CWST Inspection and Temperature Monitoring	(003)	Six-Monthly
P1C9	DWS Calorifier / Expansion Vessel Inspection	(006)	Annually
N/A	Water Services Pipework and Distribution System Checks		Annually
P1C10	Representative Tap Temperature Monitoring	(005)	Annually
N/A	Vibration coupling inspection		Annually
N/A	Carry out review of log books and Written Scheme		Annually (Sep)
N/A	Carry out review of drawings and schematics		Annually (Sep)

3.3 Required Maintenance Tasks (cont)

In addition to the tasks undertaken by NHS directly employed Competent Persons, there are also tasks undertaken by Contractors on a selection of buildings within the campus.

Appointed Contractors presently undertake the following tasks:

Procedure Reference	Operation(s)	Record Form Ref	Frequency
	External Water Mains Valve Operation and Flushing Routines		Monthly
	'TMV' and Mixing Valve Sanitation and Maintenance Checks		Three-Monthly
	Shower Head and Flexible Hose Exchange		Three-Monthly
	'TMV' Tap Outlet Sanitisation and Operational Checks		Six-Monthly
	CWST Inspection	(003a)	Annually
	Hot and Cold Tap Outlet Sanitisation and Operational Checks		Annually

3.4 Training Records

The following NHS personnel are certified to have the required ability, experience, instruction, information and training to carry out the work associated with legionella precautions at QEUH Campus.

NAME	POSITION	NATURE OF TRAINING (QUALIFICATION, TRAINING COURSES ATTENDED)	DATE
Colin Purdon	<i>Interim</i> Sector Estates Manager Deputy RP	Responsible Person Course ENAP City & Guilds Authorised Person ENWS City & Guilds Managing Water Systems	
Mel MacMillan	Estates Manager Lead AP	WHH01 – Legionella Management for Water Systems SHTM-04 01 WH003 - Legionella Control Within Hot and Cold Water Systems	
Kerr Clarkson	Estates Manager AP	WHH01 – Legionella Management for Water Systems SHTM-04 01 WH003 - Legionella Control Within Hot and Cold Water Systems	
Scott Macer	Co-Ordinating Supervisor (Shifts)	WHH01 – Legionella Management for Water Systems SHTM-04 01 WH003 - Legionella Control Within Hot and Cold Water Systems	
Darren Hopkins	Co-Ordinating Supervisor AP	WHH01 – Legionella Management for Water Systems SHTM-04 01 WH003 - Legionella Control Within Hot and Cold Water Systems	
Frank Green	Estates Manager	WHH01 – Legionella Management for Water Systems SHTM-04 01 WH003 - Legionella Control Within Hot and Cold Water Systems	

Copies of all relevant training records and appointment letters are held electronically on the QEUH Shared Drive within the folder path “Water Quality>Training and Appointments”.

The results achieved by each member of staff during their competency training are held on the central database managed by the Water Systems Compliance Manager.

NAME	POSITION	NATURE OF TRAINING (QUALIFICATION, TRAINING COURSES ATTENDED)	DATE
Martin Inglis	Tech Plumber	Competent Persons	
Andrew Hamilton	Tech Plumber	Competent Persons	
David Fickling	Tech Plumber	Competent Persons	
Peter McCabe	Tech Plumber	Competent Persons	
Mark McNally	Tech Plumber	Competent Persons	
Shawn O'Neill	Tech Plumber	Competent Persons	
Jason Weir	Tech Plumber	Competent Persons	
Paul Shorts	Tech Plumber	Competent Persons	
Bernie McCulloch	CAD Technician	Competent Persons	

Copies of all relevant training records and appointment letters are held electronically on the QEUH Shared Drive within the folder path “Water Quality>Training and Appointments”.

The results achieved by each member of staff during their competency training are held on the central database managed by the Water Systems Compliance Manager.

3.5 Training Requirements

A programme of training and procedures to assist in assessing and ensuring the competence of ALL persons responsible for the operation, maintenance, repair and alteration to the water distribution system and associated plant and equipment requires to be progressed, developed and implemented.

QEUH Estates Staff - Interim Training Requirements:

Item	Training Requirement	Applicable to	Target Date for Completion	Date Completed
1	Toolbox talks on Written Scheme Section 4 for staff.	All plumbers		
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				

NOTE:- This table should be updated on a regular basis as part of the review process described in **Section 3.10.**

3.6 Water Systems Risk Assessment

The duly appointed *Legionella* Risk Assessor for *Legionella* and Water Systems Safety will update the *Legionella* risk assessment database as directed by the board.

Risk assessments for each building have been conducted by DMA Water Ltd and are filed in the main Estates Office at QEUEH. Each contains details of individual systems and a summary of the associated risks. The risk assessments each contain unique information in regard to the water distribution systems in the buildings and also guidance on the recommended maintenance procedures for mitigating risk.

Risk Assessment Review-Escalations

During the Risk Assessment, whenever an anomaly is discovered on either the hot or cold water systems, the Risk Assessors e-mail the AP (water) with their findings. These anomalies are actioned by creating a FM job for the onsite CP Plumbing Technician. The findings are held in the Estates office in the folder named (Pre Risk Assessment Jobs completed).

Risk Assessment Process for Removal of Identified Items

Points are actioned that have been identified in the Risk Assessment, all drawings are updated to reflect the changes and the Risk Assessment action point is closed.

Risk Assessment Review Schedule

A review of the Risk Assessments MUST be carried out after or during the following:

A change to the water system or its use

A change to the use of the building/ward/clinic/dept etc.

Changes in legislation or updates in control measures

Changes in immediate management or key personnel

Control measures becoming ineffective

Increased micro-bacterial levels found in the water system or a case of legionnaires disease/legionellosis associated with the water system.

Action plan details for each risk assessment are summarised on the Smartsheet tool.

Electronic copies of the Risk Assessments are also held on the QEUEH Shared Drive at the folder path

“Water Quality>Risk Assessments”

Further information on reviewing Risk Assessments is detailed in Appendix 3.

3.7 Plant Description and Schematics

Details of the plant in each building and schematic layouts are contained within the individual log books/risk assessments for each building. The log books/risk assessments are stored in the main Estates Office at QEUH.

These details are also held on the Shared Drive

All plant details and system schematics and as-fitted drawings for the Adult & Childrens Hospitals are contained in the ZUTEC cloud based document management system. All Estates Managers and Supervisors have access to these systems.

Additional access accounts can be set up at the request of the QEUH Site Manager Operational Estates.

[Brendan.egan](#) [REDACTED]

3.8 Water Systems Audits/Review Procedures

A duly appointed Authorising Engineer (Water) will audit the entire Water Safety procedures within *NHS Board* annually.

The appointed Authorising Engineer for Water Safety will produce an annual report for management review. *See Section 3.1 pg 18 for current appointments.*

AE Audit

The Lead Authorised Person (Water) must regularly gather and maintain all the relevant information and records, including relevant Water Safety Risk Assessments and Written Schemes.

Working with the Authorising Engineer (Water) and Responsible Person (Water), the relevant Authorised Person (Water) will review and analyse all records for compliance with *Legionella* and other water safety parameters.

The relevant Authorised Person (Water) will detail on these records any deviations from the *Legionella* and other water safety parameters giving a brief description as to the reason for this deviation.

The Audit Programme will consist of planned audits on the following elements, for example:

Risk Assessments;

All documentation associated with this Written Scheme

training review and records;

schematic drawings;

Water Safety Log Books/Maintenance records;

BMS trend log comparison.

A report will be produced summarising the audit for submission to the Sector Water Safety Group.

The Lead Authorised Person (Water) will file locally, all relevant information and maintain hard copy records in the Water Safety Log Books stored within the main Estates Office. All actions identified should be tracked to ensure completion and closure.

Summary of Internal/External Audit Procedures

Frequency	Task	By Whom
Annually	Carry out Authorising Engineers Audit and produce report for submission to Sector Water Safety Group (Section 3.8 WS)	Lead AP, AE,
Annually/May	Carry out annual review of written scheme and produce report for submission to Sector Water Safety Group (Section 3.9 WS)	RP/DRP, Lead AP, Compliance Mgr
6 monthly	Carry out management review (Section 3.10 WS)	RP/DRP, Lead AP, Compliance Mgr
Monthly	Carry out regular audit of SCART topic and update database (Section 3.11 WS)	Lead AP
Monthly	Conduct contractor meetings/audits to ensure compliance with legislation and training requirements.(Section 3.12 WS)	Lead AP

3.9 Written Scheme Audit Procedure

The Written Scheme will be audited at agreed intervals but should be at least annually.

An audit schedule will be prepared to ensure the entire procedure is audited. This should be done in conjunction with the Lead AP (Water Systems), Compliance manager, and Responsible Person (Water Systems). A report should be produced and submitted to the Sector Water Safety Group.

3.10 Management Review

The Responsible Person (Water) will hold regular review meetings to confirm current compliance with Water Safety System requirements, identification of any deficiencies and actions required to resolve staff training needs.

The management review will be based on following:

results of internal audits;

results of external audits;

staff suggestions;

training records;

operation of the system and procedures over a reasonable historic period (6 to 12 months)

3.11 Water Systems SCART Report

The Lead Authorised Person (Water) must regularly gather and maintain all the relevant information for import into the Campus SCART system.

All evidence confirming the SCART position and justification for risk rating adjustments should be uploaded to the SCART database in electronic format.

3.12 Contractor Management & Audit Report

Contractor Management Process

Regular review meetings should be set up with any contractors working on the water distribution system. Minutes of the meetings are held on the QEUH Estates Shared Drive at the path: SGH Estates>Water Quality>Contractor Meetings.

Discussions should include:

- Ongoing works;
- Future task programme;
- Recording procedures;
- RAMS;

Contractor Competency

Regular checks should be performed to ensure that any contractors working on the water distribution system are deemed competent and all operatives are suitably trained to conduct the delegated tasks. Copies of all Risk Assessments and Method Statements should be refreshed and all training records reviewed by the Water Systems AP. Copies are stored on the QEUH Campus Shared Drive in Water Quality.

Contractor Audit Report

A report should be produced at least annually to record the findings of the audit.

3.13 Permit to Work, Water Systems.

The Permit to Work Water Systems as per this written scheme is solely intended to be used when works on the hot and cold water systems and its ancillary equipment are to be completed within the QEUH and RHC campus. This includes break-ins to existing pipe work, removal of dead legs and any new installation works.

The Permit to Work may only be issued to Competent Persons (L8 approved) by the Authorised Person (AP) for water. This includes in house maintenance staff and approved contractors.

The Permit to Work form will include the following;

- Name of the organisation issuing the permit.
- Permit number.
- Name of Authorising Person (AP), including emergency contact details.
- Reasons for the works on the water system, (Plant Preventive Maintenance, Planned repairs or Emergency works).
- Exact location of the works
- Reference to any as built drawing numbers, (for update purposes).
- Name of Competent Person (CP) undertaking the works.
- Hazards and Risks, (copy of Risk assessment and Method Statements (RAMS) to be submitted for approval before start of works)
- Commissioning and Testing.

The above points on the Permit Work are broken into five categories, namely;

Part 1 Description of work and authorisation/permission to proceed.

Part 2 CP acceptance of work and conditions.

Part 3 Confirmation of work completion and engineering test results.

Part 4 Authorisation to use a system.

Part 5 Acceptance of system status by Nurse Manager.

Procedure to be followed for Permit to Work on water systems within the QEUH and RHC;

Sign into Estates office within the Laboratory building on the QEUH and RHC campus.

Receive induction from Authorised Person water.

Provide L8 Competent Person certification to Authorised Person water.

Provide applicable RAMS for the works to be completed.

3.14 Tool Box Talk, Hot and Cold Water Systems.

Estates Tool Box Talk on Hot and Cold water Systems is located on the shared drive / water quality / Estates Tool Talk. This is carried out in the form of a power point presentation.

4.0 MAINTENANCE PROCEDURES

Procedure Reference	Operation
4.1	SYSTEM INFORMATION
4.2	MAINTENANCE PROCEDURES SUMMARY
4.3	WEEKLY MAINTENANCE TASKS
4.4	MONTHLY MAINTENANCE TASKS
4.5	QUARTERLY MAINTENANCE TASKS
4.6	SIX MONTHLY MAINTENANCE TASKS
4.7	ANNUAL MAINTENANCE TASKS
4.9	BI-ANNUAL MAINTENANCE TASKS

NOTE:

Completed Log Sheet to be submitted to either the Authorised Person (Water Systems) or Site Manager Operational Estates for authorisation and copies filed as indicated in Section 2.2.

Due to the volume of information required for the recording of test results for each of the assets being maintained, the Log Sheets provided within this document are for indicative purposes only.

Detailed information on the assets and test records for same will be retained within the specific 'Log Book' for the location being maintained.

4.1 System Information

4.1.1 Correct and Safe Operation of the System

Measures should be in place to ensure that the water system is operated within the specific parameters as detailed in the following paragraphs:

4.1.2 Hot Water System

The storage of domestic hot water should be arranged to ensure that a water outflow temperature of at least 60°C is achieved. No two water systems are the same and through periodic monitoring operational system performance, the system outflow temperature should be set to over 60°C to ensure an outflow of 60°C is achieved under normal draw-off demand and achieve 55°C at the supply to the furthest draw-off point in the circulating system. It is important to maintain temperatures at above this figure (Legionellae organisms will survive for only a short period of time above this temperature - approximately two minutes).

Periodic performance monitoring and a system of continuous monitoring and recording of water temperatures via a building management system (BEMS) or data logger is essential to ensure compliant system performance.

The outflow water temperature, under prolonged maximum continuous demand (at least 20 minutes) from calorifiers should not be less than 60°C.

While it is accepted that occasionally under peak instantaneous or prolonged demand the water outflow temperature will fall, it is not acceptable if this occurs frequently (more than twice in any 24 hour period) and/or for long periods (exceeding 20 minutes).

Under no circumstances should the domestic hot water flow temperature fall below 50°C.

It is recommended that disinfection by pasteurisation is undertaken if the water temperature of the calorifier falls below 45°C. A minimum domestic hot water circulation (return) temperature of 50°C shall be maintained during the hours of occupancy.

4.1.3 Cold Water System

All domestic cold water storage cisterns and tanks shall comply with the requirements of the Scottish Water Byelaws.

Duplicate tanks often create a risk of water becoming stagnant in one of them, leading to risk of Legionella, Pseudomonas Spp or similar contamination. Consideration should be given to taking one of the tanks out of service. See guidance in "Guidance for Alterations to Water Systems".

All cold water storage tanks are to be examined and the temperature tested on a regular summer / winter six monthly cycles and cleaned on an annual basis as required.

Temperatures in cold water storage tanks and the mains inlet to them should be checked during periods of high ambient temperatures (e.g. summer afternoons between June and August). Water temperatures should be less than 20°C.

At the same time, the furthest and nearest draw off points in the system should be checked to ensure that the water distribution temperatures are less than 20°C within 1 minute of running the water (at full flow). A similar temperature check regime should be undertaken during the winter months to identify the performance of cold water distribution systems and the impact of heat gain from heating systems.

4.1.4 Cold Water System Dump Valves

The cold water system installed in the Adult & Childrens Hospitals has a dump valve arrangement incorporated into the ground floor, 1st floor and 2nd floor layouts. The positions of the dump valves are shown on the Schneider BMS STRUXUREWARE system and connected via the KNX network.

Operating parameters for the dump valves are as follows:

Open at 23°C

Close at 20°C

4.1.5 End of Line Sensors (EOLs)

The hot and cold water system also incorporates End of Line (EOL) sensors which monitor the temperatures at specific sentinel points across all 11 floors of the Adult & Childrens installation. These can also be viewed via the Schneider BMS system.

4.1.6 Sampling

General microbiological and Legionella sampling in hot & cold water systems

Circumstances under which samples are taken:

- prior alterations to an existing water system;
- as part of commissioning process, prior to handover of a new building or introduction of a (altered, refurbished or new) water system into use;
- one week following handover of a new building or new water system;
- as part of the tank cleaning and disinfection process;
- as part of an assessment programme;
- in response to taste, odour or sustained discoloured water complaints.

When such samples are taken, a mains supply sample should be taken as a control to verify whether the supply could be the source of the identified problems. Scottish Water should also be contacted for distribution zone water quality data.

4.1.7 WS01 – Little Used Outlets

Control of Legionella in Water Systems, Intermittently used Water Outlets and Showers, Standard Operating Procedure WS01.

The Estates department is required to ensure that on a quarterly basis the list of ‘intermittent’ or ‘infrequently’ used water outlets or showers is reviewed to ensure it is accurate and up to date. Records of these reviews will be held within the system logbooks held locally.

If after investigation the taps or appliances identified within the reviewed list are deemed not necessary wherever possible the supply should be cut and the appliance removed from the water system. Where this is not possible then pipe work shall be cut back as close to the main circulating line as practicable to ensure that any dead-leg formed is minimised.

Nursing and other staff must be made aware of the issues surrounding legionella contamination and the link to low and underused water outlets and their assistance in formally identifying these possible outlets are sought.

Upon acknowledgement from the clinical staff of any intermittent or infrequently used outlets, the records are held on the Estates shared drive under Water Quality / WS01.

Any request from clinical staff regarding the removal of any intermittent or infrequently used outlets is assessed and surveyed by the AP (Water). If deemed appropriate a job is raised on FM for the Plumbing Technicians to remove, this is documented in the WS01 Records file in the Water Quality file on the shared drive. Subsequent hot and cold water pipe drawings are updated by the CAD Technician CP (water) where and when appropriate.

FILLING IN LOG SHEETS

Good water hygiene depends on maintaining high standards of cleanliness and freshness, together with careful temperature control. This section contains details of checks and recording sheets (marked “Log Sheets”) to be filled in when checks and measurements are made to show that the necessary standards are being kept up. Alternatively, where an electronic PPM system is used, Procedure references should be entered.

Follow the instructions within the boxes and make entries as each task is completed. The tasks are all listed at the front of each section, weekly tasks at the front of the weekly section, monthly on the monthly and so on. The summary list of tasks in this section is to remind you of what is required.

The Task and Log Sheets can be copied as required, completed Log Sheets will be filed where indicated in Section 2. **FM First ticket number MUST be included in all logsheets.**

PLANNING

The tasks and forms are organised into weekly, monthly, quarterly and annual sections. Always aim to carry out tasks early in the period when they are due to leave an opportunity to do them later if an emergency delays your plans.

ASK

If you have difficulties with the forms or do not understand the tasks, ask your Supervisor or line manager for clarification or guidance.

CHECKING

Incomplete or incorrect records are unacceptable in that they are misleading and do not do justice to the effort put in to achieve standards. Each log sheet includes a space for comment and tells you to check that all the boxes are complete: do make use of the comment space and double check the form, otherwise the record will have gaps and whoever is responsible for auditing will concentrate on what is missing and may not give you credit for the work that has been done.

LOG INSPECTION

Anyone inspecting this log (either as part of the Management Control System or not) is invited to make an entry in the inspection of Log Book record in front of Section One.

SURVEY

For survey purposes all surveys will be carried out starting left to right, where 2 off access doors are available the left access shall be taken first. Surveys shall be undertaken from top to bottom.

EQUIPMENT FITTINGS AND MATERIALS

Prior to carrying out alterations/ additions to distribution systems, the Water Fittings and Materials Directory published by the Water Regulations Advisory Scheme, should be consulted. This directory lists all materials and fittings approved for use to satisfy the requirements of current Water Byelaws.

Details of all new materials and fittings used in installations should be noted and recorded on the specific work document or project file for future reference.

SYSTEM ADDITIONS AND ALTERATIONS

Any additions, modifications or improvements to the water distribution system are to be noted and recorded and system record's amended to reflect such changes.

HYGIENE PRACTICES

Care should be taken to ensure high levels of personal hygiene, clean hands, clean clothing and PPE or gloves is maintained at all times when working on wholesome water operations. Tools, equipment, instrumentation and material's shall be free from contamination and appropriately disinfected before use.

Items such as pumps and hoses used in contact with water used for domestic purposes must be stored separately, clearly identified (ie colour coded or labelled) and **MUST NOT BE USED FOR ANY OTHER PURPOSE.**

Refer to Section 2.2 for location of maintenance records for the above.

4.2 Maintenance Procedures Summary

This section contains information in relation to the operational and maintenance checks managed by QEUH NHS Staff and appointed contractors to minimise the risk of exposure to *Legionella* and other waterborne micro-organisms within the domestic water systems, and to improve water quality. Procedures are as per the recommendations and exemplar models given in SHTM 04-01 Part G.

Procedure Reference	Operation(s)	Record Form Ref	Frequency
P1C1	BMS Temperature Monitoring	(021)	Daily
P1CC1A	Manual Temperature Monitoring	(005a)	Daily
	Filtration Plant Checks	(028c)	Twice Daily
WS01	Flushing Intermittently used outlets	(026)	Twice Weekly
WS01	Flushing Deadlegs and drain cocks	(026)	Twice Weekly
WS01	Deluge shower/Eye wash flushing	(026)	Twice Weekly
P1C3	Pump operation/duty rotation	(028)	Weekly
P1C4	Temperature Recording of Sentinel Hot and Cold Water Outlets.	(005)	Monthly
P1C4	DHW Calorifier and Plate Heat Exchanger Checks	(005)	Monthly
P1C12	Showerhead/hose replacement/disinfection	(005b)	Quarterly
P1C6	DWS Calorifier, Expansion Vessel Flushing	(006) (023)	Quarterly
WQS 001	HORNE Tap Flow Restrictor Exchange		Quarterly
WS01	Review of Rarely Used Water Outlets and Changes In-Use	WS01a	Quarterly
	TMV/TMT & Thermostatic Shower Disinfection and Function Test (HIGH RISK)		Quarterly
	TMV/TMT & Thermostatic Shower Disinfection and Function Test (Non-HIGH RISK)		Six-Monthly
P1C7	CWST Inspection and Temperature Monitoring	(003)	Six-Monthly
P1C9	DWS Calorifier / Expansion Vessel Inspection	(006)	Annually
	Water Services Pipework and Distribution System Checks		Annually
P1C10	Representative Tap Temperature Monitoring	(005)	Annually
	Vibration coupling inspection		Annually
	Carry out review of log book and control manual		Annually (Sep)
	Carry out review of drawings and schematics		Annually (Sep)

4.3 Daily Maintenance Tasks

Reference	Operation
4.31	BMS Temperature Monitoring
4.32	Manual Temperature Monitoring
4.33	Filtration Plant Checks

NOTE:

Completed Log Sheet to be submitted to either the Authorised Person (Water Systems) or Site Manager Operational Estates for authorisation and copies filed as indicated in Section 2.2.

Due to the volume of information required for the recording of test results for each of the assets being maintained, the Log Sheets provided within this document are for indicative purposes only.

Detailed information on the assets and test records for same will be retained within the specific 'Log Book' for the location being maintained.

4.31 – BMS TEMPERATURE MONITORING**DAILY**

FM First Template No 826

IN ACCORDANCE WITH SHTM 04-01 Part G (*V1 July 2015*) Page 26 para 3.11**RECORD FORM - (021)****PROCEDURE REF - P1C1****SCHEDULE REF – BMS 01****HAISCRIBE/Risk Assessment Ref – N/A** See Appendix 4The following actions must be undertaken **DAILY** as a minimum:**Description of Works**

- Refer to the BMS Temperature Monitoring Schedule BMS 01.
- Log onto both STRUXUREWARE BMS and DISTECH BMS front ends and check all temperatures from listed locations.
- Complete Schedule BMS 01 to confirm all temperatures have been checked.
- Any temperatures found outside the defined parameters stated on the BMS Temperature Monitoring Schedule should be investigated and resolved immediately. Details must be entered on Record Form (021) and escalated to the Water Systems AP.

CHECK

1. Record all details of any fault or discrepancy on the FAULT LOG and report to Manager.
2. Complete Schedule BMS 01 and Record Form (021) if required, ensuring that you date, sign it and enter FM First ticket number.
3. Return forms to the Water Systems AP.

NOTE: Both Struxureware and Distech BMS systems are capable of generating temperature trend logs. These logs will be checked on a regular basis by the Water Systems AP to confirm accuracy of information.

4.32 – MANUAL TEMPERATURE MONITORING**DAILY**

FM First Template No 830

IN ACCORDANCE WITH SHTM 04-01 Part G (*V1 July 2015*) Page 26 para 3.15**RECORD FORM – (005a) (021a)****PROCEDURE REF - P1CC1A****SCHEDULE REF – MTM 01****HAISCRIBE/Risk Assessment Ref – N/A** See Appendix 4The following actions must be undertaken **DAILY** as a minimum:**Description of Works**

- Refer to the Manual Temperature Monitoring Schedule MTM 01.
- MANUALLY visit each location and obtain and record temperatures from all plant as listed on Schedule MTM 01.
- Any temperatures found outside the defined parameters stated on the MTM 01 Temperature Monitoring Schedule should be investigated and resolved immediately. Details must be entered on Record Form (021a) and escalated to the Water Systems AP.

CHECK

1. Record all details of any fault or discrepancy on the FAULT LOG and report to Manager.
2. Complete Record Forms (005a) and (021a) if required, ensuring that you date, sign it and enter FM First ticket number.
3. Return form to the Water Systems AP.

4.33 – FILTRATION PLANT CHECKS**TWICE DAILY**

FM First Template No 836

IN ACCORDANCE WITH BOARD POLICY

RECORD FORM – (028c)**PROCEDURE REF – N/A****HAISCRIBE/Risk Assessment Ref – N/A** See Appendix 4The following actions must be undertaken **TWICE DAILY** as a minimum AM and PM:**Description of Works**

- Refer to the Filtration Plant Daily Checks Log sheet (028c).
- Complete all listed checks and ensure plant is running if selected as DUTY, or available to run if selected as STAND-BY.
- Details must be entered on Record Form (028c) and any issues escalated to the Water Systems AP immediately.

CHECK

1. Record all details of any fault or discrepancy on the FAULT LOG and report to Manager.
2. Complete Record Forms (028c) if required, ensuring that you date, sign it and enter FM First ticket number.
3. Return form to the Water Systems AP.

4.4 Weekly Maintenance Checks

Reference	Operation
4.41	Flushing of Rarely Used Water Outlets (Twice Weekly)
4.42	Flushing of Deadlegs & Drain Cocks (Twice Weekly)
4.43	Rotation of Water Services Duty/Stand-By Pumps
4.44	Operation and Checks to Emergency Deluge Shower/Eye Wash (Twice Weekly)

NOTE:

Completed Log Sheet to be submitted to either the Authorised Person (Water Systems) or Site Manager Operational Estates for authorisation and copies filed as indicated in Section 2.2.

Due to the volume of information required for the recording of test results for each of the assets being maintained, the Log Sheets provided within this document are for indicative purposes only.

Detailed information on the assets and test records for same will be retained within the specific 'Log Book' for the location being maintained.

4.41 – FLUSHING OF INTERMITTENTLY USED WATER OUTLETS

FM First Template No 824

TWICE WEEKLYIN ACCORDANCE WITH SHTM 04-01 Part G (*V1 July 2015*) Page 101 para 6.36**RECORD FORM - (026a)****PROCEDURE REF - WS01****HAISCRIBE/Risk Assessment Ref – N/A** See Appendix 4The following actions must be undertaken **TWICE WEEKLY** as a minimum:**Description of Works**

- Refer to the locations listed on Record Form (026a).
- Estates to arrange for the Schedule to be updated to record on a regular basis.
- Flush water from ALL outlets identified on Record Form (026a) at a minimum frequency of Twice Weekly for a minimum period of 3 minutes per tap outlet taking care not to cause splashing or exposure to water aerosols / droplets.

CHECK

1. Record all details of any fault or discrepancy on the FAULT LOG and report to Manager.
2. Complete Record Form (026a) ensuring that you date, sign it and enter FM First ticket number.
3. Return form to the Water Systems AP.

NOTES:

In circumstances where there has been a lapse in the flushing regime, the stagnant and potentially contaminated water from within the shower or tap and associated dead leg should be purged to drain without discharge of aerosols before the appliance is used.

NHSGG&C consider the cleaning of wash hand basins, toilets and showers etc by Domestic Services staff to fulfil the criteria of having been used /flushed

As part of the ward/departments standard cleaning schedule Domestic Services staff will clean all wash hand basins, showers, baths, WC's and bidets. For the purposes of Legionella and Pseudomonas control the Board deems this to be considered adequate to fulfil guidance on the use of water outlets.

4.42 – FLUSHING OF DEADLEGS & DRAIN COCKS

FM First Template No 827

TWICE WEEKLYIN ACCORDANCE WITH SHTM 04-01 Part G (*V1 July 2015*) Page 101 para 6.36**RECORD FORM - (026b)****PROCEDURE REF – WS01****HAISCRIBE/Risk Assessment Ref – N/A** See Appendix 4The following actions must be undertaken **TWICE WEEKLY** as a minimum:**Description of Works**

- Refer to the locations listed on Record Form (026b).
- Estates to arrange for the Schedule to be updated to record on a regular basis.
- Flush water from ALL outlets identified on Record Form (026b) on a Weekly basis for a minimum period of 3 minutes per tap outlet taking care not to cause splashing or exposure to water aerosols / droplets. Drain Cocks to be purged to ensure the removal of any built up residue in the line.

CHECK

1. Record all details of any fault or discrepancy on the FAULT LOG and report to Manager.
2. Complete Record Form (026b) ensuring that you date, sign it and enter FM First ticket number.
3. Return form to the Water Systems AP.

4.43 – ROTATION OF WATER SERVICES DUTY/STAND-BY PUMPS

FM First Template No 820

WEEKLYIN ACCORDANCE WITH SHTM 04-01 Part G (*V1 July 2015*) Page 27 para. 3.24**RECORD FORM - (028a)****PROCEDURE REF - P1C3****HAISCRIBE/Risk Assessment Ref – N/A** See Appendix 4The following actions must be undertaken **WEEKLY**:**Description of Works**

- Inspect and confirm operation of all listed duty/stand-by pumps by interrogating the programmer to check hours run for each pump motor.
- Check pump rig and associated valves for correct operation, signs of damage, leakage or corrosion.
- Record all details on Record Form (028a)

CHECK

1. Record all details of any fault or discrepancy on the FAULT LOG and report to Manager.
2. Complete Record Form (028a) ensuring that you date, sign it and enter FM First ticket number.
3. Return form to the Water Systems AP.

4.44 – OPERATION AND CHECKS TO EMERGENCY DELUGE SHOWERS/EYE WASH

FM First Template No 825

TWICE WEEKLYIN ACCORDANCE WITH SHTM 04-01 Part G (*V1 July 2015*) Page 57**RECORD FORM - (026c)****PRECEDURE REF – WS01****HAISCRIBE/Risk Assessment Ref – N/A** See Appendix 4**RISK CONTROL NOTICE - RCN 11/04**The following actions must be undertaken **TWICE WEEKLY**:**Description of Works**

- Refer to the locations listed on Record Form (026c).
- Operate shower for a minimum period of 3 minutes taking care not to cause splashing or exposure to water aerosols / droplets. Measure and record temperatures until discharge water drops to the same temperature as the incoming mains water.

NOTE: For thermostatic showers and taps, the outlet should be flushed on the full cold setting for 2 minutes, then again on the full hot setting for a further 2 minutes, using override setting where available. Cold water should be less than 20°C, Hot water should be between 55°C and 60°C, and Mixed water in the range 41-43°C.

CHECK

1. Record all details of any fault or discrepancy on the FAULT LOG and report to Manager.
2. Complete Record Form (026c) ensuring that you date, sign it and enter FM First ticket number.
3. Return form to the Water Systems AP.

4.5 Monthly Maintenance Checks

Reference	Operation
4.51	Sentinel Outlet Temperature Recording
4.52	DWS Calorifier – Temperature Checks & Blowdown

NOTE:

Completed Log Sheet to be submitted to Site Estates Manager / Authorised Person (Water) for authorisation and copies filed as indicated in Section 2.20.

Due to the volume of information required for the recording of test results for each of the assets being maintained, the Log Sheets provided within this document are for indicative purposes only.

Detailed information on the assets and test records for same will be retained within the specific 'Log Book' for the location being maintained.

4.51 – SENTINEL OUTLET TEMPERATURE RECORDING

FM First Template No 828

MONTHLYIN ACCORDANCE WITH SHTM 04-01 Part G (*V1 July 2015*) Page 28 para 3.27**RECORD FORM - (005c)****PROCEDURE REF - P1C4****HAISCRIBE/Risk Assessment Ref – N/A** See Appendix 4The following actions must be undertaken **MONTHLY**:**Description of Work**

- Check the temperatures at the sentinel taps as defined in the local plan of the system being checked. NOTE: Where the sentinel is a TMV or TMT the temperature readings should be taken from the pipework or directly from the hot and cold supply.
- Using a calibrated temperature probe, check the temperature of water from the cold water tap does not rise above 20°C after running the tap for 2 minutes.
- Using a calibrated temperature probe, check the temperature of water from the hot water tap does not drop below 50°C whilst running the tap for 1 minute.
- Record all temperatures on Record Form (005c).

CHECK

1. Record all details of any fault or discrepancy on the FAULT LOG and report to Manager.
2. Complete Record Form **(005c)** ensuring that you date, sign it and enter FM First ticket number.
3. Return form to the Water Systems AP.

4.52 - DWS CALORIFIER – TEMPERATURE CHECKS & BLOWDOWN

FM First Template No 821

MONTHLYIN ACCORDANCE WITH SHTM 04-01 Part G (*V1 July 2015*) Page 28 para 3.30**RECORD FORM - (005)****PROCEDURE REF - P1C4****HAISCRIBE/Risk Assessment Ref – N/A** See Appendix 4The following actions must be undertaken **MONTHLY**:**Description of Work**

- MANUALLY CHECK and record the flow and return temperatures on the domestic hot water system as defined on Record Form (005), using the temperature gauges fitted or a suitable surface temperature probe.
- MANUALLY CHECK and record the calorifier storage temperature at top and bottom gauges if fitted.
- The flow temperature to be at least 60°C and the return temperature shall be no less than 50°C
- MANUALLY CHECK and record the cold water feed temperature using the temperature gauges fitted or a suitable surface temperature probe.
- Blowdown drain valves (if fitted) on all calorifiers and expansion vessels by opening the drain valve 3 times, each time for a 3 minute period. Where required, the hose from the drain valve connection should be discharged to the nearest drain/gulley. If there is no drain valve make note on Record Form 005.
- Check all local pipework to and from calorifier is in good order and all insulation is intact.
- Operate all isolation valves through their full range of motion.
- Check, confirm and record operation of de-stratification pump.
- Record all information on the Record Form (005).

CHECK

1. Record all details of any fault or discrepancy on the FAULT LOG and report to Manager.

2. Complete Record Form (005) ensuring that you date, sign it and enter FM First ticket number.
3. Return form to the Water Systems AP.

4.6 Quarterly Maintenance Checks

Reference	Operation
4.61	Shower Head and Flexible Hoses Disinfection/Replacement
4.62	DHWS Calorifier and Expansion Vessel - Flush
4.63	HORNE Tap Flow Restrictor Exchange
4.64	Review of Rarely Used Water Outlets and Changes In-Use
4.65	TMV/TMT & Thermostatic Shower Disinfection and Function Test (HIGH RISK)

NOTE:

Completed Log Sheet to be submitted to either the Authorised Person (Water Systems) or Site Manager Operational Estates for authorisation and copies filed as indicated in Section 2.2.

Due to the volume of information required for the recording of test results for each of the assets being maintained, the Log Sheets provided within this document are for indicative purposes only.

Detailed information on the assets and test records for same will be retained within the specific 'Log Book' for the location being maintained.

4.61 SHOWER HEAD AND HOSE REPLACEMENT

FM First Template No 869
Schedules: 1997 to 2724

QUARTERLY

IN ACCORDANCE WITH SHTM 04-01 Part G (*VI July 2015*) Page 32 para 3.51

RECORD FORM - (005b)

PROCEDURE REF - P1C12 CURRENTLY CONTRACTED TO DMA CANYON WATER

HAISCRIBE/Risk Assessment Ref – N/A See Appendix 4

The following actions must be undertaken every **THREE MONTHS**:

NOTE: If PALL filter is fitted it must be left in place and recorded as such on Record Form (005b)

Description of Work

- Exchange shower head and hose assembly inc sealing washer with new disposable unit. Place old shower head and hose assembly into re-sealable plastic bag.
- Check that the new head and hose package is intact;
- Open replacement new shower head and hose assembly sealed packaging, remove and fit following the manufacturer's instructions;
- Run water and flush for 3 minutes in accordance with Legionella Risk Assessment in such a way as to avoid the creation of aerosols;
- Check final temperature for comfort and working order and return shower appliance to use.
- Return redundant sealed unit with shower head and hose assembly to collection point for recycling in accordance with Waste Procedures;
- Record all actions on Record Form (005b).

CHECK

1. Record all details of any fault or discrepancy on the FAULT LOG and report to Manager.
2. Complete Record Form (005b) ensuring that you date, sign it and enter FM First ticket number.
3. Return form to the Water Systems AP.

NOTE: This procedure replaces the previous Clean & Disinfect method from 1st April 2019

4.62 - DWS CALORIFIER AND EXPANSION VESSEL - FLUSH

FM First Template No 821

QUARTERLYIN ACCORDANCE WITH SHTM 04-01 Part G (*V1 July 2015*) Page 29 para 3.34**RECORD FORM - (006) and (023)****PROCEDURE REF - P1C6****HAISCRIBE/Risk Assessment Ref – N/A** See Appendix 4The following actions must be undertaken every **THREE MONTHS**:**Description of Work**

- Flush each Domestic Hot Water Calorifier and Buffer vessel through its drain valve by opening the drain valve 3 times, each time for a 3 minute period. Where required, the hose from the drain valve connection should be discharged to the nearest drain/gulley.
- Record all actions on the top section of Record Form (006).
- Where the domestic hot water system has a circulation pump(s) fitted to circulate the hot water from the top to the base of the calorifier or the storage/buffer vessel, and the history data shows no sludge deposits during flushing, then this procedure should be risk assessed to determine if the maintenance frequency can be changed. This assessment should be recorded on Record Form (023).

NOTE: this flushing process can shock the hot water system, so only carry it out when there is no hot water demand and the calorifier is valved off from the system.

CHECK

1. Record all details of any fault or discrepancy on the FAULT LOG and report to Manager.
2. Complete Record Forms (006) and/or (023) ensuring that you date, sign them and enter FM First ticket number.
3. Return form to the Water Systems AP.

4.63 – HORNE TAP FLOW RESTRICTOR EXCHANGE

FM First Template No N/A

QUARTERLY

IN ACCORDANCE WITH IC GUIDANCE

RECORD FORM – (See DMA Records)**PROCEDURE REF – WQS 001****HAISCRIBE/Risk Assessment Ref – N/A** See Appendix 4The following actions must be undertaken every **THREE MONTHS**:**Description of Work**

PPE:- Surgical gloves should be worn when carrying out this task. Cross contamination of the replacement flow restrictor should be considered and avoided at all times.

Restrictor should only be replaced at outlets without PALL filters. If PALL filter is fitted it should be left in place and noted on Record Form.

- Assemble all tools and materials required for a complete task.
- Check with ward staff to ensure access can be granted to each area without Infection Control restriction.
- Remove existing restrictor using the appropriate tool and dispose of the restrictor in general waste.
- Use disinfectant to sanitise tap outlet and tools used before re-fitting new restrictor.
- Change gloves to avoid cross contamination of new components and tools.
- Unpack new restrictor components and insert into tap as per the manufacturer's instructions.
- Test on completion and fill out log sheet to record all relevant information.

CHECK

1. Record all details of any fault or discrepancy on the FAULT LOG and report to Manager.
2. Complete Record Form (DMA WATER) ensuring that you date, sign them and enter FM First ticket number.
3. Return form to the Water Systems AP.

4.64 - REVIEW OF INTERMITTENTLY USED WATER OUTLETS/CHANGE IN-USE

IN ACCORDANCE WITH BOARD POLICY

QUARTERLY**RECORD FORM – (001) (026)****PROCEDURE REF – WS01****HAISCRIBE/Risk Assessment Ref – N/A** See Appendix 4The following actions must be undertaken every **THREE MONTHS**:**Description of Work**

- Liaise with Site Facilities Manager and Heads of Department to review existing accommodation occupancy and usage on a 3 monthly basis.
- Issue Quarterly circular email to all HoDs
- Identify any water services outlets that are not used OR changes to the occupancy.
- Schedule to be updated to record all areas which change in-use, become unoccupied or otherwise out of use.

CHECK

1. Record all details of any dept closures or little used outlets on Record Form (001) and add outlets to flushing register.
2. Ensure outlets are brought to the attention of the maintenance person carrying out the flushing activity and details added to Record Form (026)
3. All completed Record Forms to be stored in the building specific Log Book.

4.65 – TMV/TMT & THERMOSTATIC SHOWER DISINFECTION AND FUNCTION TEST (HIGH RISK)

QUARTERLY

FM First Template No

IN ACCORDANCE BOARD POLICY

RECORD FORM -**PROCEDURE REF -****HAISCRIBE/Risk Assessment Ref – N/A See Appendix 4**The following actions must be undertaken every **THREE MONTHS**:**Description of Work**

- Examine all thermostatic taps for scale build-up or other deposits. De-scale any which are not clean.
- Check and remove any installed plastic flow straighteners from tap outlet
- Inspect and Clean and Disinfect filters / strainers by removing and immersing in a solution of 1000ppm free residual chlorine (50cc CLO2 in 5 litres of water) in water for 5 minutes.
- All HORNE Optitherm taps **MUST** have the flow straightener replaced during three monthly service tasks.
- Pasteurise outlets by over-riding thermostatic controls drawing water through each thermostatic tap until a temperature of 60°C is achieved. Run the tap at this temperature for five minutes. If this is not possible disassemble tap assembly and spray all accessible components with 'Shower Head plus' mixed to a 1:3 solution, (one part chemical, 3 parts water) or equal and approved and let stand for 5 minutes.
- Reassemble and verify fail safe operation by isolating hot and cold water supplies separately.
- Ensure thermostatic controls are re-adjusted to permit blending.
- Should controls not be able to be over-ridden, verify the temperatures at the inlet connections to the thermostatic valve utilising a contact type probe and electronic thermometer.
- Run and test tap and record hot and cold water inlet temperatures and mixed water outlet temperature.
- Log all actions.

4.7 Six Monthly Checks

Reference	Operation
4.71	TMV/TMT & Thermostatic Shower Disinfection and Function Test (Non-HIGH RISK)
4.72	CWST Inspection and Temperature Monitoring

NOTE:

Completed Log Sheet to be submitted to either the Authorised Person (Water Systems) or Site Manager Operational Estates for authorisation and copies filed as indicated in Section 2.2.

Due to the volume of information required for the recording of test results for each of the assets being maintained, the Log Sheets provided within this document are for indicative purposes only.

Detailed information on the assets and test records for same will be retained within the specific 'Log Book' for the location being maintained.

4.71 – TMV/TMT & THERMOSTATIC SHOWER DISINFECTION AND FUNCTION TEST (NON HIGH RISK)

IN ACCORDANCE WITH BOARD POLICY

SIX MONTHLY**RECORD FORM -****PROCEDURE REF -****HAISCRIBE/Risk Assessment Ref – N/A See Appendix 4**The following actions must be undertaken every **SIX MONTHS**:**Description of Work**

- Examine all thermostatic taps for scale build-up or other deposits. De-scale any which are not clean.
- Check and remove any installed plastic flow straighteners from tap outlet
- Inspect and Clean and Disinfect filters / strainers by removing and immersing in a solution of 1000ppm free residual chlorine (50cc CLO2 in 5 litres of water) in water for 5 minutes.
- All HORNE Optitherm taps MUST have the flow straightener replaced during three monthly service tasks.
- Pasteurise outlets by over-riding thermostatic controls drawing water through each thermostatic tap until a temperature of 60°C is achieved. Run the tap at this temperature for five minutes. If this is not possible disassemble tap assembly and spray all accessible components with 'Shower Head plus' mixed to a 1:3 solution, (one part chemical, 3 parts water) or equal and approved and let stand for 5 minutes.
- Reassemble and verify fail safe operation by isolating hot and cold water supplies separately.
- Ensure thermostatic controls are re-adjusted to permit blending.
- Should controls not be able to be over-ridden, verify the temperatures at the inlet connections to the thermostatic valve utilising a contact type probe and electronic thermometer.
- Run and test tap and record hot and cold water inlet temperatures and mixed water outlet temperature.
- Log all actions.

4.72 – CWST INSPECTION AND TEMPERATURE MONITORING:

FM First Template No 819

SIX MONTHLYIN ACCORDANCE WITH SHTM 04-01 Part G (*V1 July 2015*) Page 29 para 3.37**RECORD FORM – (003a) (003b)****PROCEDURE REF – P1C7****HAISCRIBE/Risk Assessment Ref – N/A** See Appendix 4

The following actions must be undertaken every **SIX MONTHS** seasonally during Summer and Winter:

Description of Work

- Inspect the tank and associated pipework including insulation, valves etc for damage or corrosion and sediment.
- Operate all isolation valves through their full range of motion.
- Check the operation of the ball-valve by pressing down on it and lifting the float to confirm that water flows and stops.
- Inspect the tank overflows if visible. Confirm that there is no blockage or other foreign material and that the mesh screen is not damaged.
- Measure and record the temperature of the water in the tanks, by dipping the thermometer into the top as far from the ball-valve as possible.
- Check and record ambient outside air temp and tank room temp.
- Check the flow and record the temperature of water feeding the tanks. There should be a steady rapid flow when the ball float is down.

CHECK

1. Record all details of any fault or discrepancy on the FAULT LOG and report to Manager.
2. Complete Record Forms (003a) and (003b) ensuring that you date, sign them and enter FM First ticket number.
3. Return forms to the Water Systems AP.

4.8 Annual Maintenance Checks

Reference	Operation
4.81	DWS Calorifier / Expansion Vessel Inspection
4.82	Water Services Pipework and Distribution System Checks
4.83	Representative Tap Temperature Monitoring
4.84	Vibration coupling inspection
4.85	BMS Temperature Sensor Test and Calibration

NOTE:

Completed Log Sheet to be submitted to either the Authorised Person (Water Systems) or Site Manager Operational Estates for authorisation and copies filed as indicated in Section 2.2.

Due to the volume of information required for the recording of test results for each of the assets being maintained, the Log Sheets provided within this document are for indicative purposes only.

Detailed information on the assets and test records for same will be retained within the specific 'Log Book' for the location being maintained.

4.81 - DWS CALORIFIER/EXPANSION VESSEL INSPECTION

FM First Template No 821

ANNUALLYIN ACCORDANCE WITH SHTM 04-01 Part G (*V1 July 2015*) Page 31 para 3.44**RECORD FORM - (006)****PROCEDURE REF - P1C9****HAISCRIBE/Risk Assessment Ref – N/A** See Appendix 4The following actions must be undertaken **ANNUALLY****Description of Work**

Follow the manufacturers' maintenance instructions from O&M manuals. Record all actions where applicable on Record Form (006) for each system.

- Isolate domestic hot water calorifier or hot, cold or chilled water storage/buffer vessel service valves;
- Heat any domestic hot water calorifier or hot water storage/buffer vessel up until the contents has reached 60°C and hold at this temperature for a period of at least 1 hour;
- Drain domestic hot water calorifier and expansion vessel and remove inspection hatch;
- Hose out the domestic hot water calorifier or hot and expansion vessel to remove any debris, scale or other deposit. Care should be taken to keep aerosols to a minimum;
- If the domestic hot water calorifier or expansion vessel does not have an inspection hatch, the pipework at the top of the vessel should be disconnected to allow the insertion of a water hose to allow debris to be washed down off internal surfaces;
- Examine the internal and external condition of the domestic hot water calorifier and expansion vessel and pipework, any defects should be reported in writing to the relevant Authorised Person (Water). The safety valve should be checked, overhauled and reset as necessary. The temperature and pressure gauges to be checked for operation.
- On completion of examination and any repairs, the domestic hot water calorifier and expansion vessel should be re-assembled and the following sequence must be undertaken:
 - Refill with cold water;
 - Drain the domestic hot water calorifier and expansion vessel;
 - Refill with cold water, leave cold feed valve open;
 - Run domestic hot water calorifier or hot water storage/buffer vessel at a temperature of 60°C for at least 1 hour. Test the operation of high limit cut-out system if fitted. Check the temperature of the calorifier/vessel top and bottom with a surface thermometer;

- Adjust any controls as necessary.
- Take bacteriological samples from the base of the calorifier and submit to GRI Water Lab for analysis. (THIS TASK TO BE CARRIED OUT BY DMA CANYON WATER)

NOTE: this flushing process can air lock the hot water system, so only carry it out when there is no hot water demand and the calorifier is valved off from the system.

CHECK

1. Record all details of any fault or discrepancy on the FAULT LOG and report to Manager.
2. Complete Record Forms (006) ensuring that you date, sign them and enter FM First ticket number.
3. Return form to the Water Systems AP.

4.82 - PIPEWORK AND DISTRIBUTION SYSTEM CHECKS

FM First Template No 829

ANNUALLYIN ACCORDANCE WITH SHTM 04-01 Part G (*V1 July 2015*) Page 31 para 3.**RECORD FORM - (0)****PROCEDURE REF -****HAISCRIBE/Risk Assessment Ref – N/A** See Appendix 4The following actions must be undertaken **ANNUALLY**:

Estates Manager or Water Systems AP will define areas to be checked in each building.

Description of Work

- Check all accessible pipework for damage, or corrosion.
- Check for missing or damaged pipework insulation

CHECK

1. Record all details of any fault or discrepancy on the FAULT LOG and report to Manager.
2. Complete Record Forms (0) ensuring that you date, sign them and enter FM First ticket number.
3. Return form to the Water Systems AP.

4.83 – REPRESENTATIVE TAP TEMPERATURE MONITORING

FM First Template No 917

ANNUALLYIN ACCORDANCE WITH SHTM 04-01 Part G (*V1 July 2015*) Page 32 para 3.39**RECORD FORM - (005d)****PROCEDURE REF – P1C10****HAISCRIBE/Risk Assessment Ref – N/A** See Appendix 4

The following actions must be undertaken at regular intervals throughout the year to ensure 20% of the requirement is completed **ANNUALLY**:

Description of Work

- **OBJECTIVE:** Carry out water temperature monitoring to ensure consistency and performance of the system as per design. 20% of all outlets to be assessed annually to ensure entire system is completed within a 5 year period (*ref: SCART2 Question 54*)
- Check the temperatures at a representative number of hot and cold outlets on a rotational basis as defined in the local plan of the system being checked. Lead AP (Water) to define areas to be checked each month.
- Using a temperature probe check the temperature of the cold water tap does not go above 20°C after running the tap for 2 minutes;
- Using a temperature probe check the temperature of the hot water tap does not go below 50°C within running the tap for 1 minute;
- If the outlet being tested is protected by a TMV/TMT then temperatures should be taken directly from the supply pipework or by bypassing the thermostatic device by use of an appropriate purging kit.
- Record all temperatures and locations tested on the Record Form (005d).

CHECK

1. Record all details of any fault or discrepancy on the FAULT LOG and report to Manager.
2. Complete Record Forms (005d) ensuring that you date, sign them and enter FM First ticket number.
3. Return form to the Water Systems AP.

4.84 - VIBRATION COUPLING INSPECTION

FM First Template No 831

ANNUALLY

IN ACCORDANCE WITH HSG 274 Part 2 (2014) Page 19 para 2.35

RECORD FORM - (008)**PROCEDURE REF – WQMS 001****HAISCRIBE/Risk Assessment Ref – N/A** See Appendix 4The following actions must be undertaken **ANNUALLY**:**Description of Work**

- Refer to list of vibration coupling locations to be assessed.
- Visually check the condition of the coupling for any signs of leakage, deterioration or corrosion.
- Ensure flexible portion of coupling is intact and free from damage or deterioration.
- Record all inspection details on the Record Form (008).

CHECK

1. Record all details of any fault or discrepancy on the FAULT LOG and report to Manager.
2. Complete Record Forms (008) ensuring that you date, sign them and enter FM First ticket number.
3. Return form to the Water Systems AP.

4.85 – BMS TEMPERATURE SENSOR CALIBRATION

FM First Template No

ANNUALLY

IN ACCORDANCE WITH

RECORD FORM -**PROCEDURE REF –****HAISCRIBE/Risk Assessment Ref – N/A See Appendix 4**The following actions must be undertaken **ANNUALLY**:**Description of Work**

- This task should be included in the BMS Service Contract Specification.
- All temperature sensors related to domestic hot and cold water services to be checked and calibrated annually.
- All calorifiers, storage tanks, flow and return monitoring devices.
- Include all End of Line (EOL) sensors and cold water flushing devices.
- Records should be kept and made available to the estates dept on request.

4.9 Bi-Annual Maintenance Checks

Reference	Operation
4.91	Flexible Hose/Connection Inspection and Exchange
4.92	CWST Drop Test

NOTE:

Completed Log Sheet to be submitted to either the Authorised Person (Water Systems) or Site Manager Operational Estates for authorisation and copies filed as indicated in Section 2.2.

Due to the volume of information required for the recording of test results for each of the assets being maintained, the Log Sheets provided within this document are for indicative purposes only.

Detailed information on the assets and test records for same will be retained within the specific 'Log Book' for the location being maintained.

4.91 – FLEXIBLE HOSE/CONNECTION INSPECTION AND EXCHANGE

FM First Template No

BI-ANNUALLY

IN ACCORDANCE WITH QEUH RISK ASSESSMENT RECOMMENDATIONS 2017

RECORD FORM - (009)**PROCEDURE REF – WQMS 002****HAISCRIBE/Risk Assessment Ref – N/A** See Appendix 4The following actions must be undertaken **ANNUALLY**:**Description of Work**

- Refer to list of flexible connection locations to be assessed as per WQMS 002.
- Visually check the condition of the coupling for any signs of leakage, deterioration or corrosion.
- Safely isolate the water services and exchange the flexible connection with a BRAND NEW UNUSED replacement.
- Apply tag/label to indicate the intended date of future replacement (todays date + 24 months)
- Record all details on the Record Form (009).

CHECK

1. Record all details of any fault or discrepancy on the FAULT LOG and report to Manager.
2. Complete Record Forms (009) ensuring that you date, sign them and enter FM First ticket number.
3. Return form to the Water Systems AP.

4.92 – CWST DROP TESTS

FM First Template No 819

BI-ANNUALLY

IN ACCORDANCE WITH

RECORD FORM -**PROCEDURE REF -****HAISCRIBE/Risk Assessment Ref – N/A** See Appendix 4The following actions must be undertaken **ANNUALLY**:**Description of Work**

- Shut off mains cold water supply to tank.
- Record the start time and allow tank to drain naturally through usage. DO NOT OPEN THE DRAIN.
- Periodically monitor the tank until usage has reduced tank to exactly half of its starting capacity.
- Record the stop time and estimate the number of hours of storage of water in the tank.
- Record all inspection details on the Record Form (010).

CHECK

1. Record all details of any fault or discrepancy on the FAULT LOG and report to Manager.
2. Complete Record Forms (010) ensuring that you date, sign them and enter FM First ticket number.
3. Return form to the Water Systems AP.

5.0 INCIDENT AND EMERGENCY PROCEDURES

Procedure Reference	Operation
5.10	FAILURE OF CONTROL MEASURES
5.20	HIGH COLD WATER SUPPLY TEMPERATURE TO OUTLET
5.30	LOW HOT WATER SUPPLY TEMPERATURE TO OUTLET
5.40	CALORIFIER OR HEAT EXCHANGER TEMPERATURE FAULT
5.50	POSITIVE LEGIONELLA TEST RESULT
5.60	IDENTIFICATION OF LITTLE USED WATER OUTLET
5.70	EMERGENCY REPAIRS
5.80	DISINFECTION OF WATER SYSTEM
5.90	PSEUDOMONAS

NOTE:

Completed Log Sheet to be submitted to either the Authorised Person (Water Systems) or Site Manager Operational Estates for authorisation and copies filed as indicated in Section 2.2.

Due to the volume of information required for the recording of test results for each of the assets being maintained, the Log Sheets provided within this document are for indicative purposes only.

Detailed information on the assets and test records for same will be retained within the specific ‘Log Book’ for the location being maintained.

THE FOLLOWING PAGES DESCRIBE REMEDIAL ACTIONS TO BE TAKEN IN THE EVENT OF AN INCIDENT, EMERGENCY, OUT-OF-SPECIFICATION TEST RESULT AND / OR WHERE *LEGIONELLA* HAS BEEN IDENTIFIED AND/OR BACTERIA COUNTS BEING IN EXCESS OF THE RECOMMENDED LIMITS IN THE WATER SYSTEM ARE IDENTIFIED.

The Health and Safety at Work Act places a duty on employers to ensure, so far as is reasonably practicable, the maintenance of safe working conditions without risks to health, not only to employees, but also to the general public.

The risk to personnel associated with the presence of *Legionella* depends on a number of variables and may be quite low. However, since the actions to eradicate it are straightforward and reasonably practicable, it would be wise to put them in hand without delay if *Legionella* has been identified.

When analysis confirms that the levels of bacteriological contamination are in excess of acceptable limits, and/or the presence of Coliforms or *E.coli* is identified, the procedures recommended in this section should be applied.

5.1 Failure of Control Measures:

Where any reported test result, non-compliance issue or defect is made known which affects the integrity of the water system and indicates the failure of Control Measures and / or increased risk of Legionella the following procedures shall be followed and duly recorded within Section 2.3 of this document and brought to the attention of the relevant Infection Control Team and Water Management Group.

IN ALL CASES THE INCIDENT RECORD FORM (004) SHOULD BE COMPLETED AND INSERTED IN THE BUILDING SPECIFIC WATER SAFETY LOG BOOK.

5.2 High Cold Water Supply Temperature

Incident Plan

In the event of plant failure suppliers and installers guidance should be consulted. The location of all relevant literature should be recorded in the site logbook (e.g. Mercury fault finding guidance).

Mains and Stored Water

Currently there is no legal maximum water supply temperature from the Licensed Provider. In practice the water supply temperature to boundary point will be subject to seasonal variation. In winter this would normally be expected to be in the 5°C – 10°C range and in summer up to 20°C.

The following staged risk assessment escalation procedure should be employed where the water temperature in Cold Water Storage Tanks is 20°C or higher.

Stage 1 - Verification

- Where tepid cold water occurrence (i.e. $\geq 20^{\circ}\text{C}$) is reported from any numbers of cold water outlets, from maintenance/ppm, flushing procedures, from BEMS monitoring, or from the manual monitoring of storage tanks, the person identifying, or making a report must notify the relevant Authorised Person (Water) as soon as the problem is identified and confirm this in writing within 24 hours;
- The Authorised Person (Water) should liaise with the person identifying the problem and verify the problem by independently re-checking by means of taking the water temperature of the appropriate cold water storage tank, the temperature of each incoming mains supplies at the site boundary point (and building entry points of other buildings within the QEUH campus served by the same mains lines) and the outflow distribution temperature;
- If the cold water storage temperature is confirmed as being 20°C or higher at any of the above noted points, then the Authorised Person (Water) should record this in writing as well as conducting continuous monitoring of the incoming cold water mains, the cold water storage and the outflow temperatures to establish the temperature profiles and in more detail over at least a one week period to determine the level of risk;
- If only one of the incoming mains lines is $\geq 20^{\circ}\text{C}$ the consideration should be given to switching to the other mains supply until such times as “out-of-specification” mains line has returned to compliant parameters. Ensure if either mains line is non-operational it is included in a daily flushing regime and treated as per escalation procedures to follow.
- The Authorised Person (Water) should also review the Water Safety Log Book and take into account the recent water system history specifically to include:
 - the primary water treatment levels (for mains cold water supplied with Chlorine or Chloramination treatment);
 - any water sampling results;
 - system monitoring data including temperature monitoring and water quality chlorine or chloramination checks;
 - recent maintenance history; recent alterations, changes or additions to the water system;
 - any other changes made by Duty Holders or users of the water system; On reviewing continuous monitoring temperature profiles action as Stage 2, 3 or 4 as appropriate of this escalation procedure should be undertaken. The Authorised Person (Water) will ensure that the Responsible Person (Water) is notified immediately in writing at each stage and also recorded in the Water Safety log book.

Stage 2 - Initial Action – High Incoming Mains Cold Water Temperature

- Where the incoming mains cold water is 18°C or higher for more than a 48 hour period the Responsible Person (Water) should contact Business Stream (the Licensed Provider) who will work with Scottish Water to establish the reasons and determine a resolution. Continuous monitoring should continue and recorded in the risk assessment

Stage 3 - Water temperatures fluctuating above and below 20°C (but not higher than 25°C)

- Where water temperatures are fluctuating above and below 20°C in a regular cyclical manner over 72 hour periods in response to regular user water demand (but not higher than 25°C) and are more than 2°C higher than the incoming cold water mains supply temperature at the building entry point, then continuous monitoring should be continued by the Authorised Person (Water). The reason(s) for failure(s) should be identified and rectified as soon as possible. This should be recorded by updated risk assessment (specifically in relation to the patient risk rating – where there may be increased risk and appropriate actions may be required to mitigate exposure. An up to date register of all areas and their subsequent patient risk ratings should be maintained).
- considerations for failures include:
 - accuracy of temperature sensors (requiring recalibration);
 - temperature sensors being located in water (requiring reposition where tank storage levels been reduced and sensor no longer sensing stored water);
 - inappropriate standby tank configuration;
 - temperature sensor in standby system;
 - temperature sensor measuring stagnation (requires reposition);
 - inappropriate siting (not in a cool location);
 - heat gain to the tank and pipework (due to lack of appropriate insulation or located close to heat gain from other heat sources);
 - storage capacity not minimised to match daily use (12 hours storage is recommended);
 - ingress of hot water through cross connection or mixing valve failure (i.e. from DHW system or MTHW systems);

Stage 4 - water temperatures fluctuating above and below 25°C (and rarely below 20°C)

- In this situation continuous monitoring should be continued by the Authorised Person (Water), the reason(s) for failure(s) (as Stage 3) identified and rectified on an urgent basis. This should be recorded by updated risk assessment (specifically in relation to the patient risk rating – where there will be an increased risk and appropriate actions will be required to mitigate exposure. An up to date register of all areas and their subsequent patient risk ratings should be maintained);
- In this situation a permanent solution, such as ventilation for the plant room, or changing the water storage arrangements, or forming a circulating distribution system (with or without chilling depending on the circumstances) would require to be implemented;
- The Authorised Person (Water) should, unless instructed in writing to the contrary by Responsible Person (Water) implement the following:
 - o arrange to drain the tank contents and clean if necessary (*and/or carry out local disinfections where appropriate*);
 - o inform the users of the failed system that they must not draw off any water from the affected system until further notice;
 - o suitable disinfection of the tank and/or distribution system shall be carried out.

Please Note: *Due to the system design and installation complete disinfection of all downservices fed from the Raw and Bulk water storage tanks may not be practical as “high risk” system such as renal dialysis is fed from these tanks. Alternative protocols/method statements for local disinfections should be prepared and maintained;*

- o thereafter the tank/local area being disinfected shall be brought back into service;
- o finally the users shall be informed that the system is back in operation.

The Authorised Person (Water) shall complete an Incident Report Record Form. An entry should also be made in the Water Safety Log Book and the Responsible Person (Water) should be notified in writing as soon as possible.

5.3 Low Hot Water Supply Temperature

Incident Plan

In the event of plant failure suppliers and installers guidance should be consulted. The location of all relevant literature should be recorded in the site logbook (e.g. Mercury fault finding guidance).

Mains and Stored Water

Currently there is no legal maximum water supply temperature from the Licensed Provider. In practice the water supply temperature to boundary point will be subject to seasonal variation. In winter this would normally be expected to be in the 5°C – 10°C range and in summer up to 20°C.

The following staged risk assessment escalation procedure should be employed where the water temperature in Cold Water Storage Tanks is 20°C or higher.

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- Where tepid cold water occurrence (i.e. $\geq 20^{\circ}\text{C}$) is reported from any numbers of cold water outlets, from maintenance/ppm, flushing procedures, from BEMS monitoring, or from the manual monitoring of storage tanks, the person identifying, or making a report must notify the relevant Authorised Person (Water) as soon as the problem is identified and confirm this in writing within 24 hours;
- The Authorised Person (Water) should liaise with the person identifying the problem and verify the problem by independently re-checking by means of taking the water temperature of the appropriate cold water storage tank, the temperature of each incoming mains supplies at the site boundary point (and building entry points of other buildings within the Southern General Hospital served by the same mains lines⁸) and the outflow distribution temperature;
- If the cold water storage temperature is confirmed as being 20°C or higher at any of the above noted points, then the Authorised Person (Water) should record this in writing as well as conducting continuous monitoring of the incoming cold water mains, the cold water storage and the outflow temperatures to establish the temperature profiles and in more detail over at least a one week period to determine the level of risk;
- If only one of the incoming mains lines is $\geq 20^{\circ}\text{C}$ the consideration should be given to switching to the other mains supply until such times as “out-of-specification” mains line has returned to compliant parameters. Ensure if either mains line is non-operational it is included in a daily flushing regime and treated as per escalation procedures to follow.
- The Authorised Person (Water) should also review the Water Safety Log Book and take into account the recent water system history specifically to include:
 - the primary water treatment levels (for mains cold water supplied with Chlorine or Chloramination treatment);
 - any water sampling results;
 - system monitoring data including temperature monitoring and water quality chlorine or chloramination checks;
 - recent maintenance history; recent alterations, changes or additions to the water system;
 - any other changes made by Duty Holders or users of the water system;
 - On reviewing continuous monitoring temperature profiles action as Stage 2, 3 or 4 as appropriate of this escalation procedure should be undertaken. The Authorised Person (Water) will ensure that the Responsible Person (Water) is notified immediately in writing at each stage and also recorded in the Water Safety Logbook.

Stage 2 - Initial Action – High Incoming Mains Cold Water Temperature

- Where the incoming mains cold water is 18°C or higher for more than a 48 hour period the Responsible Person (Water) should contact Business Stream (the Licensed Provider) who will work with Scottish Water to establish the reasons and determine a resolution. Continuous monitoring should continue and recorded in the risk assessment.

Stage 3 - water temperatures fluctuating above and below 20°C (but not higher than 25°C)

- Where water temperatures are fluctuating above and below 20°C in a regular cyclical manner over 72 hour periods in response to regular user water demand (but not higher than 25°C) and are more than 2°C higher than the incoming cold water mains supply temperature at the building entry point, then continuous monitoring should be continued by the Authorised Person (Water). The reason(s) for failure(s) should be identified and rectified as soon as possible. This should be recorded by updated risk assessment (specifically in relation to the patient risk rating – where there may be increased risk and appropriate actions may be required to mitigate exposure. An up to date register of all areas and their subsequent patient risk ratings should be maintained).
- considerations for failures include:
 - accuracy of temperature sensors (requiring recalibration);
 - temperature sensors being located in water (requiring reposition where tank storage levels been reduced and sensor no longer sensing stored water);
 - inappropriate standby tank configuration;
 - temperature sensor in standby system;
 - temperature sensor measuring stagnation (requires reposition);
 - inappropriate siting (not in a cool location);
 - heat gain to the tank and pipework (due to lack of appropriate insulation or located close to heat gain from other heat sources);
 - storage capacity not minimised to match daily use (12 hours storage is recommended);
 - ingress of hot water through cross connection or mixing valve failure (i.e. from DHW system or MTHW systems);

Stage 4 - water temperatures fluctuating above and below 25°C (and rarely below 20°C)

- In this situation continuous monitoring should be continued by the Authorised Person (Water), the reason(s) for failure(s) (as Stage 3) identified and rectified on an urgent basis. This should be recorded by updated risk assessment (specifically in relation to the patient risk rating – where there will be an increased risk and appropriate actions will be required to mitigate exposure. An up to date register of all areas and their subsequent patient risk ratings should be maintained);
- In this situation a permanent solution, such as ventilation for the plant room, or changing the water storage arrangements, or forming a circulating distribution system (with or without chilling depending on the circumstances) would require to be implemented;
- The Authorised Person (Water) should, unless instructed in writing to the contrary by Responsible Person (Water) implement the following:
 - o arrange to drain the tank contents and clean if necessary (*and/or carry out local disinfections where appropriate*);
 - o inform the users of the failed system that they must not draw off any water from the affected system until further notice;
 - o suitable disinfection of the tank and/or distribution system shall be carried out.

Please Note: *Due to the system design and installation complete disinfection of all downservices fed from the Raw and Bulk water storage tanks may not be practical as “high risk” system such as renal dialysis is fed from these tanks. Alternative protocols/method statements for local disinfections should be prepared and maintained;*

- thereafter the tank/local area being disinfected shall be brought back into service;
- finally the users shall be informed that the system is back in operation.

The Authorised Person (Water) shall complete an Incident Report Record Form. An entry should also be made in the Water Safety Log Book and the Responsible Person (Water) should be notified in writing as soon as possible.

Hot Water Services

When hot water storage or distribution temperatures fall below those required (60°C storage, 55°C at outlets and returning to calorifier) these will almost inevitably be caused a mechanical fault. Appropriate maintenance procedures, including the Mercury Fault Finding guidance documents, should be created and referenced to assist in timely rectification.

This escalation procedure (taken from SHTM 04-01 Part G (Draft)) should be employed if the Calorifier/Plate Heat Exchangers outflow temperature falls below 45°C.

The table below should be used to decide on the actions necessary in the event of a plant breakdown such as power failure or gas supply failure.

Breakdown leading to temperature <45°C, lasting for:	Risk Category	Action
<12 hrs	High	Verify
	Significant	Verify
	Moderate	Verify
>12 hrs	High	Thermally pasteurise
	Significant	Verify
	Moderate	Verify
>24 hrs	High	Thermally pasteurise
	Significant	Thermally pasteurise
	Moderate	Verify
>72 hrs	High	Thermally pasteurise
	Significant	Thermally pasteurise
	Moderate	Thermally pasteurise

In the event of a reduction in domestic hot water temperature the **Authorised Person (Water)** should be notified in writing as soon as possible. The reason for failure must be identified and rectified as soon as possible.

The **Authorised Person (Water)** shall notify the **Duty Holder** and users on the failed system that they must not draw off any hot water from the affected services until further notice.

The relevant **Duty Holder** shall ensure that their staff are aware of the situation, and that they in turn shall prevent patients from using affected services.

Where thermal pasteurisation is to be carried out, the temperature of the calorifier or plate heat exchanger shall be raised to 70°C, and the water shall be circulated throughout the affected distribution system for at least one 1 hour. Each tap or appliance should be run in sequence until full temperature is achieved (this should be measured). To be effective the temperature in the calorifier or plate heat exchanger should be high enough to ensure that all distribution outlets receive water at a temperature of greater than 60°C. Ensure the return flow to the calorifier or plate heat exchanger is no less than 55°C.

The **Authorised Person (Water)** shall inform users that the system is back in operation.

Bacteriological samples should be taken in consultation with the Infection Prevention and Control team.

The **Authorised Person (Water)** shall complete an Incident Report Record and ensure the **Responsible Person (Water)** is notified in writing as soon as possible. Maintain hard copy records in the Water Safety Log

5.4 Positive Legionella Test Result

Microbiological Sampling (Legionella)

Sampling requirements and frequency are to be formulated by NHS GG&C and written scheme should be updated as appropriate.

Legionella testing may be required:

- In systems where the temperature control regimes are not consistently achieved, frequent testing e.g. weekly should be carried out to provide early warning of loss of control. Once the system is brought back under control as demonstrated by monitoring, the frequency of testing should be reviewed
- Weekly checks are recommended until the system is brought under control;
- When an outbreak is suspected or has been identified;
- In wards with at-risk patients – for example those who are immuno-compromised (“high risk patient” areas still to be confirmed to DMA).

As a minimum, samples should be taken as follows:

- From the cold water storage and the furthestmost outlet from the tank, on every loop;
- From the calorifier flow, or the closest tap to the calorifier, and the furthestmost tap on the hot water service circulating system (these should be identified on sentinel outlet register);
- Additional samples should be taken from the base of the calorifier via drain valves;
- From areas where the target control parameters are not met (i.e. where temperatures are below 55°C for hot water systems or $\geq 20^{\circ}\text{C}$ for cold water systems);
- From areas subject to low usage, stagnation, excess storage capacity, dead legs, excessive heat loss, crossflow from the water system or other anomaly.
- High Risk Patient Areas
- Additional random samples may also be considered appropriate where systems are known to be susceptible to colonisation.

The temperature control regime is the preferred strategy for reducing the risk from *Legionella* and other waterborne organisms in water systems. This will require monitoring on a regular basis. The recommended test frequencies for various outlets are set out in Table 2 in Section 7.

HSG 274 Part 2 Table 2.3 Actions to be taken following legionella sampling in hot and cold water systems in healthcare premises with susceptible patients

Legionella bacteria (cfu/Litre)	Action required
More than 100 but less than 1,000	Low risk area Estates action only If only one or two samples are positive, system should be re-sampled. If a similar count is found again, a review should be carried out to identify any remedial actions a) If the majority of samples are positive, the system may be colonised, albeit at low level, with Legionella. Disinfection of the system should be considered but an immediate review of control measures and risk assessment should be carried out to identify any other remedial actions required. If remedial action is ineffective further measures will be discussed and approved by the Board Water Safety Group
More than 100 but less than 1,000	High Risk areas Impact on patient care Discuss results with ICD and agree actions and any closure of area.
More than 1,000	Low Risk Estates action only The system should be re-sampled and an immediate review of the control measures and risk assessment carried out to identify any remedial actions, including possible disinfection of the system. If remedial action is ineffective further measures will be discussed and approved by the Board Water Safety Group
More than 1,000	High Risk areas Discuss results with ICD and agree actions and any closure of area.

Communication pathway for Legionella results from water samples:

Water samples are sent to; UKASS-accredited laboratories which provide this service for NHS and other organisations that manage buildings. Reports will come back initially to the estates department.

Negative water samples are recorded as part of the documentation of Legionella control. If they are related to investigation of an “incident” such as a clinical case or a previous positive sample then these results are communicated to those managing that incident.

The information on the report which needs to be communicated is:

- Date of sampling
- Location and type of water outlet
- Identification of the organism, (Legionella pneumophila with serogroup, or Legionella species other than L pneumophila.)
- Count of organisms per Litre.

Estates will

- Inspect the system and take further action in accordance with HSE guidance and locally agreed procedures
- Inform Charge Nurse and or Clinical Nurse Manager of the Clinical Area concerned if appropriate of any control measures being taken/required
- Inform GM for the Sector if appropriate.

The results of this initial risk assessment must be communicated to all those noted above and also to the Facilities General Manager for the site involved.

The Infection Control Manager for Infection Prevention and Control will inform NHS GG&C

If there is impact on patient care then an Incident Management Team (IMT) may be convened to assess the risk and further actions.

See table in Appendix 2

5.5 Intermittent or Infrequently Used Water Outlets

If after investigation the taps or appliances identified within the reviewed list, to be updated on a quarterly basis, is deemed not necessary wherever possible the supply pipe work shall be cut back as close to the main circulating line as practicable to ensure that any dead leg formed is minimised and the appliance is removed from the water system.

In circumstances where there has been a lapse in the flushing regime, the stagnant and potentially contaminated water from within the shower or tap and associated dead leg should be purged to drain without discharge of aerosols before the appliance is used.

Where a ward or department is closed or taken out-of-use for an extended period of time e.g.: pending refurbishment, change in-use or other reason, arrangements shall be put in place to ensure the regular flushing and recording of water outlets within such areas. If such closures are considered to be long term or permanent consideration should be given to the disconnection of all water services to the affected areas.

5.6 Emergency Repairs

Emergency repairs may be required at any time and should be undertaken by trained and competent personnel. Such repairs can vary from a simple repair to a section of pipework, replacement of a component or major burst or loss of service. In all such cases the integrity and safety of the water distribution system must be maintained at all times.

5.7 Disinfection of Water System and Components

There are a number of different chemical and thermal disinfection methods available ALL of which shall be undertaken by trained and competent personnel in strict accordance with all Statutory Requirements, Safety Precautions and Manufacturers Instructions.

Disinfection - is the process of destroying or inactivating Pathogenic organisms and is generally applied to the water supply.

Sterilisation – is the process of destroying or inactivating all Organic Life Forms and is generally applied to all systems of transmission and storage materials.

In ALL instances no matter what disinfection method is employed, due regard shall be taken of patient groups, specialist equipment and processes which may be sensitive to the disinfection process being used – eg Renal Dialysis patients **must not** be exposed to Silver Hydrogen Peroxide chemicals as such the RO Water Treatment Plant and Dialysis Machines must be disconnected from the water system until the disinfection process is completed.

Silver Hydrogen Peroxide should NOT be used for a period of 90 days or longer, as required by the Drinking Water Inspectorate.

The disinfection process may be required for the following situations:

REPAIRS -	Repair fittings and exposed pipe ends should be clean and disinfected before use. Such items should be sprayed with a suitable disinfection solution such as a Sodium Hypochlorite @ a strength of 1000 mg/l (1000ppm) with a minimum contact time of 5 minutes or equal and approved.
MINOR ALTERATIONS -	Pipework should be cleaned internally by spraying with a suitable disinfection solution such as a Sodium Hypochlorite @ a strength of 1000 mg/l (1000ppm) or where pipes are long and internal surfaces cannot be reached with sprays then a swab soaked in a solution of 50mg/l (50ppm) with a contact time of one hour or equal and approved.
NEW SUPPLY PIPEWORK -	Pipes are filled with a solution such as a Sodium Hypochlorite @ a strength of 20 mg/l (20ppm) with a contact time of 24 hours. Or Sodium Hypochlorite and water at a strength of 50mg/l (50ppm) for a contact period of one hour. Minimum free chlorine after one hour – 30mg/l (30ppm) or equal and approved
SYSTEM DISINFECTION -	This will include water storage tanks and possibly the water distribution system. The advice and use of Legionella Control Association (LCA) approved contractors will be used for this purpose

NOTE:

Appropriate Method Statements and Risk Assessments will be compiled and obtained prior to any disinfection process commencing. Water Disinfection Risk Based Assessment Form (024) should be completed prior to any disinfection process being carried out. (SHTM 04-01 Part G (V1 July 2015) Page 38 para 5.9)

An alternative to chemical disinfection is to pasteurise the system. This involves increasing the temperature to greater than 60°C by increasing the thermostat setting at the calorifier or boiler and recirculation as necessary to maintain this temperature throughout for at least one hour. This should effectively sterilise the calorifier, and kill any *Legionella* organisms present.

The water should be flushed through the system more than once. It is important that all taps are run for at least 5 minutes (preferably longer) at full temperature to ensure that the complete system is pasteurised and that the hot water has reached all parts of the system.

5.8 Pseudomonas SOP

Standard Operating Procedure for minimising the risk of Pseudomonas

This SOP provides direction and guidance for ward based staff to meet their responsibilities as stated in *HPS(2013) Guidance for neonatal units (NNUs) (levels 1,2&3), adult and paediatric intensive care units (ICUs) in Scotland to minimise the risk of Pseudomonas aeruginosa infection from water*. This document refers to critical control points 2 – 4 (inclusive) only. (Critical points 1, 5 and 6 are considered in the NHSGGC Water Safety Policy 2013.

*High Dependency Units (HDUs) which are adjoining/ integrated with an ICU should be included in this guidance.

Responsibilities:

Senior Charge Nurses (SCNs) must:

- Follow this SOP.
- Ensure that they are aware of access issues to wash hand basins. Where access is an issue they must arrange for flushing to occur and document this.
- Keep records of daily flushing for at least one month within the Facilities Folder.
- Inform a member of the local Estates Team if this SOP cannot be followed in relation to flushing water outlets.
- Inform a member of the local Estates Team of infrequently used outlets which could be removed.
- Allow members of the local Estates Team access to complete maintenance as appropriate.

Estates must:

- Undertake actions deemed the responsibility of the local Estates Department as per the Water Safety Policy.
- Keep a record of outlets reported that are deemed to be infrequently used and actions taken by them to remove this risk.
- Provide a report of maintenance actions and issues/ anomalies to the Sector Water Safety Group.
- Support staff locally to undertake their responsibilities in terms of reducing risk associated with pseudomonas.

Domestic Services must:

- Ensure that water outlets are flushed at full flow for 1 minute (not causing splashing) as part of the cleaning process
- Ensure this is the first task completed of the day
- Record this in the Domestic services Compliance Checklist “Water Outlets”
- Ensure the Checklist is retained within the facilities Folder at ward level for one month

Managers must:

- Make this SOP available to their staff.
- Support SCNs in following this SOP.

Water Systems Group must:

- Keep this SOP up-to-date.
- Audit compliance with this SOP.
- Provide guidance via the Water Systems Policy.

Flushing Water Outlets

Flushing of water outlets is necessary to control the build-up of biofilm in water systems to reduce the risk of transmission of pathogens via the environment and equipment to patients.

The Senior Charge Nurse (SCN) in each unit has responsibility (under current guidance) to ensure that the following recommendations are complied with in their area. The SCN should ensure that:

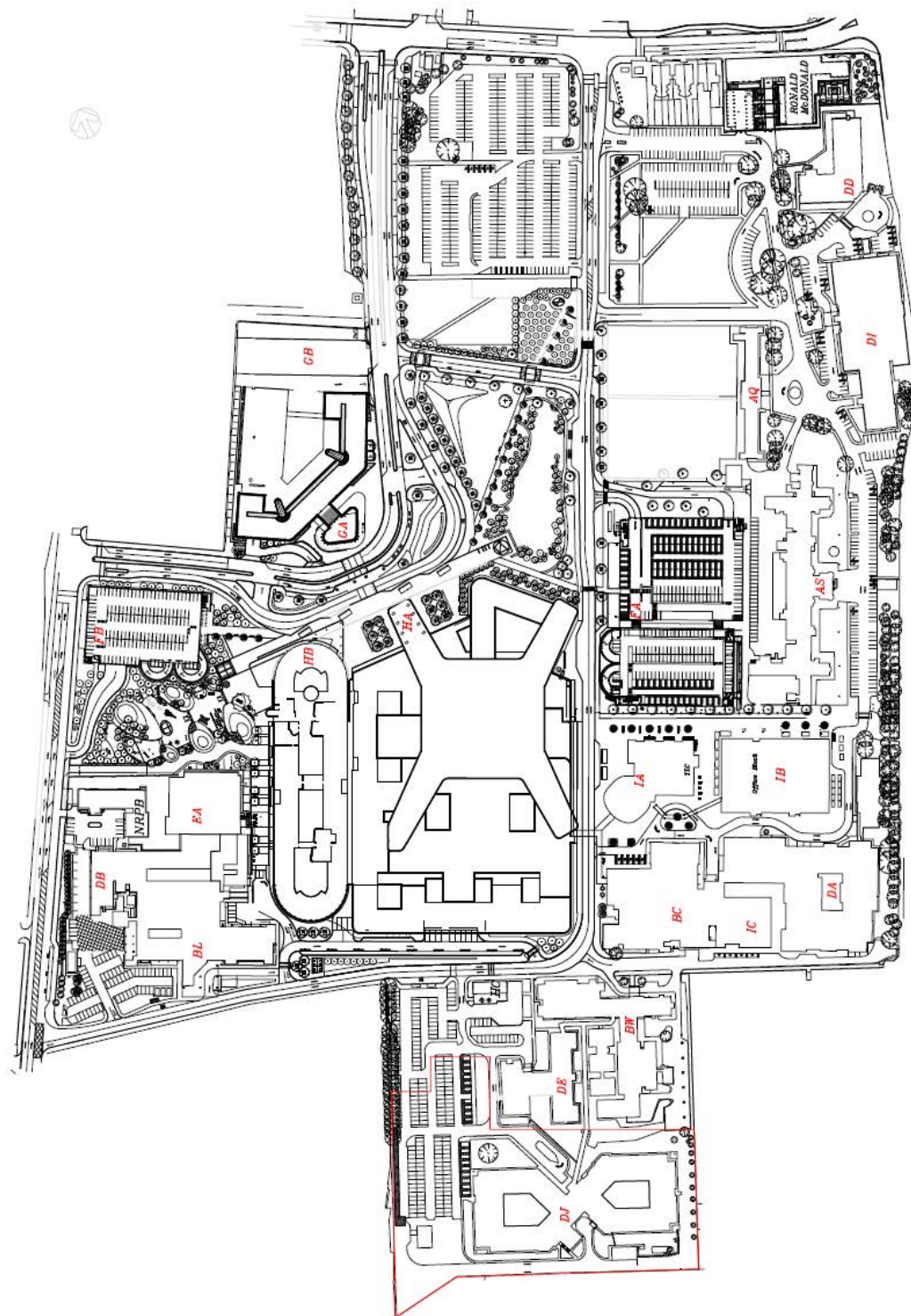
All water outlets are flushed in high-risk environments (adult, paediatric and Neonatal ICUs and associated HDU's), daily, first thing in am for 1 minute at full flow (but not so that splashing goes beyond the basin). This must be recorded. This will be completed as part of the Domestic Services local work schedule for the area. This must be reviewed on a daily basis by the SCN and appropriate action taken when this is identified as not having been completed

Any problems or concerns relating to the safety, maintenance, reduced usage, any changes in use and cleanliness of all water outlets are identified and reported to the ICT and the Estates Department as relevant.

For more information refer to NHS Greater Glasgow and Clyde
'Water Systems Safety Policy Written Scheme and Operational Procedures'

Appendix 1

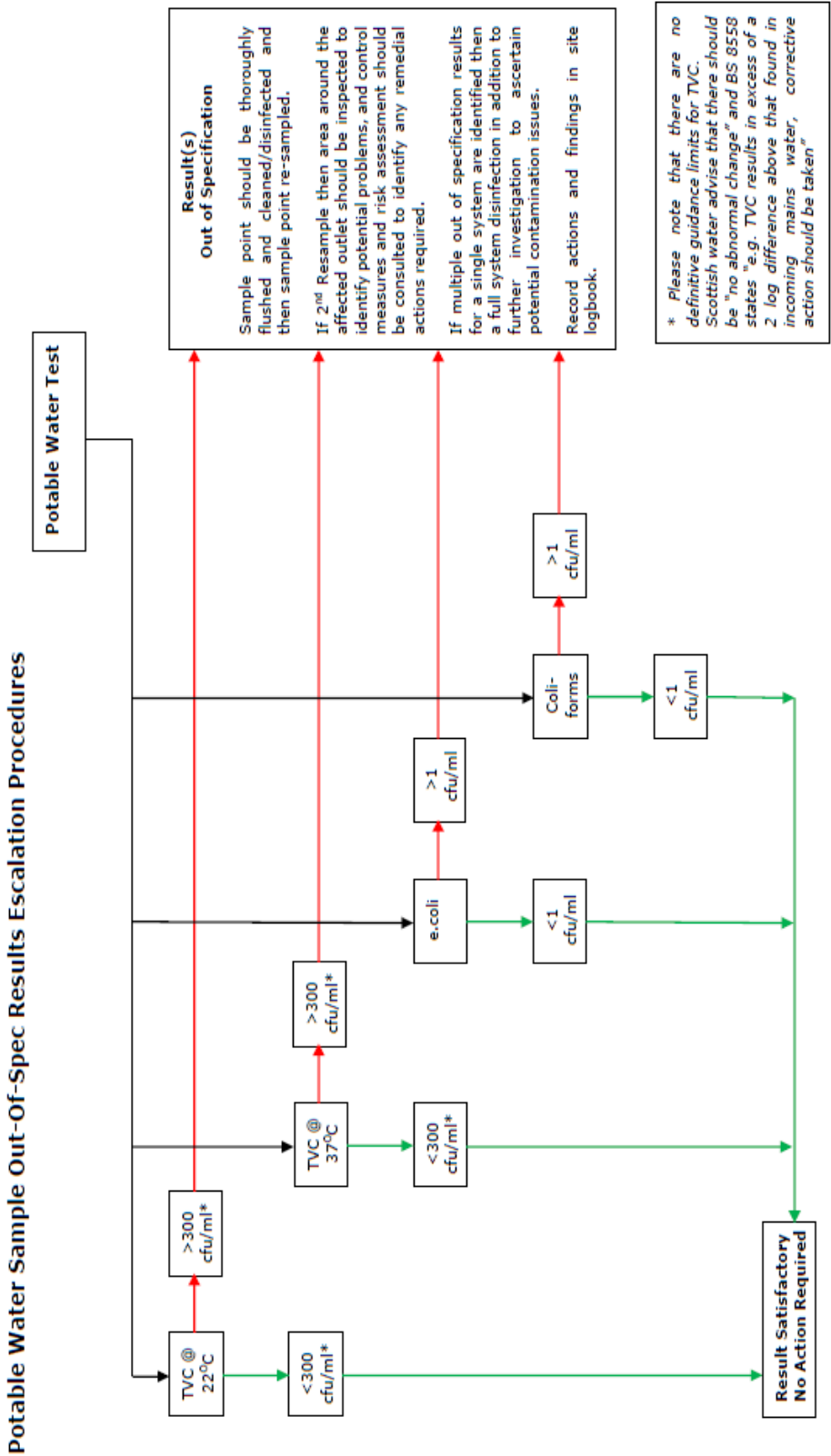
Site Plan with Block Codes



Queen Elizabeth University Hospital

Appendix 2

Escalation of Sampling Results out-of-spec.



Appendix 3

Risk Assessment Review Guidance

Summary of L8 Management Tasks Required for L8 and SHTM 04-01 Compliance

	Guidance Documents	Allocated to
Regular check to ensure that legislation and guidance has not changed	L8 HSG 274 Pt 2 SHTM 04-01	
Regular review of all policies relating to legionella control (e.g. Maintenance, Water Treatment, Water Management, Energy) to ensure still valid and correct	L8 HSG 274 Pt 2 SHTM 04-01	
Regular review of L8 Management Structure to ensure up-to-date and accurate	L8 HSG 274 Pt 2 SHTM 04-01	
Regular review of communication lines to ensure still accurate and correct	L8 HSG 274 Pt 2 SHTM 04-01	
Regular review of escalation & emergency procedures to ensure still valid and correct	L8 HSG 274 Pt 2 SHTM 04-01	
Regular review of duties allocated to site staff and ensure accurate and recorded	L8 HSG 274 Pt 2 SHTM 04-01	
Regular review of duties of sub-contractors and ensure accurate and recorded and contractors are suitably qualified/competent for tasks assigned to them (e.g. Water Hygiene contractors should be LCA Approved, Plumbing contractors should be SNIPEF and Water Safe Registered)	L8 HSG 274 Pt 2 SHTM 04-01	
Regular review of staff training requirements and update training matrix	L8 HSG 274 Pt 2 SHTM 04-01	
Regular review of method statements and risk assessments to ensure still valid and correct	L8 HSG 274 Pt 2 SHTM 04-01	
Regular review of site documentation to ensure all records up to date and present	L8 HSG 274 Pt 2 SHTM 04-01	
Regular update of "Patient Risk Rating" register for all areas of hospital.	SHTM 04-01 Part B	
Regular review of sentinel outlet locations register.	SHTM 04-01 Part B	
Regular review of primary, sub-ordinate and tertiary hot flow and return loops to reflect any system alterations.	HSG 274 Pt 2	
Regular review of plant and equipment maintenance schedules.	Manufacturer's Instructions	
Regular review of BEMS temperature sensor locations to reflect any system alterations	HSG 274 Pt 2	
Regular review of schematic/as-fitted drawings to ensure up-to-date and accurate	L8 HSG 274 Pt 2 SHTM 04-01	
Regular review of L8 risk assessment with a maximum period of two years between updates. (e.g. if change of use or changes in legislation or any other factor which could affect validity of current assessment)	L8 SHTM 04-01	

Appendix 4

HAISCRIBE Risk Assessments

All relevant HAISCRIBE risk assessments produced and approved for Water Systems related tasks are stored on the QEUH Shared Drive within the folder path “Water Quality>HAISCRIBE

QEUH and RHC Hospitals					
NHS GGC Annual Water Systems AE Audit					
Site Address:					
Queen Elizabeth University Hospital and the Royal Hospital for Children Hospital, 1345 Govan Rd, Glasgow G51 4TF					
Building	QEUH and RHC Hospitals	Date	4 th and 5 th February 2021	Auditor	Dennis H. Kelly
Staff Interviewed	Mel MacMillan and Kerr Clarkson				

Description of Levels of Risk:	
Very High	Urgent Remedial Action – Lp growth and aerosol opportunity with susceptible people present on site
High	Remedial Action is needed but not immediately – Lp growth opportunity is present
Medium	Acceptable risk but some concerns– Lp likely to be controlled but improvements should be sought
Low	Risk controlled and acceptable

Levels of Risk found during the Audit:

The levels of risk detailed below reflect the highest level of risk identified during the audit in that particular category.

The audit process reviews the following five areas:

Audited Topic	Level of Risk
B1 Risk Assessment	
B2 Schematic Drawings	
B3 Written Scheme Monitoring and Records	
B4 On Going Water Treatment	
B5 Task Completion	

Comments

There is a high level of completion of the required tasks at both hospitals and a significant improvement on the performance of the management and control systems compared to the audit that was completed in February 2020. Additionally, the record systems were simple to access and provided evidence of task and remedial action completion. There is a close working relationship with the main water hygiene contractor and this provides benefits in terms of the quality and speed of the delivery of the required tasks.

The on-site involved Estates staff at the two hospitals have a high level of technical understanding and have delivered significant improvements in the water hygiene processes and procedures compared to the audit that was undertaken on site 12 months ago.

There are ten recommendations made in this section of the audit and fourteen recommendations made in part A of this audit report. The total of 24 recommendations compares favourably and is a significant improvement on the forty three recommendations that were made in the same audit that was completed in February 2020.

Summary of Actions				
Actions		Risk Level	Completed Date	Signature
1.	It is recommended that NHS GGC formalise their approach to when risk assessments should be completed and reviewed and that a date for a review or a repeat of the QEUH and RHC risk assessment is agreed.			
2.	It is recommended that the timing and delivery of the new risk assessment/risk assessment review is clarified, agreed and implemented and that a minimum two year risk assessment review period is utilised going forward.			
3.	It is recommended that the drawings of the chlorine dioxide installations are acquired and added to the records as soon as possible.			
4.	It is recommended that schematic drawings are reviewed at least annually and amended and updated to reflect any water system changes.			
5.	It is recommended that section 4.51 on page 51 of the written scheme documented is amended to include reference to 55°C being the target temperature for domestic hot water outlets and not 50°C.			
6.	It is recommended that Scotmas are contacted and reminded that there is a need to complete and record the levels of chlorite that are being found in the hospital water systems.			
7.	It is recommended that a weekly check is made on the stock levels of chlorine dioxide feedstock chemicals as recommended in the HSG 274 document in para 2.100.			

8.	It is recommended that non TMV'd hot and cold outlets are identified in areas requiring HAI Scribes for panel removal in order that a picture can be built up of the hot and cold water temperatures in that particular area. It is recommended that the calorifier (2 in total in the building) are inspected internally on an annual basis as recommended in the HSG 274 document and also in the SHTM 04-01 document.			
9.	It is recommended that a search is made to attempt to find the missing temperature records for March and October 2020, and if found, that these records are added to the logbook.			
10.	It is recommended that TMV servicing report sheets are dated in future and that any remedial actions are recorded in a remedial action section in the logbook.			

Section B1 Risk Assessment		Y/N U/K, N/A or Partial	Comments	Risk Level
B1.1	Is there a written risk assessment in place for the building water systems?	Y	The risk assessment was undertaken by DMA Canyon Ltd.	
B1.2	Was the risk assessment completed and delivered to site within the past two years?	N	Risk assessment was completed in January 2019 with the on-site work having been completed between October and December 2018. The risk assessment is therefore just outside the 2-year recommended review period detailed in the SHTM 04-01 guidance. It is recommended that NHS GGC formalise their approach to when risk assessments should be completed and reviewed and that a date for a review or a repeat of the QEUH and RHC risk assessment is agreed.	
B1.3	Does the site/organisation have plans with regard to reviewing or redoing the risk assessment?	N	The 2019 risk assessment recommends a two year review period. It was confirmed during this audit that discussions will shortly be taking place Given that the current risk assessment is just outside the two-year review period stated in the SHTM 04-01, it is recommended that the timing and delivery of the new risk assessment/risk assessment review is clarified, agreed and implemented and that a minimum two year risk assessment review period is utilised going forward.	
B1.4	Does the risk assessment address all the water systems in the building?	Partial	Section 8 of the current risk assessment details 15 other water systems in the two hospitals and includes a brief description of each system as well as an initial assessment of risk. It further advises that specialists in each field are consulted to confirm the	

			risk assessment detail is reflective of the function of each water system. The recommendation associated with this question is covered in Part A of this audit.	
B1.5	Are there any systems that are defined as being excluded from the assessment in the RA scope?	Partial	Although the Hydrotherapy pool was mentioned in the list of additional water systems, the risk assessment document did state that the pool was not assessed in the risk assessment process. However, it did state on page 4 of section 3 of the report that the hydrotherapy pool was "covered under a separate assessment".	
Actions on Risk Assessment				
1. It is recommended that NHS GGC formalise their approach to when risk assessments should be completed and reviewed and that a date for a review or a repeat of the QEUH and RHC risk assessment is agreed. 2. It is recommended that the timing and delivery of the new risk assessment/risk assessment review is clarified, agreed and implemented and that a minimum two year risk assessment review period is utilised going forward.				
Section B2 Schematic Drawings		Y/N U/K, N/A or Partial	Comments	Risk Level
B2.1	Are schematic drawings available in the written scheme, or in some other place in the property?	Y	There is a note in the Smart Sheet electronic data management system detailing the locations of the soft copies of the drawings as being available on ZUTEC (electronic data storage system).	
B2.2	Do the schematic drawings show all the components of the water systems?	Y	The drawings are as fitted and detail the entire system configuration including all component parts.	

B2.3	Are the water system return legs shown on the schematic drawings?	Y		
B2.4	Are secondary and tertiary loops shown on the schematic drawings?	Y		
B2.5	Have any amendments been made to the schematic drawings?	N	As an example, Scotmas, who provided the chlorine dioxide dosing systems, are also contracted to supply drawings of the tank room pipework which was altered to allow for the installation of the dosage equipment. It was stated at the time of the audit that these drawings had not yet been created and delivered. It is recommended that the drawings of the chlorine dioxide installations are acquired and added to the records as soon as possible.	
B2.6	If amendments have been made are they signed and dated?	N/A	See comment B2.4 above.	
B2.7	Is there any indication that drawings are regularly inspected and updated if required?	Partial	It was stated that drawings will be checked during the working year as and when required. There is no formal process in place. Drawings will be inspected when required to trace valves for pipework isolation for example. It is recommended that schematic drawings are reviewed at least annually and amended and updated to reflect any water system changes.	
Actions on Schematic Drawings				

3. It is recommended that the drawings of the chlorine dioxide installations are acquired and added to the records as soon as possible. 4. It is recommended that schematic drawings are reviewed at least annually and amended and updated to reflect any water system changes.				
Section B3 Written Scheme, Monitoring and Records		Y/N U/K, N/A or Partial	Comments	Risk Level
B3.1	Is there a written scheme in place?	Y	The written scheme is entitled 'QEUEH Campus Water Systems - Written Scheme – Controlling the risks to Legionella and other harmful bacteria in Water Systems – 2019 Rev B'.	
B3.2	Is a copy of the written scheme available on site and does this include this building?	Y		
B3.3	Is there a statement in the written scheme of the expected “correct and safe operation” processes detailing targets for temperatures and other control measures?	Partial	The statement of correct and safe operations for the water systems can be found in section 4.1 of the written scheme document. Section 4.51 on page 51 details the target temperature for a domestic hot water outlet as being 50°C and not 55°C. It is recommended that section 4.51 on page 51 of the written scheme documented is amended to include reference to 55°C being the target temperature for domestic hot water outlets and not 50°C.	
B3.4	Is there any seasonal difference in the use profile of the water systems within this building?	N		

B3.5	Are any pieces of duty standby equipment in this building that require to be switched on a weekly basis, and do the records show that they are being switched?	N	Pump sets automatically change the lead pump on a daily basis and there is a record of checks on the pump sets in the log book.	
Actions on Written Scheme Monitoring and Records				
5. It is recommended that section 4.51 on page 51 of the written scheme documented is amended to include reference to 55°C being the target temperature for domestic hot water outlets and not 50°C.				
Section B4 On Going Water Treatment		Y/N U/K or Partial	Comments	Risk Level
B4.1	Is there any form of water treatment in use in the building?	Y	Incoming mains water is treated via a membrane filtration system and is filtered down to 0.2 micron. The filtered mains water is secondary disinfected using chlorine dioxide.	
B4.2	Is there any form of secondary disinfection in place for this building?	Y	There are a number of chlorine dioxide units installed throughout the QEUH and the RHC. These chlorine dioxide units automatically dose ClO ₂ to the hot and cold water as required. Dosing control is maintained via ClO ₂ probes installed throughout the building water systems.	
B4.3	Are the required checks for secondary disinfection levels being completed and recorded?	Partial	Discussions were held with the contractor, DMA Canyon Ltd, who complete the analytical testing of the water systems for chlorine dioxide levels. Tests are completed on the hot and cold water systems at 78 locations throughout the hospital. This does not cover all of the sentinel points in the hospital water systems but was deemed by NHS GGC to be representative of the levels	

			of chlorine dioxide that would be found throughout the hospital water systems. Tests are completed on a weekly basis and a full set of records were available from DMA Canyon Ltd. Scotmas, the suppliers of the chlorine dioxide dosing equipment, complete a monthly service check on the chlorine dioxide systems. This check used to include a measure of the chlorite levels but it is apparent that this element of the checks has been missed for the past year although it was completed in February 2021. In the HSG 274 guidance in para 2.100, there is a requirement for a weekly check to be made on the operation of the chlorine dioxide generators and also to check and record the levels of feedstock chemicals at each generator. It is recommended that Scotmas are contacted and reminded that there is a need to complete and record the levels of chlorite that are being found in the hospital water systems.	
B4.4	Are the required levels of disinfection being achieved in the building water systems?	Y	Cold water chlorine dioxide residuals are generally within accepted limits. The hot water chlorine dioxide levels are reduced as would be expected in a hot water system.	
B4.5	Is there a record of biocide stock levels in the written scheme?	Partial	Biocide stock levels are checked as part of the Scotmas monthly contract. These checks should be made on a weekly basis. It is recommended that a weekly check is made on the stock levels of chlorine dioxide feedstock chemicals as recommended in the HSG 274 document in para 2.100.	
B4.6	Is any of the building water base exchange softened?	N/A		
B4.7	Are service records for the base exchange softeners	N/A		

	available in the written scheme?			
B4.8	Is filtration in use in any of the building water systems?	Y	Mains water is treated via a membrane filtration system. There are three membrane filtration sets in the hospital to allow for servicing of any unit if required.	
B4.9	Are service records for the filtration equipment available in the written scheme?	Y	Veolia, the equipment supplier, has a service contract for the filtration equipment. The Veolia service records are held online and can be accessed when required. The records were accessed and demonstrated to the auditor during this audit.	
Actions on Ongoing Water Treatment				
6. It is recommended that Scotmas are contacted and reminded that there is a need to complete and record the levels of chlorite that are being found in the hospital water systems. 7. It is recommended that a weekly check is made on the stock levels of chlorine dioxide feedstock chemicals as recommended in the HSG 274 document in para 2.100.				

Section B5 Task Completion		Expected Task Levels	Actual Records	Comments	Risk Level
B5.1	Tank Inspections	2 with temperature taken twice per year	2	Tank inspections are undertaken by DMA Canyon Ltd.	
B5.2	Hot Water Storage	4	12	Details are held on the monthly calorifier record sheets.	

	Vessel blowdowns				
B5.3	Hot Water Storage Vessel Internal Inspections	1	1	These checks were recently started in December 2020 and will be completed by end of February 2021.	
B5.4	Shower/Spray Heads	4	4	Showers are replaced on a quarterly basis. This task is completed by DMA Canyon Ltd. Records of shower replacements were available in the estates office. A random selection of areas was sampled including ARU 1, 2, 3, 4 and 5, ward 8A and ward 11A. A full set of shower replacement records was available for each.	
B5.5	Hot Water Storage Vessel F and R Temps	12	12	The calorifier flow and return temperatures generally appear to be acceptable.	
B5.6	PH Ex F and R Temps	12	N/A		
B5.7	Hot Sentinel Temps	12	10	The record for the temperatures at the hot outlets appears to be missing for the months of March and October 2020. A lot of the temperatures that are recorded in the records are from the TMV outlet as it is not allowed to remove IPS panels without a HAI Scribe. This does not tell us what is going on in the hot and cold water elements of the water systems. The BMS does however have end of line sensors on the Adults and Children hospitals. The BMS alarms if the temperatures are getting out of specification at these sensors. It is recommended that non TMV'd hot and cold outlets are identified in areas requiring HAI Scribes for panel removal in	

				order that a picture can be built up of the hot and cold water temperatures in that particular area. It is recommended that a search is made to attempt to find the missing temperature records for March and October 2020, and if found, that these records are added to the logbook.	
B5.8	Hot Sec Loop Temps	12	10	Incumbent water hygiene supplier DMA advised secondary loop temperatures are taken whenever possible as part of the routine temperature monitoring programme. This is confirmed by the records in the logbook.	
B5.9	Tertiary Loop Hot Temperatures	4	10	As for comment 5.8	
B5.10	Hot Rep Temps	1	1	Incumbent water hygiene supplier DMA advised that secondary loop temperatures are taken whenever possible as part of the routine temperature monitoring programme. This will include non-sentinel outlet, or representative, temperatures. This is confirmed by the records in the logbook.	
B5.11	Cold Sentinel Temps	12	10	The record for the temperatures at the outlets appears to be missing for the months of March and October. A lot of the temperatures that are recorded in the records are from the TMV outlet as it is not allowed to remove IPS panels without a HAI Scribe. This does not tell us what is going on in the hot and cold water elements of the water systems. The BMS does however have end of line sensors on the Adults and Children hospitals. The BMS alarms if the temperatures are getting out of specification at these sensors. The recommendation for this is covered in the recommendation for section B5.7	

B5.12	Cold Sub Loop Temps	12	N/A		
B5.13	Cold Rep Temps	1	10	Incumbent water hygiene supplier DMA advised that representative temperatures are taken whenever possible as part of the routine temperature monitoring programme. This is confirmed by the records in the logbook.	
B5.14	POU Heater Temps	12	N/A		
B5.15	Expansion Vessels	2 – 12 Monthly to six-monthly	12	This is covered in the monthly calorifier checks which can be found in the logbook. These tasks are completed by Estates staff through the FM 1 st system. The QEUH and RHC expansion vessels are flow through units. The water is however encouraged to move on a monthly basis by opening the drain point for the vessel.	
B5.16	TMV's/TMT's	1	U/K	The logbook has records showing that tests are being completed on the TMV's. However, the report sheets for the TMV servicing are not dated so it is not possible to say when the work was completed. Additionally, there are comments regarding water flowing from TMV's after the slam tests have been performed. There are statements such as "new cartridge required". There is no indication if any of these issues have been addressed. It is recommended that TMV servicing report sheets are dated in future and that any remedial actions are recorded in a remedial action section in the logbook.	
B5.17	Little used outlet flushing	Past three months	>24	Flushing appears to be happening on a daily basis. In the RHC and the QEUH, from the beginning of November 2020 until then end of January 2021 there were 52 flushing records – this is well in excess of the twice weekly flushing requirement.	

B5.18	CIO2 testing	52	52	It was noted that the chlorite tests have not been completed for the past year. A recommendation covering this issue can be found in section 4.3.	
B5.19	Check on the cold water distribution pipework thermal insulation	1	1	In the written scheme it is confirmed that this should be completed on an annual basis. This is addressed while completing other tasks such as the monthly plant room checks, checks of cold water storage tanks and checks on calorifiers and TMV's. The fact that the insulation has been checked can be found on the calorifier monthly check sheets.	
B5.20	Tank Clean and Disinfection	1	1	The records show that the cold water storage tanks were cleaned and disinfected on the 31 st January 2020.	
B5.21	Legionella sampling	4	4	A sampling schedule is in place which covers the entire QEUH campus. Samples are taken from QEUH and RHC designated points on a monthly basis. The samples are taken by DMA Canyon Ltd and are submitted to the GRI labs. The results are then sent to Estates and they are stored in Section 22 the Campus Scart folder. Any out of specification results are listed on a separate spreadsheet. This spreadsheet contains the remedial actions that were completed in response to the out of specification result and the outcome in terms of retesting. Once an issue has been remediated and cleared the details are recorded on a further spreadsheet and this records the three clear results. This system has been in place since 2018.	
Actions on Task Completion					

8. It is recommended that non TMV'd hot and cold outlets are identified in areas requiring HAI Scribes for panel removal in order that a picture can be built up of the hot and cold water temperatures in that particular area. It is recommended that the calorifier (2 in total in the building) are inspected internally on an annual basis as recommended in the HSG 274 document and also in the SHTM 04-01 document.
9. It is recommended that a search is made to attempt to find the missing temperature records for March and October 2020, and if found, that these records are added to the logbook.
10. It is recommended that TMV servicing report sheets are dated in future and that any remedial actions are recorded in a remedial action section in the logbook.

Thanks

■ is well clinically
Continuing on fluconazole

Sent from my Samsung Galaxy smartphone.

----- Original message -----

From: "DESHPANDE, Ashutosh (NHS GREATER GLASGOW & CLYDE)"
<[ashutoshdeshpande](#)■>
Date: 13/07/2020 16:20 (GMT+00:00)
To: "Harvey-Wood, Kathleen" <[Kathleen.Harvey-Wood](#)■> 'Elizabeth Johnson' <[Elizabeth.Johnson](#)■> "Peters, Christine" <[Christine.Peters](#)■>
Cc: "Leanord, Alistair" <[Alistair.Leanord](#)■> "Bowskill, Gillian" <[Gillian.Bowskill](#)■>, "KHALSA, Kamaljit (NHS GREATER GLASGOW & CLYDE)" <[kamaljit.khalsa](#)■>, "VALYRAKI, Kalliopi (NHS GREATER GLASGOW & CLYDE)" <[kalliopivalyraki](#)■>, "Sastry, Jairam" <[Jairam.Sastry](#)■>, "Gibson, Brenda (NHSmal)" <[brenda.gibson](#)■>
Subject: [ExternaltoGGC]Re: CRAG

Dear all,

Sorry, forgot to include Jairam and Brenda.

Best wishes,

Ash

From: DESHPANDE, Ashutosh (NHS GREATER GLASGOW & CLYDE)
Sent: 13 July 2020 16:05
To: Wood Kathleen (NHS GREATER GLASGOW & CLYDE); 'Elizabeth Johnson'; Peters, Christine
Cc: Leanord Alistair (NHS GREATER GLASGOW & CLYDE); Bowskill Gillian (NHS GREATER GLASGOW & CLYDE); KHALSA, Kamaljit (NHS GREATER GLASGOW & CLYDE); VALYRAKI, Kalliopi (NHS GREATER GLASGOW & CLYDE)
Subject: CRAG

Dear colleagues,

Just to keep everyone updated, the CRAG has been repeated today as per last week's discussions, the result is positive in our QEUH lab, and a sample is on its way down to Bristol for testing too. The clinical team have been informed.

Best wishes,

Ash

From: Harvey-Wood, Kathleen <Kathleen.Harvey-Wood@nhs.uk>
Sent: 09 July 2020 11:35
To: 'Elizabeth Johnson'; Peters, Christine
Cc: Leanord Alistair (NHS GREATER GLASGOW & CLYDE); Valyraki, Kalliopi; DESHPANDE, Ashutosh (NHS GREATER GLASGOW & CLYDE)
Subject: RE: CRAG

Hi Liz

Thank you for your reply and discussion regarding the interpretation of the Cryptococcal Ag results. The patient will be monitored , followed up and treated as Christine has advised in her email.

Kind regards
 Kathleen

From: Elizabeth Johnson [<mailto:Elizabeth.Johnson@nhs.uk>]
Sent: 07 July 2020 19:31
To: Harvey-Wood, Kathleen; Peters, Christine
Cc: Leanord, Alistair; Valyraki, Kalliopi; Deshpande, Ashutosh (NHSmail)
Subject: [ExternaltoGGC]RE: CRAG

Dear Kathleen, Christine et al.

As regards clinical interpretation of any test we are not really in a position to do that without recourse to the full clinical details so as far as our reports are concerned we can only report what we find.

The fact that we reported these as lateral flow positive only and NEAT specimen suggests that it was negative by the latex agglutination test and therefore could not be titred using that kit. In this particular case it was a very weak positive line even with the neat serum whereas we normally see much stronger positives. In fact we have subsequently titred the serum samples from 26.06.20 and 27.06.20 in tandem using the lateral flow and there is a very, very faint line on the 1:2 dilution for both and possibly a shadow on the 1:4 when looked at with a magnifying glass. In the days when we only had latex agglutination testing both of these specimens would have been reported as negative. It is however as you say a more sensitive test than the latex agglutination so it is still possible that some weak positives could represent early disease. The attached paper raises concerns over such low titres with a 34% false positive rate overall, with all the false positives represented by titres $\leq$ 1:5. It would be of interest to test a later serum sample to see if there has been any change.

The CSF sample was lateral flow negative in this patient and the panfungal PCR on the blood samples from 26th and 27th June have also been negative, although this latter test lacks sensitivity for cryptococcosis. Although fluconazole treatment is certainly not unreasonable in this patient and he should be monitored for further signs and symptoms I do not think based on this evidence that a full scale look for environmental sources is warranted at this stage. I cannot be definitive that these represent false positives, although it is likely and they are less than proof of infection. If the patient does deteriorate and reveals further evidence of cryptococcosis then as you know the first-line treatment would be an initial course of amphotericin B plus flucytosine, followed by long-term fluconazole.

I am sorry for any confusion over this testing and the likely interpretation but in this case the results are not clear cut.

With best wishes,

Liz

Professor Elizabeth M. Johnson, PhD

Honorary Professor of Medical Mycology,
Director, PHE Mycology Reference Laboratory
and National Collection of Pathogenic Fungi,
National Infection Service,
PHE South West Laboratory,
Science Quarter,
Southmead Hospital,
Bristol
BS10 5NB
UK

Honorary Professor in the College of Life & Environmental Sciences,
Medical Research Council Centre for Medical Mycology,
University of Exeter

[REDACTED]

[REDACTED]

Protecting and improving the nation's health

From: Harvey-Wood, Kathleen [Kathleen.Harvey-Wood [REDACTED]]
Sent: 07 July 2020 11:26
To: Peters, Christine; Elizabeth Johnson
Cc: Alastair Leonord - GGC; Valyraki, Kalliopi; Deshpande, Ashutosh (NHSmail)
Subject: RE: CRAG

Hi Liz

Re our telephone conversation and a further conversation with Christine on 29.06.20, we discussed the reporting of the results of 2 blood samples :

1. Blood [REDACTED] Lab no [REDACTED] sent for BDG - and tested as requested for Cryptococcal Ag - verbal report : faint line will report as positive.
2. Blood [REDACTED] lab no [REDACTED] - sent for confirmation of Cryptococcal Ag - verbal report : faint line will report as positive

Both samples were Latex Agglutination - negative and was informed that the Antigen test is more sensitive

Printed reports issued :

1. **Requesting laboratory number:** [REDACTED]

CRYPTOCOCCUS NEOFORMANS ANTIGEN TEST

Cryptococcus neoformans antigen test:	POSITIVE (NEAT specimen)
--	--------------------------

Results comment:

Positive by lateral flow device only.

2. [REDACTED]

CRYPTOCOCCUS NEOFORMANS ANTIGEN TEST

Cryptococcus neoformans antigen test:	POSITIVE (NEAT specimen)
--	--------------------------

Results comment:

Positive by lateral flow device

A further 2 blood samples taken on 27.06.20 were also sent for confirmation

3 .Blood [REDACTED] Lab no [REDACTED] - sent for BDG - and also tested as requested for Cryptococcal Ag

Requesting laboratory number: [REDACTED]

CRYPTOCOCCUS NEOFORMANS ANTIGEN TEST

Cryptococcus neoformans antigen test:	POSITIVE (NEAT specimen)
--	--------------------------

Results comment:

Positive by lateral flow device

4. Blood [REDACTED] lab no [REDACTED] sent for confirmation of Cryptococcal Ag **positive** result .

CRYPTOCOCCUS NEOFORMANS ANTIGEN TEST

Requesting laboratory number: [REDACTED]

Cryptococcus neoformans antigen test:	POSITIVE (NEAT specimen)
--	--------------------------

Results comment:

Insufficient sample remained to perform titration
Positive by lateral flow device only.

The CrAg LFA pack insert (IMMY) this was used to test the 2 blood samples in our laboratory

The presence of two lines (a control line and a line in the test zone) regardless **of the intensity of the test line, including faint lines, indicates a positive result.** The control line is a migration control and not intended as a specimen addition control.

As raised by Christine , if the interpretation of the results are now being considered as false positives on the 4 separate sample detailed above, are the reports to be amended and updated with interpretative comments to aid the Clinicians with the diagnosis and treatment of the patient ?

Kind regards
Kathleen

From: Peters, Christine
Sent: 06 July 2020 09:55
To: 'Elizabeth.Johnson'; [REDACTED]
Cc: Leanord, Alistair; Valyraki, Kalliopi; Harvey-Wood, Kathleen
Subject: CRAG

Good Morning Liz,

Thanks for discussing the case of the [REDACTED] with positive CRAG testing on 3 serial samples, last week. As we discussed at the time with Kathleen, , the performance of the test is very good in determining early cryptococcal infection and we agreed that fluconazole would be worth starting pending the CSF samples to exclude meningitis. As far as I understood from our discussion the latex agglutination is less sensitive a test and the fact that 3 separate samples were positive by Crag indicated that a false positive was less likely.

I now understand that this interpretation has changed and that there is now a view that the results were false positives on 4 separate samples? I would be grateful to be included in discussion going forward as to whether a follow up sample becoming negative post treatment would be a helpful way to understand the pathophysiology of a potential early infection being detected.

Kr

Christine

Dr Christine Peters
Consultant Microbiologist
Clinical Lead Department of Microbiology QEUH

[REDACTED]

113. Cryptococcal cases in Glasgow

Julie Rothney

From: Peters, Christine
Sent: 23 September 2020 17:41
To: 'HOOD, John (NHS GREATER GLASGOW & CLYDE)'
Cc: 'MURPHY, Michael (NHS GREATER GLASGOW & CLYDE)'; Inkster, Teresa (NHSmail); 'angela.wallace [REDACTED]'
Subject: Cryptococcal cases in Glasgow

Tracking:	Recipient	Delivery	Read
	'HOOD, John (NHS GREATER GLASGOW & CLYDE)'		
	'MURPHY, Michael (NHS GREATER GLASGOW & CLYDE)'		
	Inkster, Teresa (NHSmail)	Failed: 23/09/2020 17:41	
	'angela.wallace [REDACTED]'	Delivered: 23/09/2020 17:41	
	Angela Wallace (NHS Forth Valley)		Deleted: 04/02/2021 11:25

Hi John,

We discussed the recent paediatric case of *Cryptococcus* infection at our complex case meeting.

Interestingly as part of the discussion we identified the unique epidemiology in Glasgow since 2019 where 2 paediatric haem onc patients who had inpatient stays in QEUEH building, and 3 adult cases since 2018 had at least a few nights inpatient stays also developed cryptococcosis. In the same time period there is a one case that I have not been able to identify if they had any inpatient stays. So in 5/6 confirmed cases in Glasgow there is an epi link to QEUEH site. This was noted by a relative of one of the cases that were identified at another hospital previously apparently.

This is really very striking given that between us all at the meeting, spanning over 20 years practice in GGC we can recall only 1 or two non HIV cases (one Hep B case I was involved in).

Just wanted to make sure that you were in the loop re the other 2 cases also having had inpatient stays at QEUEH. I copy in Michael as he wrote a poster on some of the cases and took part in the discussion.

Kr

Christine

Dr Christine Peters
 Clinical Lead
 Consultant Microbiologist
 QEUEH
 [REDACTED]

The Following document is a Request for Information (RFI) response received by the Scottish Hospital Inquiry from NHS GGC

Scottish Hospitals Inquiry/NHSGGC - Request for Information dated 15th April 2024 (SHI RFI 26)

Please provide the following information from NHSGGC regarding Cryptococcus at QEUH/RHC from 26th January 2015 to date:

(1) Confirmation of the total number of Cryptococcus cases/infections in patients at QEUH/ RHC between 26th January 2015 to date:

There were two known Cryptococcus cases / infections in patients at the QEUH / RHC between 26th January 2015 to date. Please see Appendix 1 Patient Summaries. These were Patient 2 and Patient 4. Their associated blood culture and serology test data is included in Appendix 2.

a) Confirmation of the number of all positive test results for Cryptococcus infection(s):

Cryptococcus infections can be detected in patients using different tests:

- Blood culture test, which is a medical laboratory test used to detect bacteria or fungi in a person's blood.
- Serology tests, these are blood tests that look for antibodies in a person's blood.

Please note a positive test does not assure infectivity, the result may be a false positive.

There were a total of **24 positive Cryptococcal Serology tests** from patients who had samples taken whilst they were in the QEUH / RHC between 26/01/15 until 12/04/24.

There were a total of **17* blood culture tests** which were positive for Cryptococcus from patients who had samples taken whilst they were in the QEUH / RHC between 26/01/15 until 12/04/24.

*Note 2 of these were non-invasive samples.

Patients have multiple tests, blood culture and/or serology throughout their inpatient stay. A total of 10 patients had samples taken whilst they were an inpatient in the QEUH/RHC which were positive for Cryptococcus (either positive blood culture and/or positive serology test).

Appendix 1 includes summaries for each of the patients who had samples taken whilst they were in the QEUH/RHC between 26/01/15 until 12/04/24 which were positive for Cryptococcus (either positive blood culture and/or positive serology test).

Appendix 2 includes corresponding details of the positive blood culture and/or serology tests for patients who had samples taken whilst in the QEUH/RHC and any associated negative serology tests. This includes patients who had a

positive blood culture and/or serology test before they were transferred to QEUH/RHC but who were subsequently cared for and had further samples taken in QEUH/RHC. For completeness, blood culture and serology test results for *Cryptococcus* from samples that were taken from these patients whilst they were in another NHSGGC hospital location are also included.

b) Confirmation of the number of all negative test results for *Cryptococcus* infection(s):

There were a total of **661 negative *Cryptococcal* Serology tests** from patients who had samples taken whilst they were a patient in the QEUH/RHC between 26/01/15 until 12/04/24.

Blood culture tests which were “negative” for *Cryptococcus* are all other blood culture tests undertaken which did not detect *Cryptococcus*, the number of which is voluminous.

c) Confirmation of the number of inconclusive test results, which have not later resulted in either a positive or negative result(s); and

There were no intermediate serology results.

d) With the numbers provided taking into account all variations or strains of *Cryptococcal* infection(s)

These have been included in the figures.

(2) Except insofar as already provided, full details of all or all or any response or reporting action taken in respect of positive cases of *Cryptococcus* at QEUH/ RHC from 26th January 2015 to date, please see the Inquiry’s position regarding information already submitted below.

NHSGGC has previously provided the Inquiry with all of the information relating to the response or reporting action taken in respect of the two confirmed positive cases of *Cryptococcus* at the QEUH/RHC from 26/01/15 until 12/04/24.

This information relating to the two confirmed positive cases was previously provided under:

- RFI 1 6 water and cryptococcus timeline (IMT minutes and commentary),
- RFI 7 2.17 (minutes of *Cryptococcus* IMT Expert Group, reports considered by that group, and final unredacted report of that group),
- RFI 7 5.3, 5.5 and 5.7 (correspondence, reports etc around IMT investigations, pigeons etc),
- RFI 7 5.6 (Dr Kennedy’s *cryptococcus* epidemiology report), RFI 7 2.23 (summary of investigations outwith IMT).

(3) In respect of the Report from the Cryptococcus Incident Management Team Expert Advisory Sub-Group dated 5th April 2022:

a) Confirmation of when this report was submitted/sent by NHS GGC to NSS, along with any accompanying correspondence.

The Report from the Cryptococcus Incident Management Team Expert Advisory Sub-Group dated 5th April 2022 was emailed to NSS on 07/04/2022, accompanying the report was a list of responses to NSS's comments on the draft version of the report.

The email is attached: ARHAI April and May correspondence 2022.pdf

b) Details of the response, if any, from NSS in respect of the report, along with any communications from NSS to NHS GGC in respect of the views if NSS regarding the report.

An initial response was received from NSS on 28/04/2022, this is contained in the attached ARHAI April and May correspondence 2022.pdf

Also attached are three tables which list comments provided by HFS and ARHAI and the response to the comments by the Sub-group.

- 250321 Response to ARHAI HFS comments on draft report.doc
- 2nd Response to ARHAI HFS comments on draft report 30 04 21.doc
- 05 11 21 Response to ARHAI HFS Comments on DRAFT Crypto Report.pdf

c) Confirmation of NHS GGC's understanding of whether NSS were supportive of the report, along with any documentation, correspondence, or information provided by NSS confirming their support of NHS GGC's position.

NHSGGC's understanding is that ARHAI were not supportive of all the findings of the report and requested to be removed as authors of the report.

Appendix 1: Patient summaries for patients who had samples taken whilst they were in the QEUH/RHC between 26/01/15 until 12/04/24 which were positive for Cryptococcus (blood culture and/or Cryptococcal Serology tests)

Patient No	Patient Summary
Patient 1	Specimen date: [REDACTED].12.2020: Skin swab and tissue sample [REDACTED] No acute features of cryptococcal infection noted at clinic however commenced on fluconazole on advice of microbiology. Patient History: Immunosuppressed patient [REDACTED]. Patient was a pigeon keeper/racer. Last admission to NHSGGC prior to specimen date was [REDACTED].10.20 [REDACTED]
Patient 2	Confirmed Cryptococcus Case – Information previously provided to the Inquiry: • RFI 1 6 water and cryptococcus timeline (IMT minutes and commentary), • RFI 7 2.17 (minutes of Cryptococcus IMT Expert Group, reports considered by that group, and final unredacted report of that group), • RFI 7 5.3, 5.5 and 5.7 (correspondence, reports etc around IMT investigations, pigeons etc), • RFI 7 5.6 (Dr Kennedy's cryptococcus epidemiology report), RFI 7 2.23 (summary of investigations outwith IMT). • RFI 7 2.17 unredacted final report includes clinical details of the case and is the most succinct source.
Patient 3	Specimen date: [REDACTED].10.16 CSF taken @ RAH Ward 2AMU. [REDACTED].02.17 CSF taken @ QEUH Ward 5c. Patient History: [REDACTED] Transferred to Ward 5c QEUH 12.10.16. During this admission patient tested positive for [REDACTED] (new diagnosis). Re admitted with Cryptococcus in CSF again February 2017.
Patient 4	Confirmed Cryptococcus Case – Information previously provided to the Inquiry: • RFI 1 6 water and cryptococcus timeline (IMT minutes and commentary), • RFI 7 2.17 (minutes of Cryptococcus IMT Expert Group, reports considered by that group, and final unredacted report of that group), • RFI 7 5.3, 5.5 and 5.7 (correspondence, reports etc around IMT investigations, pigeons etc), RFI 7 5.6 (Dr Kennedy's cryptococcus epidemiology report), RFI 7 2.23 (summary of investigations outwith IMT).

	RFI 7 2.17 unredacted final report includes the clinical details of the case and is the most succinct source.
Patient 5	Isolate from 2020, related information previously provided to the Inquiry: - IMT minutes submitted to SHI under Section 21 no.2 1.1.7. Additional correspondence in relation to this patient has also been provided with this response: - CP Email re weekly report.docx - Email re investigation 29.06.20 - Redacted V1.0.pdf - Email re lab results.docx - HIIORT 02.07.20.docx - HIIORT 09.07.20.docx - HPS Return 02.07.20.docx - JH Plant Room Inspection 03.07.20.docx - List of admissions [REDACTED].docx - RHC AHU Walk round 6 July 2020.docx - SBAR [REDACTED] case 30 June 2020.doc - Timeline for Patient [REDACTED].docx - Update on CSF PCR 08.docx - Update to HPS 08.07.20.docx
Patient 6	Transferred from [REDACTED].03.21 with suspected fungal lesions. [REDACTED] possible cryptococcal antigen detected. [REDACTED]
Patient 7	Non-invasive sample Specimen Date [REDACTED].12.15 (mouth) Mouth swab taken in ED isolated <i>Cryptococcus laurentii</i> Patient History: Patient attended RHC ED [REDACTED].12.15 presenting with rash [REDACTED] Routine bacterial screen obtained which included mouth swab. Patient had no previous admissions before or since this attendance.
Patient 8	Specimen date: [REDACTED].11.16: Clotted blood antigen positive. Discharged the day sample was taken, no further mention of this in micro notes or clinical notes. Patient history: Patient was complex congenital HIV positive. [REDACTED].

Patient 9	Specimen date: [REDACTED].04.23: Blood culture taken on admission to RAH ED isolated <i>Cryptococcus neoformans</i>, with subsequent positive isolates form CSF. Patient History: [REDACTED] [REDACTED] Transferred to QEUH ID unit [REDACTED].04.23 for treatment of <i>Cryptococcus</i> meningitis.
Patient 10	Non-invasive sample Specimen Date [REDACTED].10.17 Patient History: Patient has history of [REDACTED] kidney disease and [REDACTED]. Regular admissions to renal ward before and after isolate. Last admission to RHC prior to isolate was [REDACTED].09.17 to [REDACTED].09.17. Admitted to Ward 3c on [REDACTED].10.17 after [REDACTED] noticed peritoneal fluid was blood stained. Patient discharged home [REDACTED].10.17. Peritoneal dialysis fluid taken on admission to Ward 3c RHC [REDACTED].10.17 isolated <i>Cryptococcus curvatus</i>.

Appendix 2: Corresponding details of the positive blood culture and/or serology tests for patients who had samples taken whilst in the QEUH / RHC and any associated negative serology tests. For completeness, blood culture and serology test results for *Cryptococcus* from samples that were taken from these patients whilst they were in another NHSGGC hospital location are also included.

Patient ID	Crypto Result	Hospital Site	Organism(s)	Cryptococcal Antigen	Cryptococcal Titre: 1/	C. neoformans latex Ag
Patient 1	Culture Positive	Western Inf Gartnavel Gen	<i>Cryptococcus neoformans</i> , <i>Streptococcus</i> Group G			
	Culture Positive	Western Inf Gartnavel Gen	<i>Cryptococcus neoformans</i> , <i>Streptococcus</i> Group G			
	Serology Positive	Queen Elizabeth Univ Hosp		P	40	
	Serology Negative	Queen Elizabeth Univ Hosp		N		
	Serology Positive	Queen Elizabeth Univ Hosp		P	40	
Patient 2	Culture Positive	Queen Elizabeth Univ Hosp	<i>Cryptococcus neoformans</i>			
	Culture Positive	Queen Elizabeth Univ Hosp	<i>Cryptococcus neoformans</i>			
	Culture Positive	Queen Elizabeth Univ Hosp	<i>Cryptococcus neoformans</i>			
	Culture Positive	Queen Elizabeth Univ Hosp	<i>Cryptococcus neoformans</i>			
	Serology Positive	Queen Elizabeth Univ Hosp		P	160	
	Serology Positive	Queen Elizabeth Univ Hosp		P	160	
Patient 3	Serology Positive	Royal Alexandra Hospital				P
	Culture Positive	Royal Alexandra Hospital	<i>Cryptococcus neoformans</i>			
	Serology Positive	Queen Elizabeth Univ Hosp				P
	Culture Positive	Queen Elizabeth Univ Hosp	<i>Cryptococcus neoformans</i>			
Patient 4	Culture Positive	Glas Roy Hospit Children	<i>Cryptococcus neoformans</i>			
	Serology Positive	Queen Elizabeth Univ Hosp		P		
	Culture Positive	Glas Roy Hospit Children	<i>Cryptococcus neoformans</i>			
	Culture Positive	Queen Elizabeth Univ Hosp	<i>Cryptococcus neoformans</i>			

	Culture Positive	Queen Elizabeth Univ Hosp	Cryptococcus neoformans			
	Culture Positive	Queen Elizabeth Univ Hosp	Cryptococcus neoformans			
	Culture Positive	Queen Elizabeth Univ Hosp	Cryptococcus neoformans			
	Culture Positive	Glas Roy Hospit Children	Cryptococcus neoformans			
Patient 5	Serology Negative	Glas Roy Hospit Children		N		
	Serology Negative	Glas Roy Hospit Children		N		
	Serology Positive	Glas Roy Hospit Children		P		
	Serology Negative	Glas Roy Hospit Children		N		
	Serology Positive	Glas Roy Hospit Children		P	5	
	Serology Positive	Glas Roy Hospit Children		P		
	Serology Positive	Glas Roy Hospit Children		P	<5	
	Serology Positive	Glas Roy Hospit Children		P	<5	
	Serology Negative	Glas Roy Hospit Children		N	<5	
	Serology Negative	Glas Roy Hospit Children		N		
	Serology Negative	Glas Roy Hospit Children		N		
	Serology Negative	Glas Roy Hospit Children		N		
	Serology Negative	Glas Roy Hospit Children		N		
	Serology Negative	Glas Roy Hospit Children		N		
	Serology Negative	Glas Roy Hospit Children		N		
	Serology Negative	Glas Roy Hospit Children		N		
	Serology Negative	Glas Roy Hospit Children		N		
	Serology Negative	Glas Roy Hospit Children		N		
	Serology Negative	Glas Roy Hospit Children		N		

	Serology Negative	Glas Roy Hospit Children		N		
	Serology Negative	Glas Roy Hospit Children		N		
Patient 6	Serology Positive	Glas Roy Hospit Children		P	40	
	Serology Negative	Glas Roy Hospit Children		N		
	Serology Positive	Glas Roy Hospit Children		P	40	
	Serology Positive	Glas Roy Hospit Children		P	10	
	Serology Positive	Glas Roy Hospit Children		P	<5	
	Serology Negative	Glas Roy Hospit Children		N		
	Serology Negative	Glas Roy Hospit Children		N		
	Serology Negative	Glas Roy Hospit Children		N		
	Serology Negative	Glas Roy Hospit Children		N		
	Serology Negative	Glas Roy Hospit Children		N		
	Serology Negative	Glas Roy Hospit Children		N		
	Serology Negative	Glas Roy Hospit Children		N		
	Serology Negative	Glas Roy Hospit Children		N		
Patient 7*	Culture Positive - non-invasive sample	Glas Roy Hospit Children	Candida intermedia,Candida lipolytica,Cryptococcus laurentii			
Patient 8	Serology Negative	Queen Elizabeth Univ Hosp				N
	Serology Negative	Queen Elizabeth Univ Hosp				N
	Serology Positive	Queen Elizabeth Univ Hosp				P

	Serology Negative	Queen Elizabeth Univ Hosp		N		
	Serology Negative	Queen Elizabeth Univ Hosp		N		
Patient 9	Culture Positive	Royal Alexandra Hospital	Cryptococcus neoformans			
	Culture Positive	Royal Alexandra Hospital	Cryptococcus neoformans			
	Culture Positive	Royal Alexandra Hospital	Cryptococcus neoformans			
	Culture Positive	Royal Alexandra Hospital	Cryptococcus neoformans			
	Serology Positive	Queen Elizabeth Univ Hosp		P	1280	
	Serology Positive	Queen Elizabeth Univ Hosp		P	>2560	
	Culture Positive	Queen Elizabeth Univ Hosp	Cryptococcus neoformans			
	Serology Positive	Queen Elizabeth Univ Hosp		P	1280	
	Culture Positive	Queen Elizabeth Univ Hosp	Cryptococcus neoformans			
	Serology Positive	Queen Elizabeth Univ Hosp		P	2560	
	Culture Positive	Queen Elizabeth Univ Hosp	Cryptococcus neoformans			
	Serology Positive	Queen Elizabeth Univ Hosp		P	>2560	
	Serology Positive	Queen Elizabeth Univ Hosp		P		
	Serology Positive	Queen Elizabeth Univ Hosp		P	640	
	Serology Positive	Queen Elizabeth Univ Hosp		P	2560	
	Serology Negative	Western Inf Gartnavel Gen		N		
Patient 10*	Culture Positive - non-invasive sample	Glas Roy Hospit Children	Cryptococcus curvatus,Enterobacter cloacae ssp cloacae,Klebsiella oxytoca,Stenotrophomonas maltophilia			

Folder Path: .. / Building Services Information / Mechanical / Water Services / Plantroom 41 / 5. Test and Commissioning / 5.1 Method Statements

Review Status	Reviewed At	Title	Description	Attached Files
Reviewed by Brookfield	09/09/2015 09:52	Testing & Commissioning	Sterilisation of Water Services/DHW/TMV Temp Checks	1 0037-MS-MER-GB10008-186.pdf
Reviewed by Brookfield	09/09/2015 09:52	Hydraulic Testing of Domestic Water Systems	Method statement for hydraulic pressure testing of both cold and hot water systems	1 A&C Domestic Water Hydraulic Pressure Test MS.pdf

TMT In-Service Testing Report

Customer: GG&C			Site: QEUH		Building:			CHILDRENS HOSPITAL		Ward / Area / Department:		CLINIC 6					Date: Oct-23
Room Name / No.	Unique Room ID (Door Disc)	Outlet Type & ID e.g. (Tap, Shower, LHS, RHS)	Access	TMV Make / Model	Temp Cold Inlet °C	Temp Hot Inlet °C	Temp Mixed Outlet °C	TMV Reset Temp °C	Isolation Valves	Fail Safe Test	Strainer Condition	Strainers C&D	Further Action Required	Recommendations & Materials Required	Comments	Date of Service	Service Engineer
CONSULTING ROOM 40	OPD - 068	TAP	Good	Optitherm	15.6	58.6	40.7		On Tap	Pass	Light Debris	Yes	No			17/10/23	GG
CONSULTING ROOM 39	OPD - 095	TAP	Good	Optitherm	15.9	58.6	41.5		On Tap	Fail	Light Debris	Yes	Yes	NEW CARTRIDGE REQUIRED	NEW CARTRIDGE FITTED	17/10/23	LC
HEARING ROOM 1	OPD - 092	TAP	Good	Optitherm	15.7	58.6	40.7		On Tap	Pass	Light Debris	Yes	No			17/10/23	LC
HEARING ROOM 2	OPD - 093	TAP	Good	Optitherm	15.5	58.6	40.9		On Tap	Pass	Light Debris	Yes	No			17/10/23	GG
HEARING ROOM 3	OPD - 094	TAP	Good	Optitherm	15.5	58.6	40.9		On Tap	Pass	Light Debris	Yes	No			17/10/23	GG
DISABLED TOILET		TAP	Good	Optitherm	17.1	58.0	41.9		Behind Panel	Pass	Clean	Yes	No			17/10/23	JH
WORKSHOP	OPD - 090	TAP	Good	Optitherm	15.5	58.6	40.9		On Tap	Pass	Light Debris	Yes	No			17/10/23	LC
TOILET	OPD - 074	TAP	Good	Optitherm	16.8	58.6	41.2		Behind Panel	Pass	Clean	Yes	No			17/10/23	JH
DISABLED TOILET	OPD - 157	TAP	Good	Contour 21	15.6	58.3	40.8		Behind Panel	Pass	Heavy Debris	Yes	No			17/10/23	JH
DISABLED TOILET	OPD - 113	TAP	Good	Contour 21	15.8	58.6	42.3		Behind Panel	Fail	Blocked	Yes	Yes	NEW CARTRIDGE REQUIRED	NEW CARTRIDGE FITTED	17/10/23	JH



TMT In-Service Testing Report

Customer: GG&C			Site:	QEUH		Building:		CHILDRENS HOSPITAL		Ward / Area / Department:		CLINIC 6				Date:	Oct-23
Room Name / No.	Unique Room ID (Door Disc)	Outlet Type & ID e.g. (Tap, Shower, LHS, RHS)	Access	TMV Make / Model	Temp Cold Inlet °C	Temp Hot Inlet °C	Temp Mixed Outlet °C	TMV Reset Temp °C	Isolation Valves	Fail Safe Test	Strainer Condition	Strainers C&D	Further Action Required	Recommendations & Materials Required	Comments	Date of Service	Service Engineer



TMT Remedial Information
(from In-Service Testing)

Customer: GG&C			Site: QEUH				Building: CHILDRENS HOSPITAL		Ward / Area / Department:		CLINIC 6					Date:	Oct-23
Room Name / No.	Unique Room ID (Door Disc)	Outlet Type & ID e.g. (Tap, Shower, LHS, RHS)	Access	Further Action Required	Remedial Works Order No.	Comments from Original Service Sheet	Remedial Actions Required (From Original Service Sheet)	Parts / Materials Ordered and / or Additional Actions Required	DMA CPL PO No.	Materials Cost	Labour Time	Remedial Works Status	DMA Quote Ref:	Remedial Acitons Completed By	Date Remedials Completed	Comments	Manager Sign Off (Initial)
CONSULTING ROOM 40	OPD - 068	TAP	Good	No		0	0										
CONSULTING ROOM 39	OPD - 095	TAP	Good	Yes		NEW CARTRIDGE FITTED	NEW CARTRIDGE REQUIRED	NHS STOCK				COMPLETE		LC	17/10/23		
HEARING ROOM 1	OPD - 092	TAP	Good	No		0	0										
HEARING ROOM 2	OPD - 093	TAP	Good	No		0	0										
HEARING ROOM 3	OPD - 094	TAP	Good	No		0	0										
DISABLED TOILET	0	TAP	Good	No		0	0										
WORKSHOP	OPD - 090	TAP	Good	No		0	0										
TOILET	OPD - 074	TAP	Good	No		0	0										
DISABLED TOILET	OPD - 157	TAP	Good	No		0	0										
DISABLED TOILET	OPD - 113	TAP	Good	Yes		NEW CARTRIDGE FITTED	NEW CARTRIDGE REQUIRED	NHS STOCK				COMPLETE		JH	17/10/23		
0	0	0	0	0		0	0										
0	0	0	0	0		0	0										
0	0	0	0	0		0	0										
0	0	0	0	0		0	0										
0	0	0	0	0		0	0										

[illegible]

Access Responses	Make / Model Response
Good	Altecnic
Isolation Room - No Access	Arjo Bath
Barrier Room - No Access	Ausimix
Clinical Instruct - No Access	Bossmix
HiScribe Req - No Access	Bristan
See Comment - No Access	Caleffi
See Comment	Caremix
	Contour 21
	Contour 21+
	Dart Valley
	Horne Shower
	Horne TMV
	Ideal Standard
	Intamix
	Markwik 21
	Markwik 21+
	Mira
	Optitherm
	Other - See Comment
	Rada
	Reliance
	RVB
	Saracen
	Sirrus

Isolation Responses	Fail Safe responses	Strainer Condition Responses	Strainer C&D Responses	Further Action Rec'd Responses
Above Ceiling Tile	Pass	Clean	Yes	Yes
Behind IPS	Fail	Light Debris	No	No
Behind Panel	No Isolation	Heavy Debris	No Access	See Comment
No Isolation	See Comment	Blocked	Unable to Remove	
On Shower		No Access	No Strainers	
On Tap		Unable to Remove	See Comment	
On TMV		No Strainers		
Pipework to TMV		See Comment		
See Comment				
Valves Chewed				

THERMOSTATIC MIXING VALVE (TMV) MONITORING REPORT

SRF012 (V1)

Customer	NHS & GGHB			Date	02/08/17		Report No (Part 1)	TMV/1/			DMA CANYON OFFICE INFO		
Site Address	QEU HOSPITAL ADULTS WARD 4A			Responsible Person	TOMMY ROMEO		Site Contact				RAMS Ref No.		
												Additional RAMS ☐	
Location / Room No.	TMV ID No.	TMV Make & Model	TMV Type & Size	Temp °C Pre		Temp °C Mix	Fail Safe Test	Filters Clean & Disinfect	Check Valves Working	Isolation Valves	Pressure Test (Bar)		Access & Comments
				Cold	Hot						Hot	Cold	
ADULTS WARD 4A BED 2		HORNE OPTITHERM	TMV TAP	17.9	N/A	41.6	N/A	N/A	N/A	FAULTY			UNABLE TO OPERATE ISOLATION VALVES THEREFOR UNABLE TO CARRY OUT APPROPRIATE TESTS
ADULTS WARD 4A SHOWER ROOM AT BED 2		ARMITAGE SHANKS MONO BLOCK TAP	TMV TAP	19.0	55.8	41.4	N/A	N/A	N/A	NO			NO ISOLATION VALVES AVAILABLE SO UNABLE TO CARRY OUT APPROPRIATE TESTS
ADULTS WARD 4A BED 5		HORNE OPTITHERM	TMV TAP	19.1	N/A	43.0	N/A	N/A	N/A	FAULTY			UNABLE TO OPERATE ISOLATION VALVES THEREFOR UNABLE TO CARRY OUT APPROPRIATE TESTS
ADULTS WARD 4A LAB		HORNE OPTITHERM	TMV TAP	18.4	58.7	42.0	PASS	YES	YES	YES			THERMAL FLUSH CARRIED OUT
ADULTS WARD 4A BED 4		HORNE OPTITHERM	TMV TAP	19.1	N/A	42.7	N/A	N/A	N/A	FAULTY			UNABLE TO ISOLATE VALVES THEREFOR UNABLE TO CARRY OUT APPROPRIATE TESTS
ADULTS WARD 4A SHOWER ROOM AT BED 6		ARMITAGE SHANKS MONO BLOCK TAP	TMV TAP	19.4	56.2	39.6	N/A	N/A	N/A	NO			NO ISOLATION VALVES AVAILABLE SO UNABLE TO CARRY OUT APPROPRIATE TESTS
Notes:				DMA Canyon Signature		RYAN SCANLON			Customer Signature				

THERMOSTATIC MIXING VALVE (TMV) MONITORING REPORT

SRF012 (V1)

Customer	NHS & GGHb			Date	02/08/17		Report No (Part 1)	TMV/2/			DMA CANYON OFFICE INFO		
Site Address	QEU HOSPITAL ADULTS WARD 4A			Responsible Person	TOMMY ROMEO		Site Contact				RAMS Ref No. Additional RAMS ☐		
Location / Room No.	TMV ID No.	TMV Make & Model	TMV Type & Size	Temp °C Pre		Temp °C Mix	Fail Safe Test	Filters Clean & Disinfect	Check Valves Working	Isolation Valves	Pressure Test (Bar)		Access & Comments
				Cold	Hot						Hot	Cold	
ADULTS WARD 4A BED 7		HORNE OPTITHERM	TMV TAP	18.6	N/A	43.0	N/A	N/A	N/A	NO			UNABLE TO ISOLATE VALVES THEREFOR UNABLE TO CARRY OUT APPROPRIATE TESTS
ADULTS WARD 4A BED 9		HORNE OPTITHERM	TMV TAP	19.5	59.0	41.0	PASS	PASS	PASS	YES			THERMAL FLUSH CARRIED OUT
ADULTS WARD 4A BED 9 TOILET		ARMITAGE SHANKS MONO BLOCK TAP	TMV TAP	19.2	58.7	40.7	N/A	N/A	N/A	NO			NO ISOLATION VALVES AVAILABLE SO UNABLE TO CARRY OUT APPROPRIATE TESTS
ADULTS WARD 4A BED 11		HORNE OPTITHERM	TMV TAP	19.0	58.9	41.6	PASS	PASS	PASS	YES			THERMAL FLUSH CARRIED OUT
ADULTS WARD 4A BED 11 TOILET		ARMITAGE SHANKS MONO BLOCK TAP	TMV TAP	19.6	58.1	39.1	N/A	N/A	N/A	NO			NO ISOLATION VALVES AVAILABLE SO UNABLE TO CARRY OUT APPROPRIATE TESTS
ADULTS WARD 4A BED 13		HORNE OPTITHERM	TMV TAP	20.9	58.6	42.0	PASS	YES	YES	YES			THERMAL FLUSH CARRIED OUT
ADULTS WARD 4A BED 13 TOILET		HORNE OPTITHERM	TMV TAP	19.4	56.7	39.7	N/A	N/A	N/A	NO			NO ISOLATION VALVES AVAILABLE SO UNABLE TO CARRY OUT APPROPRIATE TESTS
ADULTS WARD 4A BED 14		HORNE OPTITHERM	TMV TAP	19.6	59.1	40.3	PASS	YES	YES	YES			THERMAL FLUSH CARRIED OUT
Notes:				DMA Canyon Signature		RYAN SCANLON			Customer Signature				

THERMOSTATIC MIXING VALVE (TMV) MONITORING REPORT

SRF012 (V1)

Customer	NHS & GGHB			Date	02/08/17		Report No (Part 1)	TMV/3/			DMA CANYON OFFICE INFO		
Site Address	QEU HOSPITAL ADULTS WARD 4A			Responsible Person	TOMMY ROMEO		Site Contact				RAMS Ref No.		
												Additional RAMS ☐	
Location / Room No.	TMV ID No.	TMV Make & Model	TMV Type & Size	Temp °C Pre		Temp °C Mix	Fail Safe Test	Filters Clean & Disinfect	Check Valves Working	Isolation Valves	Pressure Test (Bar)		Access & Comments
				Cold	Hot						Hot	Cold	
ADULTS WARD 4A BED 14 TOILET		ARMITAGE SHANKS MONO BLOCK TAP	TMV TAP	19.6	56.4	41.6	N/A	N/A	N/A	NO			NO ISOLATION VALVES AVAILABLE SO UNABLE TO CARRY OUT APPROPRIATE TESTS
ADULTS WARD 4A BED 15		HORNE OPTITHERM	TMV TAP	19.7	58.9	41.5	PASS	YES	YES	YES			THERMAL FLUSH CARRIED OUT
ADULTS WARD 4A BED 15 TOILET		ARMITAGE SHANKS MONO BLOCK TAP	TMV TAP	19.7	56.3	42.1	N/A	N/A	N/A	NO			NO ISOLATION VALVES AVAILABLE SO UNABLE TO CARRY OUT APPROPRIATE TESTS
ADULTS WARD 4A BED 18		HORNE OPTITHERM	TMV TAP	18.9	59.7	41.1	PASS	YES	YES	YES			THERMAL FLUSH CARRIED OUT
ADULTS WARD 4A BED 18 TOILET		ARMITAGE SHANKS MONO BLOCK TAP	TMV TAP	19.4	57.2	41.5	N/A	N/A	N/A	NO			NO ISOLATION VALVES AVAILABLE SO UNABLE TO CARRY OUT APPROPRIATE TESTS
ADULTS WARD 4A BED 8		HORNE OPTITHERM	TMV TAP	19.0	N/A	42.3	N/A	N/A	N/A	FAULTY			ISOLATION VALVES ARE INOPERABLE SO UNABLE TO CARRY OUT APPROPRIATE TESTS
ADULTS WARD 4A BED 1		HORNE OPTITHERM	TMV TAP	19.2	N/A	42.0	N/A	N/A	N/A	FAULTY			ISOLATION VALVES ARE INOPERABLE SO UNABLE TO CARRY OUT APPROPRIATE TESTS
Notes:				DMA Canyon Signature		RYAN SCANLON		Customer Signature					

THERMOSTATIC MIXING VALVE (TMV) MONITORING REPORT

SRF012 (V1)

Customer	NHS & GGHB			Date	02/08/17		Report No (Part 1)	TMV/4/			DMA CANYON OFFICE INFO		
Site Address	QEU HOSPITAL ADULTS WARD 4A			Responsible Person	TOMMY ROMEO		Site Contact				RAMS Ref No.		
												Additional RAMS ☐	
Location / Room No.	TMV ID No.	TMV Make & Model	TMV Type & Size	Temp °C Pre		Temp °C Mix	Fail Safe Test	Filters Clean & Disinfect	Check Valves Working	Isolation Valves	Pressure Test (Bar)		Access & Comments
				Cold	Hot						Hot	Cold	
ADULTS WARD 4A ROOM 10		HORNE OPTITHERM	TMV TAP	19.3	N/A	41.1	N/A	N/A	N/A	FAULTY			UNABLE TO ISOLATE WATER THEREFOR UNABLE TO CARRY OUT APPROPRIATE TESTS
ADULTS WARD 4A ROOM 10 TOILET		ARMITAGE SHANKS MONO BLOCK TAP	TMV TAP	19.5	57.1	40.2	N/A	N/A	N/A	NO			NO ACCESS TO ISOLATION VALVES SO UNABLE TO CARRY OUT APPROPRIATE TESTS
ADULTS WARD 4A ROOM 19 FOYER		HORNE OPTITHERM	TMV TAP	18.6	58.6	42.4	PASS	YES	YES	YES			THERMAL FLUSH CARRIED OUT
ADULTS WARD 4A ROOM 19		HORNE OPTITHERM	TMV TAP	18.5	58.9	43.0	PASS	YES	YES	YES			THERMAL FLUSH CARRIED OUT
ADULTS WARD 4A ROOM 19 TOILET		ARMITAGE SHANKS MONO BLOCK TAP	TMV TAP	18.6	57.0	40.7	N/A	N/A	N/A	NO			NO ISOLATION VALVES AVAILABLE SO UNABLE TO CARRY OUT APPROPRIATE TESTS
ADULTS WARD 4A ROOM 20 FOYER		HORNE OPTITHERM	TMV TAP	19.2	59.0	41.3	PASS	YES	YES	YES			THERMAL FLUSH CARRIED OUT
ADULTS WARD 4A ROOM 20		HORNE OPTITHERM	TMV TAP	18.3	59.2	42.0	PASS	YES	YES	YES			THERMAL FLUSH CARRIED OUT
ADULTS WARD 4A ROOM 20 TOILET		ARMITAGE SHANKS MONO BLOCK TAP	TMV TAP	19.4	55.8	40.6	N/A	N/A	N/A	NO			NO ISOLATION VALVES AVAILABLE SO UNABLE TO CARRY OUT APPROPRIATE TESTS
Notes:				DMA Canyon Signature		RYAN SCANLON			Customer Signature				

THERMOSTATIC MIXING VALVE (TMV) MONITORING REPORT

SRF012 (V1)

Customer	NHS & GGHB			Date		02/08/17		Report No (Part 1)		TMV/5/		DMA CANYON OFFICE INFO	
Site Address	QEU HOSPITAL ADULTS WARD 4A			Responsible Person		TOMMY ROMEO		Site Contact				RAMS Ref No. Additional RAMS ☐	
Location / Room No.	TMV ID No.	TMV Make & Model	TMV Type & Size	Temp °C Pre		Temp °C Mix	Fail Safe Test	Filters Clean & Disinfect	Check Valves Working	Isolation Valves	Pressure Test (Bar)		Access & Comments
				Cold	Hot						Hot	Cold	
ADULTS WARD 4A ROOM 6		HORNE OPTITHERM	TMV TAP	18.4	59.1	43.6	N/A	HOT ONLY	N/A	COLD FAULTY			COLD ISOLATION VALVE FAULTY SO UNABLE TO CARRY OUT APPROPRIATE TESTS
ADULTS WARD 4A ROOM 16		HORNE OPTITHERM	TMV TAP	19.3	58.6	42.4	PASS	YES	YES	YES			THERMAL FLUSH CARRIED OUT
ADULTS WARD 4A ROOM 16 TOILET		ARMITAGE SHANKS MONO BLOCK TAP	TMV TAP	19.4	56.7	40.3	N/A	N/A	N/A	NO			NO ACCESS TO ISOLATION VALVES SO UNABLE TO CARRY OUT APPROPRIATE TESTS
ADULTS WARD 4A ROOM 17		HORNE OPTITHERM	TMV TAP	18.7	58.7	42.4	PASS	YES	YES	YES			THERMAL FLUSH CARRIED OUT
ADULTS WARD 4A ROOM 17 TOILET		ARMITAGE SHANKS MONO BLOCK TAP	TMV TAP	19.0	56.4	41.3	N/A	N/A	N/A	N/A			NO ACCESS TO ISOLATION VALVES SO UNABLE TO CARRY OUT APPROPRIATE TESTS
ADULTS WARD 4A ROOM 3													NO ACCESS TO VALVES ON 02/08/17
ADULTS WARD 4A ROOM 12													NO ACCESS TO VALVES ON 02/08/17
Notes:				DMA Canyon Signature		RYAN SCANLON		Customer Signature					

THERMOSTATIC MIXING VALVE (TMV) MONITORING REPORT

SRF012 (V1)

Customer	NHS & GGHb			Date		04/08/17		Report No (Part 1)		TMV/6/		DMA CANYON OFFICE INFO			
Site Address	QEU HOSPITAL ADULTS WARD 4A			Responsible Person		TOMMY ROMEO		Site Contact				RAMS Ref No.			
														Additional RAMS ☐	
Location / Room No.	TMV ID No.	TMV Make & Model	TMV Type & Size	Temp °C Pre		Temp °C Mix	Fail Safe Test	Filters Clean & Disinfect	Check Valves Working	Isolation Valves	Pressure Test (Bar)		Access & Comments		
				Cold	Hot						Hot	Cold			
ADULTS WARD 4A ROOM 3		HORNE OPTITHERM	TMV TAP	18.1	58.9	41.2	PASS	YES	YES	YES			THERMAL FLUSH CARRIED OUT		
ADULTS WARD 4A BED 12		HORNE OPTITHERM	TMV TAP	19.6	N/A	41.2	N/A	N/A	N/A	FAULTY			UNABLE TO OPERATE ISOLATION VALVES THEREFOR UNABLE TO CARRY OUT APPROPRIATE TESTS		
ADULTS WARD 4A BED 12 TOILET		ARMITAGE SHANKS MONO BLOCK TAP	TMV TAP	19.4	56.2	42.3	N/A	N/A	N/A	NO			NO ACCESS TO ISOLATION VALVES SO UNABLE TO CARRY OUT APPROPRIATE TESTS		
Notes:				DMA Canyon Signature		RYAN SCANLON		Customer Signature							

Scottish Water Byelaws Inspection Report

SPID: 200003690101

Byelaws Compliance Officer: Colin Semple

Premise: Queen Elizabeth University Hospital
1345 Govan Road,
Glasgow,
G51 4TF

Contraventions

Maternity Building

Premise Fitting	Area	Location	Due By	Risk	Contravention	Rectification	Comments
Filling Loop	Maternity Boiler Room	Boiler Room	03/08/2020	4	Insufficient Backflow Prevention for Category 4 Contamination Risk	Install suitable backflow prevention to provide Fluid Category 4 protection.	Provide Fluid Category 4 protection for quick fill filling loop for heating system.
Fire Hose Reel	Maternity Building	Full Building	03/08/2020	3	Insufficient Backflow Prevention for Category 3 Contamination Risk	Install a double check valve	Install a double check valve back at source or on supply pipe to each fire reel. Also put in place a flushing program for fire reels.
Main Inlet	Maternity Boiler Room	Plant Room	03/08/2020	3	Insufficient Backflow Prevention for Category 3 Contamination Risk	install stop valve, double check valve and drain valve on incoming supply	
Main Inlet	Maternity Building	Unknown	03/08/2020	3	Insufficient Backflow Prevention for Category 3 Contamination Risk	install stop valve, double check valve and drain valve on incoming supply	Locate incoming supply pipe and install stop valve (BS1010), double check valve and drain valve.
Shower	Maternity Building	Full Building	03/08/2020	5	Insufficient Backflow Prevention for Category 5 Contamination Risk	Restrain shower head	Restrain all shower heads.

Energy Centre

Premise Fitting	Area	Location	Due By	Risk	Contravention	Rectification	Comments
Filling Loop	Energy Centre Building	Next to heating pressure unit	03/08/2020	4	Insufficient Backflow Prevention for Category 4 Contamination Risk	Install suitable backflow prevention to provide Fluid Category 4 protection.	Quick fill filling loop to top up heating system requires category 4 protection.
Main Inlet	Energy Centre Building	Mains Incoming Water Supply	03/08/2020	3	Insufficient Backflow Prevention for Category 3 Contamination Risk	install stop valve, double check valve and drain valve on incoming supply	

Adult and Children Building

Premise Fitting	Area	Location	Due By	Risk	Contravention	Rectification	Comments
Hose Union Taps	Adult and Children Building	Basement Hydro Pool Plant Room	03/08/2020	5	Insufficient Backflow Prevention for Category 5 Contamination Risk	Install a backflow prevention device to provide Fluid Category 5 protection.	This union hose tap must be fed from a storage cistern which incorporates a category 5 air gap or replace with bib tap and install double check valve on supply pipe.
Pipework	Adult and Children Building	Water Tank Room	03/08/2020	5	Dead Leg of Pipe Work - High Risk	Disconnect at relevant point so that no stop end at pipe work remains. Failure to remove may increase the risk of Legionella bacterial growth	Put flushing program in place at trade tank 1 & 2 on drain off outlets to lower the risk of Legionella bacterial growth.
Reduced Pressure Zone Valve (RPZ)	Adult And Children Building	Plant Room 31 3rd Floor	03/08/2020	4	RPZ Valve has not been commissioned/tested	RPZ Valve must be commissioned / tested by qualified tester annually.	Please provide test certificate from qualified tester.
Reduced Pressure Zone Valve (RPZ)	Adult And Children Building	Children Building Plant Room	03/08/2020	4	RPZ Valve has not been commissioned/tested	RPZ Valve must be commissioned / tested by qualified tester annually.	RPZ valve feeding hydrotherapy pool needs commissioned /tested by qualified tester also re-installed away from electrical appliances.
Shower	Adult And Children Building	Full Building	03/08/2020	5	Insufficient Backflow Prevention for Category 5 Contamination Risk	Restrain shower head	Restrain all shower heads on site.
Stop Valve	Adult And Children Building	Basement Fire Fighting Tank	03/08/2020	3	Insufficient Backflow Prevention for Category 3 Contamination Risk	Install BS1010 stop valve	Install BS1010 stop valves on the main inlet supply pipe to both firefighting tank.
Warning Pipe	Adult and Children Building	Water Tank Room	03/08/2020	3	Insufficient Backflow Prevention for Category 3 Contamination Risk	Install warning pipe	Reconfigure all early warning pipes in water tank area to correct air gap.

Teaching and Learning

Premise Fitting	Area	Location	Due By	Risk	Contravention	Rectification	Comments
Filling Loop	Teaching and Learning	4th Floor Boiler Room	03/08/2020	4	Insufficient Backflow Prevention for Category 4 Contamination Risk	Install suitable backflow prevention to provide Fluid Category 4 protection.	Install category 4 protection on supply pipe to the quick fill filling loop for heating system.
Reduced Pressure Zone Valve (RPZ)	Teaching And Learning	4th Floor Boiler Room	03/08/2020	4	Insufficient Backflow Prevention for Category 4 Contamination Risk	RPZ Valve must be commissioned / tested by qualified tester annually.	RPZ Valve supplying heating system must be commissioned / tested by qualified tester annually.
Shower	Teaching And Learning	Full Building	03/08/2020	5	Insufficient Backflow Prevention for Category 5 Contamination Risk	Restrain shower head	Restrain all shower heads.

Westmarc Building

Premise Fitting	Area	Location	Due By	Risk	Contravention	Rectification	Comments
Filling Loop	Westmarc Building	Boiler room	03/08/2020	4	Insufficient Backflow Prevention for Category 4 Contamination Risk	Install suitable backflow prevention to provide Fluid Category 4 protection.	Quick fill filling loop for heating system must have fluid category 4 protection installed.
Main Inlet	Westmarc Building	Boiler Room	03/08/2020	3	Insufficient Backflow Prevention for Category 3 Contamination Risk	Install a Double Check Valve and a Drain Valve	Install a double check valve and drain valve on the mains water incoming supply pipe.

Neonatal Building

Premise Fitting	Area	Location	Due By	Risk	Contravention	Rectification	Comments
Filling Loop	Neonatal Building	Plant Room	03/08/2020	4	Insufficient Backflow Prevention for Category 4 Contamination Risk	Install suitable backflow prevention to provide Fluid Category 4 protection.	Quick fill filling loop for heating system must have Fluid Category 4 protection.
Main Inlet	Neonatal Building	unknown	03/08/2020	3	Insufficient Backflow Prevention for Category 3 Contamination Risk	install stop valve, double check valve and drain valve on incoming supply	Locate and install - Possible location ground floor fire exit door in pipe chase.
Pumps	Neonatal Building	Secondary Filter Water Tank	03/08/2020	5	Insufficient Backflow Prevention for Category 5 Contamination Risk	This equipment must be fed from a storage cistern that incorporates a AA, AB or AD air gap	Pump booster Set must be fed from a storage cistern that incorporates an AA, AB or AD air gap.
Shower	Neonatal Building	Full Site	03/08/2020	5	Insufficient Backflow Prevention for Category 5 Contamination Risk	Restrain shower head	Restrain all shower heads on site.

Neurology Building

Premise Fitting	Area	Location	Due By	Risk	Contravention	Rectification	Comments
Pumps	Neurology Building	Level 6 Plant Room Water tank	03/08/2020	5	Insufficient Backflow Prevention for Category 5 Contamination Risk	This equipment must be fed from a storage cistern that incorporates a AA, AB or AD air gap	All booster sets fed from storage cistern must incorporate a AA,AB or AD air gap
Reduced Pressure Zone Valve (RPZ)	Neurology Building	Neurology Boiler House	03/08/2020	4	Insufficient Backflow Prevention for Category 4 Contamination Risk	RPZ Valve must be commissioned / tested by qualified tester annually.	This RPZ valve also needs re-installed sighted wrongly too high.
Shower	Neurology Building	Full Building	03/08/2020	5	Insufficient Backflow Prevention for Category 5 Contamination Risk	Restrain shower head	Restrain all Shower heads.

Landlangs Building

Premise Fitting	Area	Location	Due By	Risk	Contravention	Rectification	Comments
Filling Loop	Landlangs Building	Boiler room	03/08/2020	4	Insufficient Backflow Prevention for Category 4 Contamination Risk	Install suitable backflow prevention to provide Fluid Category 4 protection.	Quick fill filling loop for heating system requires fluid category 4 protection.
Filling Loop	Landlangs Building	Boiler room	03/08/2020	4	Insufficient Backflow Prevention for Category 4 Contamination Risk	Install suitable backflow prevention to provide Fluid Category 4 protection.	Quick fill filling loop for heating system requires fluid category 4 protection.
Pumps	Langlands Building	2nd floor plant room b	03/08/2020	5	Insufficient Backflow Prevention for Category 5 Contamination Risk	This equipment must be fed from a storage cistern that incorporates a AA, AB or AD air gap	Booster pump sets must be fed from a storage cistern that incorporates an AA, AB or AD air gap.
Shower	Langlands Building	Full Building	03/08/2020	5	Insufficient Backflow Prevention for Category 5 Contamination Risk	Restrain shower head	Restrain all shower heads.

PDRU And Vascular Building

Premise Fitting	Area	Location	Due By	Risk	Contravention	Rectification	Comments
Main Inlet	PDRU And Vascular Building	Unknown	03/08/2020	3	Insufficient Backflow Prevention for Category 3 Contamination Risk	install stop valve, double check valve and drain valve on incoming supply	Locate incoming supply pipe and install stop valve (BS1010) ,double check valve and drain valve.
Pumps	PDRU And Vascular Building	Loft Area	03/08/2020	5	Insufficient Backflow Prevention for Category 5 Contamination Risk	This equipment must be fed from a storage cistern that incorporates an AA, AB or AD air gap	The booster pump set in loft area must be fed from a storage cistern that incorporates an AA, AB or AD air gap.
Shower	PDRU And Vascular Building	Full Building	03/08/2020	5	Insufficient Backflow Prevention for Category 5 Contamination Risk	Restrain shower head	Restrain all Shower Heads.

Laboratory and Medicine Building

Premise Fitting	Area	Location	Due By	Risk	Contravention	Rectification	Comments
Pipework	Laboratory and Medicine Building	Laboratory Level 4	03/08/2020	5	Insufficient Backflow Prevention for Category 5 Contamination Risk	Install a backflow prevention device to provide Fluid Category 5 protection.	Laboratory taps must be fed from a designated category 5 tank supply which feeds labs only. Please confirm if level 4 laboratory taps are fed from domestic tank on level 4 or laboratory tank in basement.
Pumps	Laboratory and Medicine Building	Mortuary Tank 2 In Basement	03/08/2020	5	Insufficient Backflow Prevention for Category 5 Contamination Risk	Install a backflow prevention device to provide Fluid Category 5 protection.	Booster pump set fed from mortuary tank 2 requires category 5 protection.

CMB Building

Premise Fitting	Area	Location	Due By	Risk	Contravention	Rectification	Comments
Fire Hydrant	CMB Building	At hydrant on grass verge left hand side of main entrance door	03/08/2020	3	Insufficient Backflow Prevention for Category 3 Contamination Risk	Remove	Remove temporary water supply from fire hydrant to CMB building and install a permanent supply which meets the water bylaws regulations.
Main Inlet	CMB Building	Unknown	03/08/2020	5	Dead Leg of Pipe Work - High Risk	Disconnect at relevant point so that no stop end at pipe work remains. Failure to remove may increase the risk of Legionella bacterial growth	The old water mains incoming supply pipe needs disconnected back at source. Please confirm if this has been done.

AMB Building

Premise Fitting	Area	Location	Due By	Risk	Contravention	Rectification	Comments
Pipework	AMB Building	Unknown	03/08/2020	5	Dead Leg of Pipe Work - High Risk	Disconnect at relevant point so that no stop end at pipe work remains. Failure to remove may increase the risk of Legionella bacterial growth	This building is vacant please confirm if pipework has been capped off back at source.

Max Fax Building

Premise Fitting	Area	Location	Due By	Risk	Contravention	Rectification	Comments
Pipework	Max Fax Building	Lab Area - Grinder Machine	03/08/2020	3	Insufficient Backflow Prevention for Category 3 Contamination Risk	Install a double check valve	Install double check valve on supply pipe to dental grinder.

Podiatry Building

Premise Fitting	Area	Location	Due By	Risk	Contravention	Rectification	Comments
Main Inlet	Podiatry Building	Plant Room	03/08/2020	3	Insufficient Backflow Prevention for Category 3 Contamination Risk	Install a Double Check Valve and a Drain Valve	Install Double check valve and drain valve on incoming supply pipe.

Whole Site

Premise Fitting	Area	Location	Due By	Risk	Contravention	Rectification	Comments
Bath	All Buildings	Arjo Baths	03/08/2020	5	Insufficient Backflow Prevention for Category 5 Contamination Risk	This equipment must be fed from a storage cistern that incorporates a AA, AB or AD air gap	Arjo Baths must be fed from a designated storage cistern that incorporates a AA, AB or AD air gap. Rhapsody/Primo P200+ Location- NSGH-02-DMW-013 NSGH-02-DMW-011 NSGH-01-STW-079 NSGH-06-GENW1-001 NCH-04-DCFP-038 NCH-03-GW3-059 NCH-03-GW1-068 NCH-02-SCH-079 NCH-02-ARU-006 NCH-01-CCW-051 NCH-01-CAR-048
Main Inlet	Full Site	All boundary incoming supply	03/08/2020	3	Insufficient Backflow Prevention for Category 3 Contamination Risk	Install a double check valve to give whole site protection	Install a double check valve to all main inlet boundary's supply points. location- Meter -11W712602 150MM X-253618/Y-665875 06M440901/03H000872 80/20 COMBI X-253329 Y-665758 3K220000653954 150MM X-253443 Y-665842 09H701812/09M102281 80/20 COMBI X-253547 Y-665541 11W727521/19W711190 100MM X-253815 Y-665585 11H762937/11M686368 80/20 COMBI X-253790 Y-666042

Recommendations

Premise Fitting	Area	Location	Recommendation
Fire Hydrant	Full Site	Full Site	All fire hydrants on site to have flushing program in place to remove any risk of legionella bacterial growth.

Comment/Issues

Premise Fitting	Area	Location	Comment/Issue
Pipework	Neuro-Surgical Plant Room 9	Plant Room 9	This area is under renovation and has double check valve in place. This area will require a revisit in one years' time once work has been completed.

Scottish Water Byelaws Inspection Report

SPID: 200003690101

Byelaws Compliance Officer: Colin Semple

Premise:

Queen Elizabeth University Hospital
1345 Govan Road,
Glasgow,
G51 4TF

Contraventions

Premise Fitting	Area	Location	Due By	Risk	Contravention	Rectification	Comments
Bath	Full site	'Arjo' baths	21/03/2022	5	Insufficient backflow prevention for fluid category 5 contamination risk.	Install suitable backflow prevention to provide fluid category 5 protection.	Arjo Baths - this equipment must be fed from a designated storage cistern that incorporates an AA, AB or AD air gap. Rhapsody/Primo P200+ Location-NSGH-02-DMW-013 NSGH-02-DMW-011 NSGH-01-STW-079 NSGH-06-GENW1-001 NCH-04-DCFP-038 NCH-03-GW3-059 NCH-03-GW1-068 NCH-02-SCH-079 NCH-02-ARU-006 NCH-01-CCW-051 NCH-01-CAR-048
Filling Loop	Energy Centre Building	Next to heating pressure (unit	21/03/2022	4	Insufficient backflow prevention for fluid category 4 contamination risk.	Install suitable backflow prevention to provide fluid category 4 protection.	Quick fill filling loop to top up heating system requires fluid category 4 protection.
Filling Loop	Teaching and Learning	4th floor boiler room	21/03/2022	4	Insufficient backflow prevention for fluid category 4 contamination risk.	Install suitable backflow prevention to provide fluid category 4 protection.	Quick fill filling loop to top up heating system requires fluid category 4 protection.
Filling Loop	Westmarc Building	Boiler room	21/03/2022	4	Insufficient backflow prevention for fluid category 4 contamination risk.	Install suitable backflow prevention to provide fluid category 4 protection.	Quick fill filling loop to top up heating system requires fluid category 4 protection.

Filling Loop	Neonatal Building	Plant room	21/03/2022	4	Insufficient backflow prevention for fluid category 4 contamination risk.	Install suitable backflow prevention to provide fluid category 4 protection.	Quick fill filling loop to top up heating system requires fluid category 4 protection.
Filling Loop	Maternity boiler room	Boiler room	21/03/2022	4	Insufficient backflow prevention for fluid category 4 contamination risk.	Install suitable backflow prevention to provide fluid category 4 protection.	Quick fill filling loop to top up heating system requires fluid category 4 protection.
Filling Loop	Landlans Building	Boiler room	21/03/2022	4	Insufficient backflow prevention for fluid category 4 contamination risk.	Install suitable backflow prevention to provide fluid category 4 protection.	Quick fill filling loop to top up heating system requires fluid category 4 protection.
Hose Union Taps	Adult and Children Building	Basement hydro pool plant room	21/03/2022	5	Insufficient backflow prevention for fluid category 5 contamination risk.	Install suitable backflow prevention to provide fluid category 5 protection.	This union hose tap must be fed from a storage cistern which incorporates a fluid category 5 air gap or replace with bib tap and install double check valve on supply pipe.
Main Inlet	Energy Centre Building	Mains incoming water supply	21/03/2022	3	Insufficient backflow prevention for fluid category 3 contamination risk.	Install suitable backflow prevention to provide fluid category 3 protection.	Install stop valve (BS1010), double check valve and drain valve on incoming supply.
Main Inlet	PDRU And Vascular	Unknown	21/03/2022	3	Insufficient backflow prevention for fluid category 3 contamination risk.	Install suitable backflow prevention to provide fluid category 3 protection.	Locate incoming supply pipe and install stop valve (BS1010), double check valve and drain valve.
Main Inlet	Full site	All boundary incoming supply	21/03/2022	3	Insufficient backflow prevention for fluid category 3 contamination risk.	Install suitable backflow prevention to provide fluid category 3 protection.	Whole site protection - install a double check valves to all main inlet boundary supply points. Meters and locations: 11W712602 150MM X-253618/Y-665875 06M440901/03H000872 80/20 COMBI X-253329 Y-665758 3K220000653954 150MM X-253443 Y-665842 09H701812/09M102281 80/20 COMBI X-253547 Y-665541 11W727521/19W711190 100MM X-253815 Y-665585 11H762937/11M686368 80/20 COMBI X-253790 Y-666042
Main Inlet	Westmarc Building	Boiler room	21/03/2022	3	Insufficient backflow prevention for fluid category 3 contamination risk.	Install suitable backflow prevention to provide fluid category 3 protection.	Install a double check valve and drain valve on the mains water incoming supply pipe.
Main Inlet	Neonatal Building	Unknown	21/03/2022	3	Insufficient backflow prevention for fluid category 3 contamination risk.	Install suitable backflow prevention to provide fluid category 3 protection.	Locate and install stop valve (BS1010), double check valve and drain valve on incoming supply. Possible location ground floor fire exit door in pipe chase.
Main Inlet	Podiatry Building	Plant room	21/03/2022	3	Insufficient backflow prevention for fluid category 3 contamination	Install suitable backflow prevention to provide fluid	Install double check valve and drain valve on incoming supply

					risk.	category 3 protection.	pipe.
Main Inlet	Maternity boiler room	Plant room	21/03/2022	3	Insufficient backflow prevention for fluid category 3 contamination risk.	Install suitable backflow prevention to provide fluid category 3 protection.	Install stop valve (BS1010), double check valve and drain valve on incoming supply.
Main Inlet	Maternity Building	Unknown	21/03/2022	3	Insufficient backflow prevention for fluid category 3 contamination risk.	Install suitable backflow prevention to provide fluid category 3 protection.	Locate incoming supply pipe and install stop valve (BS1010), double check valve and drain valve.
Pipework	Adult and Children Building	Water tank room	21/03/2022	5	Insufficient backflow prevention for fluid category 5 contamination risk.	Install suitable backflow prevention to provide fluid category 5 protection.	Dead leg of pipework - disconnect at relevant point so that no stop end at pipe work remains. Put flushing program in place at trade tank 1 & 2 on drain off outlets.
Pipework	Max Fax Building	Lab area - grinder machine	21/03/2022	3	Insufficient backflow prevention for fluid category 3 contamination risk.	Install suitable backflow prevention to provide fluid category 3 protection.	Install double check valve on supply pipe to dental grinder.
Pipework	Laboratory and Medicine	Laboratory level 4	21/03/2022	5	Insufficient backflow prevention for fluid category 5 contamination risk.	Install suitable backflow prevention to provide fluid category 5 protection.	Laboratory taps must be fed from a designated fluid category 5 tank supply which feeds laboratories only. Please confirm if level 4 laboratory taps are fed from domestic tank on level 4 or laboratory tank in basement.
Pumps	PDRU And Vascular	Loft area	21/03/2022	5	Insufficient backflow prevention for fluid category 5 contamination risk.	Install suitable backflow prevention to provide fluid category 5 protection.	Booster pump set - this equipment in loft area must be fed from a storage cistern that incorporates an AA, AB or AD air gap.
Pumps	Neurology Building	Level 6 plant room water tank	21/03/2022	5	Insufficient backflow prevention for fluid category 5 contamination risk.	Install suitable backflow prevention to provide fluid category 5 protection.	Booster pump sets - this equipment must be fed from a storage cistern that incorporates an AA, AB or AD air gap.
Pumps	Neonatal Building	Secondary filter water tank	21/03/2022	5	Insufficient backflow prevention for fluid category 5 contamination risk.	Install suitable backflow prevention to provide fluid category 5 protection.	Booster pump set - this equipment must be fed from a storage cistern that incorporates an AA, AB or AD air gap.
Pumps	Laboratory and Medicine	Mortuary tank 2 in basement	21/03/2022	5	Insufficient backflow prevention for fluid category 5 contamination risk.	Install suitable backflow prevention to provide fluid category 5 protection.	Booster pump set - this equipment must be fed from a storage cistern that incorporates an AA, AB or AD air gap.
Pumps	Langlands Building	2nd floor plant room B	21/03/2022	5	Insufficient backflow prevention for fluid category 5 contamination risk.	Install suitable backflow prevention to provide fluid category 5 protection.	Booster pump sets - this equipment must be fed from a storage cistern that incorporates an AA, AB or AD air gap.
Reduced Pressure Zone (RPZ) Valve	Adult And Children Building	Plant room 31 3rd floor	21/03/2022	4	Insufficient backflow prevention for fluid category 4 contamination risk.	Install suitable backflow prevention to provide fluid category 4 protection.	RPZ valve must be commissioned/tested by a qualified tester annually. For guidance, please refer to the RPZ AIM document.
Reduced Pressure Zone (RPZ) Valve	Adult And Children Building	Children Building plant room	21/03/2022	4	Insufficient backflow prevention for fluid category 4 contamination risk.	Install suitable backflow prevention to provide fluid category 4 protection.	RPZ valve feeding hydrotherapy pool must be commissioned/tested by a qualified tester annually. Also

							must be re-installed away from electrical appliances. For guidance, please refer to the RPZ AIM document.
Reduced Pressure Zone (RPZ) Valve	Neurology Building	Neurology boiler house	21/03/2022	4	Insufficient backflow prevention for fluid category 4 contamination risk.	Install suitable backflow prevention to provide fluid category 4 protection.	RPZ valve must be commissioned/tested by a qualified tester annually. This RPZ valve is currently too high. For guidance, please refer to the RPZ AIM document.
Reduced Pressure Zone (RPZ) Valve	Teaching And Learning	4th floor boiler room	21/03/2022	4	Insufficient backflow prevention for fluid category 4 contamination risk.	Install suitable backflow prevention to provide fluid category 4 protection.	RPZ valve supplying heating system must be commissioned/tested by a qualified tester annually. For guidance, please refer to the RPZ AIM document.
Shower	Adult And Children Building	Full building	21/03/2022	5	Insufficient backflow prevention for fluid category 5 contamination risk.	Install suitable backflow prevention to provide fluid category 5 protection.	Restrain all shower heads.
Shower	Neurology Building	Full building	21/03/2022	5	Insufficient backflow prevention for fluid category 5 contamination risk.	Install suitable backflow prevention to provide fluid category 5 protection.	Restrain all shower heads.
Shower	PDRU And Vascular	Full building	21/03/2022	5	Insufficient backflow prevention for fluid category 5 contamination risk.	Install suitable backflow prevention to provide fluid category 5 protection.	Restrain all shower heads.
Shower	Teaching And Learning	Full building	21/03/2022	5	Insufficient backflow prevention for fluid category 5 contamination risk.	Install suitable backflow prevention to provide fluid category 5 protection.	Restrain all shower heads.
Shower	Neonatal Building	Full site	21/03/2022	5	Insufficient backflow prevention for fluid category 5 contamination risk.	Install suitable backflow prevention to provide fluid category 5 protection.	Restrain all shower heads.
Shower	Maternity Building	Full building	21/03/2022	5	Insufficient backflow prevention for fluid category 5 contamination risk.	Install suitable backflow prevention to provide fluid category 5 protection.	Restrain all shower heads.
Shower	Langlands Building	Full building	21/03/2022	5	Insufficient backflow prevention for fluid category 5 contamination risk.	Install suitable backflow prevention to provide fluid category 5 protection.	Restrain all shower heads.

Recommendations

Premise Fitting	Area	Location	Recommendation
Fire Hydrant	Full site		All fire hydrants on site to have flushing program in place to remove possible risk of bacterial growth.

Comment/Issues

SW Internal
A48946859
General

Premise Fitting	Area	Location	Comment/Issue
Double Check Valve	All areas		All double check valves to be maintained and if required replaced every 10 years.
Pipework	Neuro-Surgical plant room 9	Plant room 9	This area is under renovation and has double check valve in place. This area will require a revisit in one years' time once work has been completed.

**Complete within 24 hours for all HIIAT Red and Amber;
for HIIAT Green complete only if HPS Support requested.**

Section 1 :Contact Details			
NHS Board/Care organisation		GGG&C	
Date and time of reporting		01/03/18 @ 1400hrs	
Person Reporting and designation		Dr Teresa Inkster – Lead ICD Susie Dodd – Lead IPCN	
Telephone number and email		Teresa.Inkster@ Susie.dodd@	
Section 2: Infection Incident/outbreak Details			
Care facility/hospital		Royal Hospital for Children	
Clinical area/ward and speciality		Haemato-oncology ward	
Total number of beds		25 (2 out of use for refurb & 2 out of use due to contaminated water outlets) = 21 beds in use	
Total number of beds occupied		21	
Section 3: Initial assessment			
Type: Incident/outbreak/ data exceedance e.g. Gastrointestinal, decontamination failure		Water contamination	
Infectious agent known or suspected		Cupriavidus pauculus/Pseudomonas aeruginosa	
Case definition	Patient with bacteraemia secondary to Cupriavidus pauculus or Pseudomonas aeruginosa Patient with bacteraemia due to Stenotrophomonas		
Date of first case (if applicable)			
Total number of confirmed patient cases	Total number of probable patient cases	Total number of possible patient cases:	Total number of staff cases:
4	0	0	0
Number of patients giving clinical cause for concern as a consequence of this incident/outbreak		0	
Number of deaths as a consequence of this incident/outbreak		0	
Was the infectious agent cited as a cause of death on a death certificate* (if yes, state which part of the certificate)			
Additional information: Patient presented at end of January with Cupriavidus pauculus bacteraemia. Responded to treatment. As part of the investigations a selection of water outlets in ward 2A were sampled and have tested positive - 4 patient rooms , treatment room and prep room. Note there is currently a patient on the unit with Pseudomonas aeruginosa bacteraemia which is healthcare associated. One outlet has tested positive for this organism Due to the number of positive outlets we will not test anymore at present . We assume widespread problem so will proceed straight to dosing the system with Silver Hydrogen peroxide. Taps and components including flow straighteners have been removed for sampling. Water tanks have also been sampled			
Section 4: Healthcare Infection Incident Assessment Tool (HIIAT) (link to tool)			
Severity of illness	Minor/Moderate/Major	Moderate	
Impact on services	Minor/Moderate/Major	Minor	
Risk of transmission	Minor/Moderate/Major	Major	
Public anxiety	Minor/Moderate/Major	Minor	
HIIAT Assessment	Red Amber Green	Red	

Section 5: Organisational Arrangements		
PAG/IMT meeting held	Yes	Date: 5/2/18 & 19/2/18 & 1/3/18
Next planned IMT	Early week beginning 5 th March	Date:
Press statement (send with HIIORT or provide date for receipt)	Draft awaited Date:	
HPS support requested	Not at present	Date.....
Other information: e.g. decisions from IMT	Water checklist carried out – concerns identified and issued as an SBAR to clinical SMT Initial rooms identified as having contaminated outlets taken out of use. All showers out of use. Patients going for line insertion in theatre will have a bed bath down in theatre. All staff and patients to use alcohol based hand rub after washing hands Bottled water for teeth brushing Ongoing surveillance by ICT for further cases 2/3/18 IMT held. Water dosing will take place today with Sanosil. Estates have commenced replacement of outlets. Results from main water tanks are negative suggesting outlets themselves are the source. Water supply to ward will go down for 4 hours , hand hygiene stations will be put in place using bottled water. Patients will be given sterile water to drink. Once dosing complete outlets will be put back in use and resampling will take place early next week. HIIAT remains at Red. 06/03/18 IMT held. No new patient cases. Patient with Pseudomonas is stable. Microbiological testing is still in progress but several components of the tap including the flow straighteners have tested positive for Cupriavidus. Showerhead has also grown the organism. All flow straighteners will be replaced. Disposable showerheads will be purchased and fitted for this ward. Water sampling to move from 6 monthly to monthly. Alerts set up on ICNet for Cupriavidus in blood cultures. One other Cupriavidus pauculus bacteraemia in 2A , September 2017 but water testing had been negative so not clear if linked to current incident . Isolate has been sent for typing. Working hypothesis is that outlets are positive due to contact spread as main tanks are negative. HIIAT remains Red 09/03/18 IMT held. No new patient cases. A program of tap exchange, thermal disinfection and replacement of flow straighteners is ongoing. Once all taps have been changed there will be a further chemical disinfection . Resampling will take place after chemical disinfection. Water testing has been extended to ward 2B which is the outpatient area. HIIAT will remain at Red until repeat sampling post 2nd chemical disinfection . 12/03/18 Urgent IMT reconvened following positive water isolates after sanitisation indicating that the sanitisation process has been ineffective. Water has grown Cupriavidus(multiple outlets) and Stenotrophomonas (one shower head only). The most likely scenario is that dosing has disrupted the biofilm leading to the release of bacteria into the water. One patient colonised with Stenotrophomonas (not related to the positive room) . No patients giving cause for concern. Following control measures were immediately put in place; • All showers and baths out of use for patients. • Patients going for line insertion in theatre will have a bed bath down in theatre. • All staff and patients to use alcohol based hand rub after washing hands on ward 2A and 2B. • Bottled water for teeth brushing in ward 2A & 2B • Ongoing surveillance by ICT for further cases • Disposable shower heads to be installed this evening • Portable sinks will be delivered to the ward this evening and filled over night. • All taps to be cleaned and have replacement flow straighteners and TMVs • Chemical sanitisation of the ward will commence at 6am tomorrow • Portable sinks will be deployed and remain in use until clear samples are achieved post sanitisation.	

- The program of replacing Horne taps ASAP will re-commence following sanitisation.
- Water supply in ward 3C will be tested as a contingency for failure of the current plan.
- Comms prepared for parents.
- Holding press statement updated.
- Further IMT to be arranged later in the week.

IMT 19.03.19 Update

Infection Control Measures

The following control measurements are for immunocompromised patients with Ward 4B, 4C, 7A, 7D which include Cystic Fibrosis and Renal transplant patients:-

- Patient must not wash/be washed/drink or brush teeth with water from the sink or shower outlets.
- Only drink bottle water (Patients are allowed to drink cups of tea)
- Use bottle water to brush teeth
- Washing must be used with single use patient wipes/bottled water.

Please note that sterile water should be used if it is a Bone Marrow Transplant (BMT) patient.

All rooms with immunocompromised patients are to get a twice daily Actichlor cleans.

The group asked about patients within critical care, Dr Inkster informed them that the patients would not be taking showers or using clinical hand wash basins if in critical care.

Water Control Measures

Point of use filters will be installed on all Clinical Hand Wash basins within Ward 4B as well as replacement of shower heads and hoses. Once complete testing of the water will recommence and when negative specimens obtained, patients can start using the main water supply. This should take approximately 48 hours.

The above precautions are for short term only. Long term solutions are currently being investigated which include replacing all current taps within the hospital and the dosing of the water supply with Chlorine Dioxide.

HIIAT Assessment

The group agreed that the HIIAT should be RED.

IMT 21.03.19 Update

Patient Update RHC

Ward 2A

All 3 positive blood culture *Stenotrophomonas* patients have had their lines taken out and are currently stable and causing no concerns to staff.

Patient Update QEUH

No positive blood cultures for *Stenotrophomonas* or *Cupriavidus* in Ward 4B

There have been no new cases since the implementation of the control measures.

Epidemiology

Since the opening of the RHC site there have been 3 cases of Cupriavidus reported. This is a very rare pathogen which is linked to dialysis lines and water. Strong epidemiology link with the Cupriavidus and water with the positive results from the water outlets.

Cases of Stenotrophomonas have spiked to 4 cases during the month of March 2018 in RHC 2A. There is usually about 1 case of Stenotrophomonas a month within the RHC site. In ward 4B QEUH site only one case of Stenotrophomonas has ever been reported since opening. In ward 2A it is unclear whether we can link to this to water as it has only been found in one shower outlet. However the counts were high at >100 and we only sampled limited outlets assuming widespread contamination with Cupriavidus. Originally it was thought the Stenotrophomonas was being transmitted through patients taking showers. The other possibility is that the index case is water related and subsequent cases were transmitted from HCW to other patients or all cases may be completely independent from the water supply.

Typing results will shed light on the Cupriavidus as it will show if there has been a link with cross transmission from water outlet to patient.

Cannot determine if Stenotrophomonas is water source or cross transmission until typing results come back.

RHC Water Report

Ward 2A wide spread positive results for Cupriavidus in multiple sink outlets, 2 positive shower outlets with Stenotrophomonas and 1 outlet with pseudomonas. Dosed system 4 times and have seen the counts being lowered but Cupriavidus still present in number of outlets.

Ward 2B and 3C still have widespread Cupriavidus

Fungal matter found in water supply in 2B and 3C but levels not dramatic and it is not uncommon to find this in hospital environments. None of the fungus has been identified as significant to date. No issues with Aspergillus were found within the samples although noted an issue with lab contaminants. Fungus in the water supply is a concern particularly for BMT patients and this has been discussed with experts. Control measures will need to take this into account moving forward.

Ward 4B QEUH Water Report

Two positive results of Cupriavidus from shower head in ward 4B. Multiple water samples positive from outlets in 4B

Sampling being carried out on 21.03.18 within occupied bed areas in Ward 4B QEUH.

Other Reports

The two sources of water coming into the hospital from Hardgate road and Govan road have both came back negative from samples taken by Scottish Water. Low levels of another bacteria were identified but within acceptable limits and there is no evidence of this bacteria in our tanks indicating that filtration is working.

It was reported that the two main water storage tanks, filter tanks and booster pumps have all came back negative.

Renal dialysis samples are within normal limits

There are no concerns re aseptic pharmacy results – successive results are negative

Other Relevant reports

Samples were taken of soap dispensers, liquid soap, wipes and an array of commonly used items domestic use. Initial results from the samples after 24 hours is negative but still have to wait until 48 hours until incubation period is complete.

Current Infection Control Measures

The following specific control measurements for immunocompromised patients are as follows

- Patient must not wash/be washed/drink or brush teeth with water from the sink or shower outlets.
- Only drink bottle water
- Use bottle water to brush teeth
- Wash must be used by single use patient wipes/bottled water or water from the mobile hand wash units which are available in Ward 2A.
- Parents and staff can use sinks for hand hygiene but use AHR afterwards.

Please note that sterile water should be used if it is a Bone Marrow Transplant (BMT) patient.

All rooms with immunocompromised patients are to get a twice daily Actichlor cleans which consists of all rooms in ward 2A and any inpatients throughout RHC.

If staff are to carry out an aseptic technique on a patient then they must carry out hand hygiene a surgical scrub with bottled water then followed by use of sterillium.

Ciprofloxacin is still to be given to all immunosuppressed patients in the meantime but this will not be a long term. Janice Watt informed the group that Pharmacy are currently going through 50 bottles of Ciprofloxacin a week. She is mostly concerned that the long term supply of liquid form Ciprofloxacin mostly used for paediatric patients compared to the tablet form given to adults.

Water Control Measures

Tap and shower filters have been fitted in Ward 2A, 2B, 3C in the RHC and occupied beds in Ward 4B Haematology, QEUH (unoccupied rooms being done later this week). Filters are currently being fitted to NICU today with sampling being taken from PICU before filters being installed.

Director of regional will inform facilities colleagues regarding what areas should be prioritised within the QEUH for the fitting of water filters into Ward 4A, 4C, 4D, 7A and 7D.

Quality assurance of the fitting of the filters will be carried out by Facilities.

The group was informed that that to completely know if the filters work they would need to identify a positive water outlet that has not been dosed with silver nitrate, fit the filter and resample to see the results.

It was agreed once facilities can confirm that filters have been fitted to all CWHB and showers and checked they have been fitted correctly then patients can resume using showers and wash hand wash basins.

Facilities will carry out tests on the water outlets on a weekly basis to ensure the filter is working. If the counts start to get high then they can change the filters on the affected outlets. The filters currently fitted to the taps have a working life of 30 days. Facilities have are introducing a rolling program to change these filters from day 25.

Water coolers are to be kept out of use within in patient areas.

There was extensive discussions within the IMT re whether microbiological efficacy of filters was required prior to using the water. The consensus of the IMT was that we would proceed with filters without these results. Post meeting this decision was supported by Peter Hoffman Public Health England and Susanne Lee, International water expert.

Future Preventative Measures

Currently two future preventable measures are being looked at.

One of the measures is the installation and replacing of all horne taps within high risk areas or throughout the whole QEUH and RHC campus with the later being very time costly and time consuming. Two tap models are currently being investigated

The other preventable measure being looked at is the dosing of the water system with Chlorine dioxide. This would need expert opinion on how this could be implemented due to the size of the campus and the water holding tanks.

Hypothesis

It was explained that Scottish water reported that main tanks are negative. Post filtration tanks and risers are negative. The bacteria concerned like oxygen and taps/showers are heavily contaminated. Tap and shower components are conducive to biofilm especially flow straighteners and plastic.

It was explained there may have been contamination in the past with organisms being flushed through the system but forming biofilm on the outlets .

HIIAT Assessment

The group agreed that the HIIAT should remain at RED.

IMT 27.03.18

Patient Update RHC

Ward 2A

The three affected patients are not giving medical staff any cause for concern.

PICU

No concerns regarding the patient in PICU.

Patient Update QEUH

No cases reported

RHC Water Report

Pre filter water results have come back showing numerous outlets within PICU positive with Cupriavidus and numerous outlets positive with Sphingomonas in NICU. Point of use filters have been fitted to CWHB outlets in these areas.

The group were informed that most of the positive tests are coming back as Cupriavidus, although these checks were all pre filter tests.

Positive results for Delftia has come back from testing carried out in theatres, RHC. LICD has requested filters are to be fitted there.

RHC therefore has evidence of widespread problem

Ward 4B QEUE Water Report

Pre filter results from water sampling within Ward 4B QEUE have different Microbiology results than Ward 2A, RHC. There is a mixture of gram negative pathogens with some outlets testing positive for high counts of fungal growth. Bacteria include Delftia sp, Commanonas sp, Achromobacter sp and Cupriavidus.

The water risers for Ward 4A and 4D have come back positive, but some of the water outlets are negative. Samples from Level 6 & 7 have come back negative. Dr Inkster has requested water testing on Level 5 to see if any pathogens are moving up the building.

Overall gram negative pathogens and fungal counts some greater than 100 have been found throughout the QEUE and RHC sites. Fungal counts should not be higher than 10 and some of the gram negative pathogens are significant, particularly for immunosuppressed patients.

Additional alerts have been put on IC net within NHSGGC to capture a suggested list of microorganisms associated with water at the suggestion of HPS. These infections will now be monitored at least in the short term to identify and issues.

Other Reports

Neuro and Maternity buildings are negative for everything with counts of zero due to historic chlorine dioxide dosing to the water supply to the buildings.

Initial typing results are showing 2 different strains of Cupriavidus. The group will need to wait until the patient typing results are returned to see if they are the same.

Patient pseudomonas bacteraemia is a different organism from the pseudomonas found from sampling. The group has decided to exclude this patient case from the incident as it is not linked to any of the samples taken.

Did not sample Ward 2A drains as numerous doses of Sansil has been put down the drains. Ward 2B, RHC and ward 4B, QEUE have been sampled. Both have come back with Stenotrophomonas, Elizabethkingia and Pseudomonas species.

Current Infection Control Measures

The group agreed to step down the Infection Control measures put in place for affected wards within the QEUE and RHC sites as point of care filters have been fitted to all water outlets and showers. Patients can now use the CHWB to carry out hand hygiene and also use the showers if required. Patients no longer require Ciprofloxacin.

For the time being BMT patients within the RHC will still have all precautions kept in place.

This was agreed as we need to wait for quality assurance process (4 weeks testing) of the point of use filters. There is a quality assurance from the company but NHGS GG&C has not approved it. The group said a lot of this is down to confidence and can we guarantee the safety of the BMT patients.

Concern was expressed re the testing of filters and whether it was comparable to our situation with multiple bacteria and fungi. Furthermore when used in these situations filters are usually applied for a single organism problem. There are currently 4 BMT patients in RHC at the moment with 1 more BMT expected to be admitted within the

next 4 weeks. Addition precautions would be put in place after discussion within Clinical Staff W & C SMT and IPCT.

*Post IMT it was agreed to proceed with BMT patients but that filters would need to be changed every 7 days as we have proven microbiological efficacy to that point. This will mean BMT patients can shower. One patient was discussed with Edinburgh but will come to RHC –this patient has C diff and strict IC precautions will be applied.

Hypothesis

There are 3 main hypothesis the group are looking into which are -

Could the outlets be contaminated from a back flow from the drains. There is currently no evidence of back flow from drains. Ward 4B and 2B both have positive microbiology but this is different from the water results. LICD observed no backflow and noted that the showers, whilst they can dangle are sitting high above the drains, The group have decided to exclude this as a possible issue.

There is small number of organisms coming in from the main supply in low levels, which over time has built up and formed biofilm on the outlets

Contamination of the pipes during the commissioning of the building. Also the possibility that the taps had been kept in a dusty area for some time until they were all fitted without being cleaned.

The group agreed to look into the air handling system as they use a very coarse filter that does not stop microbiology organisms. LICD stated that you would expect perhaps to see Gram positive organisms also and not just water associated Gram negatives. HFS has experience regarding this and will speak to IPCT when he gets back.

Current Water Control Measures

It was agreed that 12 water tests will be carried within each ward 2A and Ward 4B on a weekly basis. The outlets tested will remain the same throughout the month. Sampling will be carried out on a Monday so that the results will be available later on the week with no results coming in during the weekend. This will be carried out for 4 weeks which is lifetime of the filters and then each filter will be replaced through a rolling program

Facilities have got a table of all point of use filters and shower filters that have been fitted and will forward this onto the group.

Future Preventative Measures

New taps preferable without flow straighteners.

The introduction of a chlorine dioxide dosing of the water supply to RHC and QEUH.

Filters being used on a much longer term basis in high risk wards, defined as 2A and 4B

How do we clean drains throughout the RHC/QEUH sites – Dr Inkster advised using acetic acid and focusing on 2a and 4B first.

HIIAT

The group agreed that the HIIAT score of AMBER after the group agreed there was moderate risk to service and public anxiety and minor risk to severity of illness and risk of transmission.

No further IMT are planned at this time but a separate group chaired by the Acting Director of facilities would be convened to look at long term solutions.

Complete this update section weekly as a minimum if red or amber or as agreed with IMT and HPS for onward reporting to SGHSCD.

Section 6: Update						
On this date:						
Cumulative total of confirmed patient cases						
Cumulative total of probable patient cases						
Cumulative total of possible patient cases						
Cumulative total of staff cases						
Total number of symptomatic patients today						
Number of patients giving cause for concern						
Total number of deaths as a consequence of the incident since last HIIORT report						
Is the ward/services closed						
Is a service restricted						
HIIAT assessment						
<i>Organisation update certification information</i> <i>Comments (including changes to any control measures, case definition or death)</i>						
Date: 23/1/18						
Date:						
Date:						
Date:						
Date:						

ONCE COMPLETED, EMAIL TO: NSS.HPSInfectionControl@nhs.net



**Bundle of documents for Oral hearings commencing from 19 August 2024 in relation to the
Queen Elizabeth University Hospital and the Royal Hospital for Children, Glasgow**

Bundle 20 – Documents referred to in the Expert Reports by Andrew Poplett and Allan Bennett
A48946859